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): **March 2, 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:

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 March 2, 2023, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the fourth quarter and fiscal year ended December 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 March 2, 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: March 2, 2023

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Reports Fourth Quarter and Full Year 2022 Results and Provides Business Update

Phase 1b/2 trial in lead KRAS-mutated metastatic colorectal cancer (mCRC) program continues to show our lead candidate onvansertib demonstrates an objective response rate, durability and progression-free survival that substantially exceed those seen in historical control trials

Strengthened leadership team with appointments of Fairooz Kabbinavar, MD, FACP, as CMO, Tod Smeal, Ph.D., as CSO and Charles Monahan, R.Ph., as SVP, regulatory affairs

Multiple data readouts expected from clinical programs and IITs in 2023

Strong cash financial position of approximately $105.3 million at December 31, 2022; projected runway into 2025

SAN DIEGO, March 2, 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 fourth quarter and full year ended December 31, 2022, and provided a business update.

“2022 was an important year for demonstrating the benefits onvansertib could bring to patients with KRAS-mutated mCRC, an area where no targeted therapies are currently approved. The results of our Phase 1b/2 trial in KRAS-mutated mCRC continue to show onvansertib plus standard-of-care was well-tolerated and outperformed historical control trials on key endpoints including the durability of response. Furthermore, we observed an unexpectedly high objective response rate and progression-free survival in the bevacizumab-naïve subgroup of patients which will be evaluated in the ongoing ONSEMBLE trial,” said Mark Erlander, PhD, chief executive officer of Cardiff Oncology. “Looking forward, this will be an important year for advancing our ONSEMBLE randomized Phase 2 trial and generating additional safety and efficacy signals from our other company-sponsored and investigator-initiated clinical programs.”

“As we build on these findings and accelerate onvansertib’s clinical development, we will benefit greatly from the deep clinical expertise of our new CMO, Dr. Fairooz Kabbinavar, who served as the lead investigator for two practice-changing trials of bevacizumab combinations leading to the approval of bevacizumab in mCRC,” continued Dr. Erlander. “We are confident we can fund our onvansertib clinical programs into 2025, and we believe our clinical data supports our approach to leveraging PLK1 inhibition to address current gaps in cancer therapies and make an important contribution to oncology patient care.”

Upcoming potential milestones

- mPDAC data readout from Phase 2 trial expected Q2/Q3 ’23
- SCLC data readout from investigator-initiated (with UPMC) Phase 2 trial expected Q2/Q3 ’23
- TNBC data readout from investigator-initiated (with Dana-Farber Cancer Institute) Phase 1b/2 trial expected Q4 ‘23/Q1 ‘24
- mCRC randomized data readout from Phase 2 ONSEMBLE trial expected Q3/Q4 ‘24

Company highlights for the year ended December 31, 2022, and subsequent weeks include:

- **Strengthened management team with appointments of Fairooz Kabbinavar, MD, FACP, as CMO, Tod Smeal, Ph.D., as CSO and Charles Monahan, R.Ph., SVP, regulatory affairs.** Overseeing the clinical development program for onvansertib, Dr. Kabbinavar brings world class capabilities and deep expertise in colorectal cancer and other solid tumor indications to Cardiff Oncology from his 30-plus years of experience across the academic and biotech/pharmaceutical sectors. During his time as an academic oncologist, he was the lead investigator on two practice-changing clinical trials of bevacizumab (Avastin®) combinations leading to approval of bevacizumab in mCRC[1,2]. As principal medical director of Genentech's immuno-oncology program, he led the clinical development of atezolizumab (TECENTRIQ®) in extensive stage small cell lung cancer and oversaw the filing of the supplemental biologics license application that led to the drug's FDA approval. 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.

- **Announced ONSEMBLE, a Phase 2, open-label, randomized trial for second line treatment of KRAS/NRAS-mutated mCRC, as the next step in our mCRC clinical development program.** We designed the ONSEMBLE trial to corroborate the robust efficacy signal observed in the Phase 1b/2 trial of onvansertib plus standard-of-care (SoC) FOLFIRI/bevacizumab in second-line KRAS-mutated mCRC, demonstrate onvansertib's contribution above SoC alone and confirm the optimal dose.

- **Presented robust data from the Phase 1b/2 trial of onvansertib plus FOLFIRI/bevacizumab in second line KRAS-mutated mCRC on a company webcast in September 2022.** Objective response rate (ORR) across all evaluable patients was 35% (n=48) as compared to an ORR of 5-13% observed historically, and the median duration of response (mDoR) across all evaluable patients was 11.7 months. Median progression-free survival (mPFS) was 9.3 months across all evaluable patients, as compared to mPFS of ~4.5 – 5.7 months observed historically in combination trials that included the standard-of-care FOLFIRI with bevacizumab.[3-6]

- **Completed subgroup analysis from Phase 1b/2 mCRC trial shows improved ORR and mPFS in bevacizumab-naïve patients.** A subgroup analysis from the ongoing Phase 1b/2 clinical trial of onvansertib plus FOLFIRI/bevacizumab in second line KRAS-mutated mCRC showed an ORR of 69% and mPFS of 13.5 months in bevacizumab naïve patients (n=13). These data compare favorably to historical control trials in mCRC, which show an ORR of approximately 25% and a mPFS of approximately 6.9 months in bevacizumab naïve patients[6-11].

