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): **May 6, 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:

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 2.02 Results of Operations and Financial Conditions.

On May 6, 2021, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the first quarter ended March 31, 2021. 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 May 6, 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: May 6, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Announces First Quarter 2021 Results and Recent Highlights

SAN DIEGO (May 6, 2021) – Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company developing onvansertib to treat cancers with the greatest medical needs for new treatment options, including KRAS-mutated colorectal cancer, pancreatic cancer and castrate-resistant prostate cancer, today announced recent company highlights and financial results for the first quarter ended March 31, 2021. The Company is issuing this press release in lieu of conducting a conference call.

“We are off to a strong start in 2021 thanks in large part to our successful financing late last year, which has allowed us to advance our clinical development programs, more fully leverage onvansertib combination trials across multiple cancer indications, and work towards strengthening company leadership,” said Dr. Mark Erlander, chief executive officer of Cardiff Oncology. “As presented at ASCO-GI in January and our KOL Event in early April, our KRAS-mutated metastatic colorectal cancer (mCRC) trial continues to generate consistent and encouraging data, with a robust overall response rate and median progression free survival that compare favorably to historical controls. These data also provide a strong scientific rationale for our Phase 2 trial in pancreatic ductal adenocarcinoma (PDAC), an indication where approximately 95% of patients have a KRAS mutation. We recently activated our first sites for this trial, which, similar to our mCRC trial, will treat patients with onvansertib in combination with irinotecan and 5-FU.”

Dr. Erlander continued, “The progress in our KRAS-mutated cancer programs is complemented by promising data from our Phase 2 trial in metastatic castrate-resistant prostate cancer (mCRPC), which continues to demonstrate durable disease control in patients showing initial abiraterone resistance and highlights onvansertib’s ability to disrupt or inhibit additional tumor-promoting pathways. In parallel, in vitro studies in mCRPC indicate that onvansertib and abiraterone can synergistically interact by upregulating a mitosis related gene signature and disrupting mitotic spindle orientation. We are currently testing this prospectively in our ongoing trial to assess whether the presence of this signature in the tumor can predict which patients are most likely to respond to onvansertib-abiraterone combination therapy. We look forward to the continued progression of this trial as well as our other clinical programs, which together are expected to drive increased value throughout 2021."

Program highlights for the quarter ended March 31, 2021, along with recent developments, include:

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:

Announced updated data from the Phase 1b/2 trial evaluating onvansertib plus FOLFIRI/bevacizumab that continues to demonstrate robust response to treatment and progression-free survival in KRAS-mutated mCRC

Updated data from Cardiff Oncology’s Phase 1b/2 mCRC trial were presented in conjunction with the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI) in January and as part of a separate Key Opinion Leader webinar in April. Results from the trial continue to show robust patient response and progression-free survival when onvansertib is combined with standard-of-care therapy in second line KRAS-mutated mCRC. Data highlights from the Phase 1b trial, as of April 4, 2021, include:

- 7 of 18 (39%) evaluable patients achieved a partial response (PR); 4 patients had a confirmed PR with 1 patient going on to curative surgery; 1 patient with a non-confirmed PR went off study following PR prior to confirmatory scan due to a treatment-unrelated adverse event; 2 patients with non-confirmed PRs await confirmatory scans and results
- Evaluable patients have a median progression free survival (mPFS) of 9.4 months (95% confidence interval: 7.85 months – not reached), more than double the historical 4.5-month mPFS from analysis of 23 randomized trials in second-line metastatic colorectal cancer (data from ~10,800 patients)[1]
- 7 patients remain on treatment
- Clinical responses were observed across different KRAS mutations, including the 3 most common in colorectal cancer (G12D, G12V, G13D)
- The greatest decreases in plasma KRAS mutant allelic frequency (MAF) after 1 cycle of treatment were observed in patients achieving a PR
- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no major or unexpected toxicities attributed to onvansertib

Enrollment of patients in the Phase 1b segment of the trial concluded in December 2020 and the first patient in the Phase 2 segment of the trial had their first treatment in February 2021. Phase 2 is rapidly accruing the approximately 26 patients needed to complete the study across 7 trial sites: USC Norris Comprehensive Cancer Center, Mayo Clinic Cancer Centers (Arizona, Rochester, Jacksonville), Kansas University Medical Center, CARTI Cancer Center and Inova Schar Cancer Institute.

