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 4, 2023**

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 May 4, 2023, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the first quarter ended March 31, 2023. 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 4, 2023.

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 4, 2023

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Reports First-Quarter 2023 Results and Provides Business Update

First Patient Dosed in ONSEMBLE Phase 2 Randomized Trial of Onvansertib in Patients with KRAS/NRAS-mutated Metastatic Colorectal Cancer (mCRC)

Introduced full membership of Scientific Advisory Board (SAB)

Announced appointment of Fairooz Kabbinavar, MD, FACP, as Chief Medical Officer

Cash, cash equivalents, and short-term investments of approximately $97 million as of March 31, 2023, projected runway into 2025

SAN DIEGO, May 4, 2023 - Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers, today announced financial results for the first-quarter ended March 31, 2023, and provided a business update.

"We are delighted to have dosed the first patient in our Phase 2 ONSEMBLE trial. This randomized trial will evaluate the efficacy of onvansertib combined with standard of care in patients with KRAS/NRAS-mutated mCRC, who historically have limited treatment options," said Mark Erlander, PhD, Chief Executive Officer of Cardiff Oncology. "In addition, we are excited to have appointed Fairooz Kabbinavar, MD, FACP, as our new Chief Medical Officer, who brings deep expertise in the treatment of patients with CRC as well as expertise in using bevacizumab in the clinical setting. We believe Dr. Kabbinavar adds significant value to our clinical development program for onvansertib. We also formally introduced the full membership of our Scientific Advisory Board, a group of highly esteemed oncology experts who are providing a diverse range of insights that strengthen our clinical programs."

Upcoming potential milestones

- Metastatic pancreatic ductal adenocarcinoma (mPDAC) data readout from Phase 2 trial expected in mid-2023
- Small cell lung cancer (SCLC) data readout from investigator-initiated (with UPMC) Phase 2 trial expected in mid-2023
- Triple negative breast cancer (TNBC) data readout from investigator-initiated (with Dana-Farber Cancer Institute) Phase 1b/2 trial expected in the fourth-quarter of 2023 or first-quarter of 2024
- mCRC randomized data readout from Phase 2 ONSEMBLE trial expected in the second-half of 2024

Company Highlights for the quarter ended March 31, 2023

- **Announced the Appointment of Fairooz Kabbinavar, MD, FACP, as Chief Medical Officer.** Dr. Kabbinavar oversees the clinical development program for the Company's investigational drug onvansertib and reports directly to Chief Executive Officer, Mark Erlander, PhD.
- **Formally introduced the full membership of its Scientific Advisory Board (SAB).** The SAB is comprised of a distinguished group of academic and industry experts who bring depth and breadth of knowledge in oncology drug development, clinical trial design, translational science and clinical research. In most cases, these individuals have been advising the Company for several years and will now collectively serve a critical role as we advance the clinical development of

onvansertib. The Company anticipates that over time the membership of the SAB may expand to add additional expertise in new indications or stages of clinical development.

- **Announced First Patient Dosed in ONSEMBLE Phase 2 Randomized Trial of Onvansertib in Patients with Metastatic Colorectal Cancer.** The Phase 2 ONSEMBLE trial includes patients with mCRC who have a documented KRAS or NRAS mutation and have previously received one prior chemotherapy regimen with or without bevacizumab in the first line metastatic setting. Patients are being randomized to onvansertib plus FOLFIRI/bevacizumab versus FOLFIRI/bevacizumab (standard of care).

First-Quarter 2023 Financial Results

Liquidity, cash burn, and cash runway

As of March 31, 2023, Cardiff Oncology had approximately $97.0 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the first quarter of 2023 was approximately $8.7 million, a decrease of approximately $1.5 million from $10.2 million for the same period in 2022.

Based on its current expectations and projections, the Company believes its current cash resources are sufficient to fund its operations into 2025.

Operating results

Total operating expenses were approximately $12.1 million for the three months ended March 31 2023, an increase of $1.0 million from $11.1 million for the same period in 2022. The increase in operating expenses was primarily due to higher costs associated with clinical programs and outside service costs related to the development of the company’s lead drug candidate, salaries and staff costs primarily due to increased headcount.

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers. The Company's lead asset is onvansertib, a PLK1 inhibitor being evaluated in combination with standard-of-care (SoC) therapeutics in clinical programs targeting indications such as KRAS/NRAS-mutated metastatic colorectal cancer (mCRC) and metastatic pancreatic ductal adenocarcinoma (mPDAC), as well as in investigator-initiated trials in triple negative breast cancer (TNBC) and small cell lung cancer (SCLC). These programs and the Company's broader development strategy are designed to target tumor vulnerabilities in order to overcome treatment resistance and deliver superior clinical benefit compared to the SoC alone. 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 candidate; 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 our product candidate 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, 2022, 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:
James Levine
Chief Financial Officer
858-952-7670
jlevine@cardiffoncology.com

Investor Contact:
Kiki Patel, PharmD
Gilmartin Group
332-895-3225
Kiki@gilmartinir.com

Media Contact:
Richa Kumari
Taft Communications
551 344-5592
richa@taftcommunications.com
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Cardiff Oncology, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Royalty revenues	$ 83	$ 74
Costs and expenses:		
Research and development	9,052	7,208
Selling, general and administrative	3,083	3,940
Total operating expenses	12,135	11,148
Loss from operations	(12,052)	(11,074)
Interest income, net	940	130
Other income (expense), net	(111)	(49)
Net loss	(11,223)	(10,993)
Preferred stock dividend	(6)	(6)
Net loss attributable to common stockholders	$ (11,229)	$ (10,999)
Net loss per common share — basic and diluted	$ (0.25)	$ (0.25)
Weighted-average shares outstanding — basic and diluted	44,677	43,231

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 15,017	$ 16,347
Short-term investments	81,951	88,920
Accounts receivable and unbilled receivable	676	771
Prepaid expenses and other current assets	4,109	5,246
Total current assets	101,753	111,284
Property and equipment, net	1,320	1,269
Operating lease right-of-use assets	2,115	2,251
Other assets	1,361	1,387
Total Assets	$ 106,549	$ 116,191
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,914	$ 1,956
Accrued liabilities	4,555	5,177
Operating lease liabilities	679	675
Total current liabilities	8,148	7,808
Operating lease liabilities, net of current portion	1,898	2,040
Total Liabilities	10,046	9,848
Stockholders' equity	96,503	106,343
Total liabilities and stockholders' equity	$ 106,549	$ 116,191

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating activities		
Net loss	$ (11,223)	$ (10,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	90	31
Stock-based compensation expense	1,064	1,152
Amortization of premiums on short-term investments	(163)	346
Release of clinical trial funding commitment	—	139
Changes in operating assets and liabilities	1,573	(924)
Net cash used in operating activities	(8,659)	(10,249)
Investing activities:		
Capital expenditures	(8)	(171)
Net purchases, maturities and sales of short-term investments	7,337	18,529
Net cash provided by investing activities	7,329	18,358
Financing activities:		
Net cash provided by financing activities	—	—
Net change in cash and cash equivalents	(1,330)	8,109
Cash and cash equivalents—Beginning of period	16,347	11,943
Cash and cash equivalents—End of period	$ 15,017	$ 20,052