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 24, 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 2.02 Results of Operations and Financial Conditions.

On February 24, 2022, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the fourth quarter and fiscal year ended December 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 February 24, 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: February 24, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology™

Cardiff Oncology Reports Fourth Quarter and Full Year 2021 Results and Recent Highlights

- Phase 1b/2 trial in lead KRAS-mutated metastatic colorectal cancer program continues to show an objective response rate and median progression-free survival that substantially exceed those seen in historical control trials
- Received $15 million equity investment from Pfizer through the Pfizer Breakthrough Growth Initiative
- Adam Schayowitz, Ph.D., MBA, Vice President, Medicine Team Group Lead for Breast Cancer, Colorectal Cancer and Melanoma at Pfizer to join Cardiff Oncology Scientific Advisory Board
- Strengthened leadership team with appointments of Tod Smeal, Ph.D., as chief scientific officer (CSO) and Charles Monahan, R.Ph., as senior vice president (SVP), regulatory affairs
- Cash, cash equivalents, and short-term investments of approximately $141 million as of December 31, 2021

SAN DIEGO, February 24, 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 recent company highlights and financial results from the fourth quarter and full year ended December 31, 2021.

“Our recent progress has provided additional clinical and external validation of onvansertib, including a Pfizer Breakthrough Growth Initiative collaboration,” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. “As the number of evaluable patients in our lead program in KRAS-mutated metastatic colorectal cancer increased from 14 to 48 over the past year, we continued to see consistent objective response rates and median progression-free survival that substantially exceed those from historical control trials. We have also seen responses across multiple KRAS-mutation variants, which differentiates onvansertib from agents designed to target a specific KRAS mutation. We look forward to advancing our mCRC clinical program and moving into a pivotal trial.”

Dr. Erlander added, “Alongside our lead program in mCRC, we continue our work to leverage onvansertib in other cancer indications. The addition of Tod Smeal, Ph.D., as our chief scientific officer was an important step towards this goal, and his experience developing targeted cancer therapies is already proving to be an invaluable asset. Looking ahead, we are eager to continue exploring synergistic combinations with onvansertib, which include DNA damaging agents, microtubule inhibitors and epigenetic factors, as we pursue additional indications."

Program highlights for the quarter ended December 31, 2021, and recent business updates include:

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:

Announced new data from Phase 1b/2 trial evaluating onvansertib plus FOLFIRI/bevacizumab that continue to show robust objective response rate and progression-free survival

The data were presented on a webcast and conference call hosted by Cardiff Oncology, and a subset were featured in a poster presented by Heinz-Josef Lenz, M.D., FACP, principal investigator, USC Norris Comprehensive Cancer Center, at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI). Highlights from the webcast and conference call included:

Efficacy data in evaluable patients:

- Among patients treated per protocol at the recommended Phase 2 dose (RP2D; 15 mg/m^2) in combination with FOLFIRI/bevacizumab:

    - 12 of 35 (34%) achieved an initial complete response (CR) or partial response (PR)
    - 10 of 35 (29%) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
    - Objective response rates of 5-13% observed in historical control trials in similar patient populations treated with various different drug combinations, including the standard-of-care chemotherapy of FOLFIRI with bevacizumab[1-4]
- Patients evaluable for response treated at all dose levels (12 mg/m^2, 15 mg/m^2, 18 mg/m^2)
    - 17 of 48 (35%) achieved an initial CR or PR
    - 13 of 48 (27%) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)

Median progression-free survival (mPFS), biomarker, and safety data:

- mPFS has not yet been reached in patients treated per protocol at the RP2D
- mPFS across all response-evaluable patients (n = 48) is 9.4 months (95% confidence interval: 7.1 – not yet reached)
- mPFS of ~4.5-5.7 months has been reported in trials used as historical controls[1-4]
- Responses (CRs or PRs) were observed across seven different KRAS mutation variants, including the 3 most commonly observed in colorectal cancer (G12D, G12V, G13D)
- The combination of onvansertib and FOLFIRI/bevacizumab was shown to be well-tolerated with only 11% (84/788) of reported treatment-emergent adverse events (TEAEs) being G3/G4

Corporate Highlights:

Received a $15 million equity investment from Pfizer as part of the Pfizer Breakthrough Growth Initiative

Pfizer purchased 2.4 million shares of Cardiff Oncology's common stock at a price of $6.22 per share, which represented a 19% premium compared to the prior closing price. In connection with the equity investment, Adam Schayowitz, Ph.D., MBA, Vice President & Medicine Team Group Lead for Breast Cancer, Colorectal Cancer and Melanoma at Pfizer, will join Cardiff Oncology's Scientific Advisory Board. Additionally, Cardiff Oncology agreed to grant Pfizer rights of first access to data from its development programs.

Strengthened management team with the appointments of Tod Smeal, Ph.D., as CSO and Charles Monahan, R.Ph., SVP, 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 the Oncology Research Unit of Pfizer. Mr. Monahan is a registered pharmacist with over 20 years of regulatory experience developing drugs and biologics for oncology, infectious diseases, and ocular indications. Prior to joining Cardiff Oncology, he most recently served as the global head of regulatory affairs for Erytech PharmaSA.

Fourth Quarter and Full Year 2021 Financial Results:

As of December 31, 2021, Cardiff Oncology had approximately $141 million in cash, cash equivalents, and short-term investments.