Presented findings from the Expanded Access Program (EAP) for onvansertib in KRAS-mutated mCRC highlighting the clinical benefit of onvansertib in heavily pretreated patients

Findings from Cardiff Oncology's EAP were presented at ASCO-GI in January and at the American Association for Cancer Research (AACR) Annual Meeting 2021 in April. The EAP has enrolled participants who failed or progressed on multiple lines of standard-of-care treatment and uses the same combination regimen (onvansertib 15 mg/m2 + FOLFIRI/bevacizumab) and dosing schedule as the ongoing Phase 1b/2 mCRC clinical trial. In the most recent update at the AACR Annual Meeting, the Company presented findings from 20 evaluable participants who were heavily pre-treated (median of 3 prior lines of treatment). Highlights from the AACR presentation included:

- 15 of 20 (75%) evaluable participants received an irinotecan-based regimen as their last therapy prior to enrolling in the EAP.
- 13 of 20 (65%) evaluable participants were progressing prior to enrolling in the EAP
- Median progression free survival (mPFS) was 5.6 months (95% confidence interval: 2.7 months – not reached), which is significantly greater than historical controls (2-3 months)2
- 62.5% of participants had a greater than 50% decrease in KRAS MAF after one cycle of treatment and continue to show a durable response and have not reached mPFS
- 11 of 20 of evaluable participants remain on treatment

- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no serious adverse events (SAEs) reported

Hosted a Key Opinion Leader (KOL) webinar highlighting the findings from the onvansertib Phase 1b/2 trial and EAP

The call featured KOLs Daniel H. Ahn, D.O., M.S. (Mayo Clinic Arizona), and Manish R. Sharma, M.D. (START Midwest). In addition to highlighting the latest data and findings from the onvansertib Phase 1b/2 mCRC trial and EAP, the call also included an overview of the current treatment landscape in KRAS-mutated mCRC and a discussion of the response rates and progression free survival historically achieved with the current second-line standard of care. You may access a replay of the event by clicking here.

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 the primary efficacy endpoint (30% DCR at 12 weeks). Additional highlights from the ASCO-GU 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, with 63% (5/8) of cohort C patients achieving 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 all dosing cohorts.

Additional information on the trial and dosing cohorts can be found here.

Identified an androgen-independent mechanism of synergy between onvansertib and abiraterone in mCRPC

Collaborative studies with the Massachusetts Institute of Technology featured in a virtual oral poster presentation at the AACR Annual Meeting 2021 suggest that the androgen receptor signaling inhibitor abiraterone sensitizes certain prostate cancer cells to onvansertib via the induction of a mitosis related gene signature and disruption of mitotic spindle orientation. These results are consistent with previous findings showing that onvansertib and abiraterone synergize in an androgen receptor-independent manner in vitro and in vivo. Data from the studies also suggest that the identified mitosis related gene

signature may be predictive of patient response to onvansertib-abiraterone combination therapy, a hypothesis that is being further assessed in the ongoing Phase 2 mCRPC trial.

Metastatic Pancreatic Ductal Adenocarcinoma (PDAC) Program:

Opened enrollment for a Phase 2 trial of onvansertib in metastatic PDAC

Cardiff Oncology recently activated the first clinical sites for its Phase 2 clinical trial of onvansertib in metastatic PDAC, which is now open for enrollment. The trial is designed to assess the safety and preliminary efficacy of onvansertib in combination with nanoliposomal irinotecan (Onivyde®), 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 KRAS-mutated mCRC patients treated with the combination of onvansertib, irinotecan and 5-FU (FOLFIRI).

Sale of Common Stock to Institutional Investor:

On May 5, 2021, the Company agreed to sell 2.0 million shares of its Common Stock to a healthcare institutional investor for gross proceeds of $20.0 million under the Sales Agreement with Jeffries LLC.

