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 5, 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 May 5, 2022, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the third quarter ended March 31, 2022. 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 5, 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: May 5, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Reports First Quarter 2022 Results and Provides Business Updates

- Reported new Phase 1b/2 data from lead KRAS-mutated metastatic colorectal cancer (mCRC) clinical program showing objective response rate and median progression-free survival that substantially exceed those recorded in historical control trials

- Announced new data from Phase 2 metastatic castration-resistant prostate cancer (mCRPC) trial showing clinically meaningful disease control rates that rose with increasing onvansertib dose density

- Presented new genomic analyses from Phase 2 mCRPC trial that show a positive association between treatment response and alterations in *MTOR* and *PTEN*, two key genes in the PI3K signaling pathway

- Reported new preclinical data that show onvansertib combining with a PARP inhibitor to overcome PARP inhibitor resistance in *BRCA1*-mutant and wild-type patient-derived xenograft ovarian cancer models

- Cash, cash equivalents, and short-term investments of approximately $129.4 million as of March 31, 2022

SAN DIEGO, May 5, 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 for the first quarter ended March 31, 2022.

“With a strong balance sheet and clinical data highlighting onvansertib’s potential to improve patient outcomes by combining synergistically with the standard-of-care, we believe we are well positioned for success,” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. "Phase 1b/2 data from our lead KRAS-mutated metastatic colorectal cancer (mCRC) program show clear improvements in treatment response and durability compared to historical controls. These results also clinically demonstrate onvansertib’s KRAS-agnostic mechanism of action, setting it apart from competing agents that target only the G12C variant.”

Dr. Erlander added, “We are also highly encouraged by recent data from our Phase 2 prostate cancer trial showing clinically meaningful disease control rates in patients who showed signs of progression on prior therapy, and preclinical studies that showed onvansertib-PARP inhibitor combination therapy leading to statistically significant survival benefits in patient-derived xenograft models of PARP-inhibitor-resistant ovarian cancer. These results further highlight how onvansertib’s ability to inhibit PLK1 positions it to target tumor vulnerabilities and overcome treatment resistance across a spectrum of indications. We look forward to building on these results as we move towards the second half of the year.”

Program highlights for the quarter ended March 31, 2022, and recent business updates include:

KRAS-mutated mCRC Program:

Reported new Phase 1b/2 data showing treatment with onvansertib plus FOLFIRI/bevacizumab leading to an objective response rate (ORR) and median progression-free survival (mPFS) that substantially exceed those recorded in historical control trials

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

Efficacy data in evaluable patients:

- Among patients treated per protocol with onvansertib at the recommended Phase 2 dose (RP2D; 15 mg/m^2) in combination with FOLFIRI/bevacizumab:
  - 34% (12 of 35) achieved an initial complete response (CR) or partial response (PR)
  - 29% (10 of 35) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)
  - Historical control trials evaluating different drug combinations, including the standard-of-care of FOLFIRI with bevacizumab, in similar patient populations have shown ORRs of 5-13%[1-4]

- Patients evaluable for response treated at onvansertib dose levels 12 mg/m^2, 15 mg/m^2, and 18 mg/m^2
  - 35% (17 of 48) achieved an initial CR or PR
  - 27% (13 of 48) achieved a confirmed CR or PR (awaiting confirmatory scan for 1 patient)

mPFS, biomarker, and safety data:

- mPFS not yet 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 historical control trials[1-4]
- Complete or partial responses were observed across seven different KRAS mutation variants, including the 3 most commonly observed in colorectal cancer (G12D, G12V, G13D)
- Onvansertib in combination with FOLFIRI/bevacizumab has been well-tolerated with only 11% (84/788) of reported treatment-emergent adverse events (TEAEs) being G3/G4

Metastatic Castration-resistant Prostate Cancer (mCRPC) Program:

Announced updated clinical and new biomarker data from Phase 2 trial evaluating onvansertib in combination with abiraterone/prednisone in mCRPC patients showing initial abiraterone resistance

Results from the trial, which were presented in a poster at the American Association for Cancer Research (AACR) Annual Meeting, showed clinically meaningful disease control rates that rose with increasing onvansertib dose density. Additional highlights from the announcement include:

- 75% (15 of 20) evaluable patients in Arm C, which represents the trial's most dose dense treatment schedule, showed disease control by radiographic stable disease (SD/PR) at 12-weeks, compared to 9 of 17 (53%) and 11 of 19 (58%) in the less dose-dense Arms A and B, respectively
- 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
- Onvansertib in combination with abiraterone/prednisone has been well tolerated in the trial

Each arm in the trial 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.