Total operating expenses were approximately $9.6 million for the three months ended December 31, 2021, an increase of $3.0 million from $6.6 million for the same period in 2020. The increase in operating expenses was primarily due to ongoing and new onvansertib clinical development programs and preclinical activities, additional outside services, and recruiting fees.

Research and development expenses increased by approximately $2.6 million to $5.8 million for the three months ended December 31, 2021, from $3.2 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 and recruitment fees to fill critical research and development positions.

Selling, general and administrative expenses increased by approximately $0.4 million to $3.8 million for the three months ended December 31, 2021, from $3.4 million for the same period in 2020. The increase in selling, general and administrative expenses was primarily due to strategic valuation consulting related to our lead drug candidate onvansertib offset by lower legal expenses.

Net cash used in operating activities for the fourth quarter of 2021 was approximately $7.4 million, an increase of approximately $2.3 million from $5.1 million for the same period in 2020. This increase is primarily due to advancing clinical program activities and outside services and recruiting fees, and net changes in assets and liabilities.

Total operating expenses were approximately $29.2 million for the full year ended December 31, 2021, an increase of $9.8 million from $19.4 million for the full year 2020. The increase in operating expenses was primarily due to advancing existing and new onvansertib clinical development programs and preclinical activities, additional outside services, recruiting fees and stock compensation expense.

Research and development expenses increased by approximately $6.2 million to $17.4 million for the full year ended December 31, 2021, from $11.2 million for the full year 2020. The increase in research and development expenses was primarily due to advancing existing and new preclinical programs and collaborations.

Selling, general and administrative expenses increased by approximately $3.6 million to $11.8 million for the full year ended December 31, 2021, from $8.2 million for the full year 2020. The increase in selling, general and administrative expenses was primarily due to strategic valuation consulting, recruitment fees, and stock-based compensation expense.

Net cash used in operating activities for the full year 2021 was approximately $23.0 million, an increase of approximately $6.7 million from $16.3 million for the full year 2020.

References

1. Giessen et al., Acta Oncologica 2015, 54: 187-193
2. Cremolini et al., Lancet Oncol 2020, 21: 497–507
3. Antoniotti et al., Correspondence Lancet Oncol June 2020
4. Bennouna et al., Lancet Oncol 2013; 14: 29–37

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 the third generation PLK1 inhibitor onvansertib, 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.

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:
Amy Jobe, Ph.D.
LifeSci Communications
315-879-8192
ajobe@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,	
	2021	2020	2021	2020
	(unaudited)			
Royalty revenues	133	119	359	366
Costs and expenses:				
Research and development	5,824	3,199	17,376	11,235
Selling, general and administrative	3,835	3,417	11,838	8,217
Total operating expenses	9,659	6,616	29,214	19,452
Loss from operations	(9,526)	(6,497)	(28,855)	(19,086)
Net interest income	79	21	264	88
Gain (loss) from changes in fair value of derivative financial instruments—warrants	5	(95)	285	(281)
Other (loss) income, net	—	(26)	15	(28)
Net loss	(9,442)	(6,597)	(28,291)	(19,307)
Preferred Stock Dividend	(6)	(6)	(24)	(3,291)
Net loss attributable to common stockholders	$ (9,448)	$ (6,603)	$ (28,315)	$ (22,598)
Net loss per common share - basic and diluted	$ (0.23)	$ (0.19)	$ (0.73)	$ (1.08)
Weighted-average shares outstanding - basic and diluted	40,601	35,566	39,030	20,875

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 11,943	$ 130,981
Short-term investments	128,878	—
Accounts receivable and unbilled receivable	535	320
Prepaid expenses and other assets	4,771	2,055
Total current assets	146,127	133,356
Property and equipment, net	382	624
Operating lease right-of-use assets	2,796	343
Other assets	239	404
Total Assets	$ 149,544	$ 134,727
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,439	$ 1,366
Accrued liabilities	4,527	3,851
Operating lease liabilities	551	860
Other current liabilities	42	42
Total current liabilities	6,559	6,119
Derivative financial instruments warrants	—	285
Operating lease liabilities, net of current portion	2,568	9
Other liabilities	—	156
Total Liabilities	9,127	6,569
Stockholders' equity	140,417	128,158
Total liabilities and stockholders' equity	$ 149,544	$ 134,727

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

	Year Ended December 31,	
	2021	**2020**
Operating activities		
Net loss	$ (28,291)	$ (19,307)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	1	—
Impairment loss	—	34
Depreciation	451	466
Stock based compensation expense	3,234	1,765
Amortization of premiums on short-term investments	1,607	—
Change in fair value of derivative financial instruments - warrants	(285)	281
Release of clinical trial funding commitment	2,032	1,100
Changes in operating assets and liabilities	(1,789)	(654)
Net cash used in operating activities	(23,040)	(16,315)
Investing activities:		
Capital expenditures	(205)	(211)
Net purchases, maturities and sales of short-term investments	(131,243)	—
Net cash used in investing activities	(131,448)	(211)
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	34,187	112,300
Costs related to the clinical trial funding commitment	—	(8)
Proceeds from exercise of warrants	1,263	24,872
Proceeds from exercise of options	—	148
Borrowings under note payable	—	305
Repayments of note payable	—	(305)
Net cash provided by financing activities	35,450	137,312
Net change in cash and cash equivalents	(119,038)	120,786
Cash and cash equivalents Beginning of period	130,981	10,195
Cash and cash equivalents End of period	$ 11,943	$ 130,981