First Quarter 2021 Financial Results:

As of March 31, 2021, Cardiff Oncology had approximately $125.6 million in cash, cash equivalents and short-term investments.

Total operating expenses were approximately $5.5 million for the three months ended March 31, 2021, an increase of $1.3 million from $4.2 million for the same period in 2020. The increase in operating expenses is attributed to advancing onvansertib drug development activities, additional clinical studies, and increased outside services for legal fees mainly related to the expansion of our patent portfolio and recruiting fees.

Net cash used in operating activities in the first quarter of 2021 was $5.9 million, an increase of $2.5 million from $3.4 million for the same period in 2020. The increase is attributed to expanding and advancing drug development and clinical program activities, and net changes in assets and liabilities .
Research and development expenses increased by approximately $0.6 million to $3.3 million for the three months ended March 31, 2021, from $2.7 million for the same period in 2020. The increase in research and development expenses was primarily due to advancing the onvansertib clinical and preclinical programs.

Selling, general and administrative expenses increased by approximately $0.7 million to $2.2 million for the three months ended March 31, 2021, from $1.5 million for the same period in 2020. The increase is primarily due to increased outside services for legal fees mainly related to the expansion of our patent portfolio and recruiting fees.

References

1. Giessen et al, Acta Oncologica, 2015; 54:187-193

2. Bekaii-Saab et al., Clin. Colorectal Cancer, 2019

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 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 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castration-resistant prostate cancer (mCRPC); and 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). A Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML) completed enrollment in 2020. 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.

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Cardiff Oncology, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenues:		
Royalties	$ 72	$ 68
Total revenues	72	68
Costs and expenses:		
Research and development	3,279	2,706
Selling, general and administrative	2,235	1,486
Total operating expenses	5,514	4,192
Loss from operations	(5,442)	(4,124)
Interest income, net	57	36
Gain from change in fair value of derivative financial instruments—warrants	207	2
Other income (expense), net	(1)	(3)
Net loss	(5,179)	(4,089)
Preferred stock dividend	(6)	(6)
Deemed dividend on preferred stock	—	—
Net loss attributable to common stockholders	$ (5,185)	$ (4,095)
Net loss per common share — basic and diluted	$ (0.14)	$ (0.41)
Weighted-average shares outstanding — basic and diluted	37,164	9,910

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 14,662	$ 130,981
Short-term investments	110,922	—
Accounts receivable and unbilled receivable	242	320
Prepaid expenses and other current assets	2,744	2,055
Total current assets	128,570	133,356
Property and equipment, net	504	624
Operating lease right-of-use assets	261	343
Other assets	238	404
Total Assets	$ 129,573	$ 134,727
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 803	$ 1,366
Accrued expenses	2,999	3,851
Operating lease liabilities	635	860
Other current liabilities	42	42
Total current liabilities	4,479	6,119
Derivative financial instruments—warrants	78	285
Operating lease liabilities, net of current portion	8	9
Other Liabilities	191	156
Total Liabilities	4,756	6,569
Stockholders' equity	124,817	128,158
Total liabilities and stockholders' equity	$ 129,573	$ 134,727

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating activities		
Net loss	$ (5,179)	$ (4,089)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	1	—
Depreciation	119	119
Stock based compensation expense	268	177
Amortization of premiums on short-term investments	204	—
Change in fair value of derivative financial instruments—warrants	(207)	(2)
Release of clinical trial funding commitment	380	293
Changes in operating assets and liabilities	(1,470)	128
Net cash used in operating activities	(5,884)	(3,374)
Investing activities:		
Net purchases and sales of short-term investments	(111,698)	—
Net cash used in investing activities	(111,698)	—
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	—	1,000
Proceeds from exercise of warrants	1,263	1,456
Net cash provided by financing activities	1,263	2,456
Net change in cash and cash equivalents	(116,319)	(918)
Cash and cash equivalents—Beginning of period	130,981	10,195
Cash and cash equivalents—End of period	$ 14,662	$ 9,277