- **Data presented at the ESMO Congress 2022 suggest combining onvansertib with irinotecan (a component of FOLFIRI) overcomes irinotecan-resistance in RAS-mutated mCRC.** Findings from our Expanded Access Program (EAP) of onvansertib in KRAS-mutated mCRC as well as preclinical data from patient-derived xenograft (PDX) models of irinotecan-resistant, RAS-mutated mCRC were featured in a poster at the ESMO Congress 2022 showing EAP patients with prior irinotecan treatment (43 of 51) showed clinical benefit following treatment and the combination of onvansertib and irinotecan showed significantly greater anti-tumor activity compared to onvansertib monotherapy in 5 of 6 tested PDX models of irinotecan-resistant, RAS-mutated mCRC.

- **Presented preliminary data from our clinical trial in Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC).** Preliminary data from five evaluable patients in an ongoing open-label Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan and 5-FU in second-line metastatic PDAC provide early signal of efficacy and compare favorably to historical control trials.

- **Enrolled first patients in two investigator-initiated trials in triple negative breast cancer (TNBC) and small cell lung cancer (SCLC).**

Full Year 2022 Financial Results:

Liquidity, cash burn, and cash runway

As of December 31, 2022, Cardiff Oncology had approximately $105.3 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the full year 2022 was approximately $33.8 million, an increase of approximately $10.8 million from $23.0 million for the same period in 2021.

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 $40.3 million for the full year ended December 31, 2022, an increase of $11.1 million from $29.2 million for the same period in 2021. The increase in operating expenses was primarily due to advancing the development of onvansertib through chemistry, manufacturing, and controls (CMC) activities, pharmacology and other development programs, salaries and staff costs primarily due to increased headcount, stock-based compensation for additional grants to employees and higher facility costs for insurance and the amending of our operation lease.

References

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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 is 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.

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Cardiff Oncology, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

	Year Ended December 31,	
	2022	2021
Royalty revenues	$ 386	$ 359
Costs and expenses:		
Research and development	27,107	17,376
Selling, general and administrative	13,181	11,838
Total operating expenses	40,288	29,214
Loss from operations	(39,902)	(28,855)
Interest income, net	1,581	264
Gain (loss) from change in fair value of derivative financial instruments—warrants	—	285
Other income (expense), net	(383)	15
Net loss	(38,704)	(28,291)
Preferred stock dividend	(24)	(24)
Net loss attributable to common stockholders	$ (38,728)	$ (28,315)
Net loss per common share — basic and diluted	$ (0.89)	$ (0.73)
Weighted-average shares outstanding — basic and diluted	43,600	39,030

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 16,347	$ 11,943
Short-term investments	88,920	128,878
Accounts receivable and unbilled receivable	771	535
Prepaid expenses and other current assets	5,246	4,771
Total current assets	111,284	146,127
Property and equipment, net	1,269	382
Operating lease right-of-use assets	2,251	2,796
Other assets	1,387	239
Total Assets	$ 116,191	$ 149,544
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,956	$ 1,439
Accrued liabilities	5,177	4,527
Operating lease liabilities	675	551
Other current liabilities	—	42
Total current liabilities	7,808	6,559
Operating lease liabilities, net of current portion	2,040	2,568
Total Liabilities	9,848	9,127
Stockholders' equity	106,343	140,417
Total liabilities and stockholders' equity	$ 116,191	$ 149,544

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

	Year ended December 31,	
	2022	**2021**
Operating activities		
Net loss	$ (38,704)	$ (28,291)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	1	1
Depreciation	236	451
Stock-based compensation expense	4,256	3,234
Amortization of premiums on short-term investments	632	1,607
Change in fair value of derivative financial instruments—warrants	—	(285)
Release of clinical trial funding commitment	139	2,032
Changes in operating assets and liabilities	(380)	(1,789)
Net cash used in operating activities	(33,820)	(23,040)
Investing activities:		
Net capital expenditures	(892)	(205)
Net purchases, maturities and sales of short-term investments	39,041	(131,243)
Net cash provided by (used in) investing activities	38,149	(131,448)
Financing activities:		
Proceeds from sales of common stock, net of expenses	—	34,187
Proceeds from exercise of options	75	—
Proceeds from exercise of warrants	—	1,263
Net cash provided by financing activities	75	35,450
Net change in cash and cash equivalents	4,404	(119,038)
Cash and cash equivalents—Beginning of period	11,943	130,981
Cash and cash equivalents—End of period	$ 16,347	$ 11,943