Preclinical Highlights:

Reported new preclinical data that show onvansertib combining with a PARP inhibitor to overcome PARP inhibitor (PARPi) resistance in BRCA1-mutant and wild-type patient-derived xenograft ovarian cancer models

Preclinical studies featured in a poster presentation at the AACR Annual Meeting evaluated onvansertib in combination with the PARPi olaparib in three olaparib-resistant patient-derived xenograft (PDX) ovarian cancer models. Two of the three PDX models studied were cisplatin-sensitive with a mutated *BRCA1* gene, while the third was cisplatin-resistant with wild type *BRCA1*. Results showed that treatment with onvansertib plus olaparib led to a statistically significant survival benefit compared to treatment with either agent alone in each of the three evaluated PDX models. The combination regimen was also shown to be well tolerated in mice.

First Quarter 2022 Financial Results:

Liquidity and cash burn

As of March 31, 2022, Cardiff Oncology had approximately $129.4 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the first quarter of 2022 was approximately $10.2 million, an increase of approximately $4.3 million from $5.9 million for the same period in 2021.

Operating Expenses

(in millions)	Three Months Ended March 31,		
	2022	2021	Increase (Decrease)
Costs and expenses:			
Research and development	$ 7.2	$ 3.3	$ 3.9
Selling, general and administrative	3.9	2.2	1.7
Total operating expenses	$ 11.1	$ 5.5	$ 5.6

The overall increase in research and development expenses was primarily due to costs associated with an increase in outside service costs related to chemistry, manufacturing, and controls ("CMC") and pharmacology for the development of our lead drug candidate, onvansertib. Salaries and staff costs increased due to a higher headcount in the current period, as compared to the prior period. The increase in stock-based compensation is due to additional stock option grants to employees granted subsequent to the prior period.

The overall increase in selling, general and administrative expense was primarily due to costs associated with outside services and stock-based compensation. The increase in outside services is related to strategic valuation consulting related to our lead drug candidate, onvansertib. The increase in stock-based compensation is due to additional stock option grants to employees and directors granted subsequent to the prior period.

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 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, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Royalty revenues	$ 74	$ 72
Costs and expenses:		
Research and development	7,208	3,279
Selling, general and administrative	3,940	2,235
Total operating expenses	11,148	5,514
Loss from operations	(11,074)	(5,442)
Interest income, net	130	57
Gain (loss) from change in fair value of derivative financial instruments—warrants	—	207
Other income (expense), net	(49)	(1)
Net loss	(10,993)	(5,179)
Preferred stock dividend	(6)	(6)
Net loss attributable to common stockholders	$ (10,999)	$ (5,185)
Net loss per common share — basic and diluted	$ (0.25)	$ (0.14)
Weighted-average shares outstanding — basic and diluted	43,231	37,164

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,052	$ 11,943
Short-term investments	109,310	128,878
Accounts receivable and unbilled receivable	447	535
Prepaid expenses and other current assets	5,997	4,771
Total current assets	135,806	146,127
Property and equipment, net	550	382
Operating lease right-of-use assets	2,660	2,796
Other assets	188	239
Total Assets	$ 139,204	$ 149,544
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,261	$ 1,439
Accrued liabilities	4,738	4,527
Operating lease liabilities	665	551
Other current liabilities	—	42
Total current liabilities	6,664	6,559
Operating lease liabilities, net of current portion	2,438	2,568
Total Liabilities	9,102	9,127
Stockholders' equity	130,102	140,417
Total liabilities and stockholders' equity	$ 139,204	$ 149,544

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Operating activities		
Net loss	$ (10,993)	$ (5,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	1
Depreciation	31	119
Stock-based compensation expense	1,152	268
Amortization of premiums on short-term investments	346	204
Change in fair value of derivative financial instruments—warrants	—	(207)
Release of clinical trial funding commitment	139	380
Changes in operating assets and liabilities	(924)	(1,470)
Net cash used in operating activities	(10,249)	(5,884)
Investing activities:		
Capital expenditures	(171)	—
Net purchases, maturities and sales of short-term investments	18,529	(111,698)
Net cash provided by/(used in) investing activities	18,358	(111,698)
Financing activities:		
Proceeds from exercise of warrants	—	1,263
Net cash provided by financing activities	—	1,263
Net change in cash and cash equivalents	8,109	(116,319)
Cash and cash equivalents—Beginning of period	11,943	130,981
Cash and cash equivalents—End of period	$ 20,052	$ 14,662