
**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): **August 8, 2024**



Cardiff Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-35558
(Commission File Number)

27-2004382
(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 August 8, 2024, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the second quarter ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated June 30, 2024.](#)

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: August 8, 2024

CARDIFF ONCOLOGY, INC.

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



Cardiff Oncology Reports Second Quarter 2024 Results and Provides Business Update

- Initial readout from first-line RAS-mut. mCRC randomized CRDF-004 trial expected in 2H 2024 -

- Published preclinical data underscores the ability of onvansertib to overcome resistance to PARP inhibitors in high-grade serous ovarian carcinomas -

- Five abstracts presented at AACR provide strong scientific rationale for the clinical development of onvansertib across multiple tumor types and various combinations -

- Cash and equivalents of \$60 million as of June 30, 2024, projected runway through the end of Q3 2025 -

- Company will hold a conference call today at 4:30 p.m. ET/1:30 p.m. PT -

SAN DIEGO, August 8, 2024 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced financial results for the second quarter ended June 30, 2024, and provided a business update.

"The first half of 2024 has been productive for Cardiff Oncology as we have been focused on the enrollment of our CRDF-004 trial for first-line treatment of RAS-mutated mCRC evaluating onvansertib + chemo/bev," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "We are working closely with our clinical operations partner, Pfizer Ignite, and are encouraged by ongoing enrollment trends at the 33 sites currently open to enrollment. We believe the robust body of evidence generated to date from our Phase 1b/2 and ONSEMBLE trials lays a strong foundation for our upcoming data readout for CRDF-004 later this year. Furthermore, we are optimistic about the potential of onvansertib to change the treatment paradigm for the entire first-line RAS-mutated mCRC patient population who has not had access to any new therapies in over 20 years."

Upcoming expected milestones

- First-line RAS-mutated mCRC randomized data readout expected in 2H 2024

Company highlights for the quarter ended June 30, 2024 and subsequent weeks include:

- **Updated clinical development plan for metastatic pancreatic ductal adenocarcinoma (mPDAC) with a planned new investigator-initiated trial**
 - The new mPDAC trial will evaluate onvansertib in combination with the recently approved first-line standard of care, NALIRIFOX, details of which we will announce when available. The trial replaces a previously planned Phase 2 trial of onvansertib in combination with first-line standard of care, Gemzar® and Abraxane®.
- **Published preclinical data of the combination of onvansertib and olaparib in olaparib-resistant ovarian cancer models in a peer-reviewed journal**
 - The combination of onvansertib and olaparib, a PARP inhibitor approved in ovarian cancer, demonstrated inhibition of tumor growth and prolonged survival in olaparib-resistant high-grade serous ovarian carcinomas. The combination was well tolerated *in vivo*, and these findings underscore onvansertib's ability to slow the progressions of ovarian carcinomas. Resistance to olaparib has been shown in clinical settings and these data support the ability of onvansertib to resensitize ovarian cancers to PARP inhibitors.
- **Presented five abstracts at AACR providing a strong scientific rationale for the clinical development of onvansertib across multiple tumor types and various combinations**

- The posters are located in the “[Scientific Presentations](#)” section of the Cardiff Oncology website and a press release summarizing the data can be found [here](#).

Second Quarter 2024 Financial Results

Liquidity, cash burn, and cash runway

As of June 30, 2024, Cardiff Oncology had approximately \$60.3 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the second quarter of 2024 was approximately \$9.2 million, an increase of approximately \$2.1 million from \$7.1 million for the same period in 2023.

Based on its current expectations and projections, the Company believes its current cash resources are sufficient to fund its operations through the end of Q3 2025.

Operating results

Total operating expenses were approximately \$12.7 million for the three months ended June 30, 2024, an increase of \$0.4 million from \$12.3 million for the same period in 2023. The increase in operating expenses was primarily due to clinical programs and outside service costs related to the development of our lead drug candidate, onvansertib, offset by an employee severance agreement which occurred during the previous period.

Conference Call and Webcast

Cardiff Oncology will host a corresponding conference call and live webcast at 4:30 p.m. ET/1:30 p.m. PT on August 8, 2024. Individuals interested in listening to the live conference call may do so by using the webcast link in the "Investors" section of the company's website at www.cardiffoncology.com. A webcast replay will be available in the investor relations section on the company's website following the completion of the call.

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 RAS-mutated metastatic colorectal cancer (mCRC), as well as in ongoing and planned investigator-initiated trials in metastatic pancreatic ductal adenocarcinoma (mPDAC), small cell lung cancer (SCLC) and triple negative breast cancer (TNBC). 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; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for

additional financing; risks related to business interruptions, including the outbreak of an epidemic or pandemic such as the COVID-19 coronavirus and cyber-attacks on our information technology infrastructure, 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 our product candidate 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, 2023, 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:

Grace Spencer
Taft Communications
609-583-1151
grace@taftcommunications.com

Cardiff Oncology, Inc.
Condensed Statements of Operations
(in thousands, except for per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Royalty revenues	\$ 163	\$ 108	\$ 368	\$ 191
Costs and expenses:				
Research and development	9,493	8,020	17,501	17,072
Selling, general and administrative	3,215	4,296	6,345	7,379
Total operating expenses	12,708	12,316	23,846	24,451
Loss from operations	(12,545)	(12,208)	(23,478)	(24,260)
Interest income, net	805	1,053	1,731	1,993
Other income (expense), net	(38)	5	(42)	(106)
Net loss	(11,778)	(11,150)	(21,789)	(22,373)
Preferred stock dividend	(6)	(6)	(12)	(12)
Net loss attributable to common stockholders	\$ (11,784)	\$ (11,156)	\$ (21,801)	\$ (22,385)
Net loss per common share — basic and diluted	\$ (0.26)	\$ (0.25)	\$ (0.49)	\$ (0.50)
Weighted-average shares outstanding — basic and diluted	44,825	44,677	44,752	44,677

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,501	\$ 21,655
Short-term investments	34,818	53,168
Accounts receivable and unbilled receivable	451	288
Prepaid expenses and other current assets	1,476	2,301
Total current assets	62,246	77,412
Property and equipment, net	1,095	1,238
Operating lease right-of-use assets	1,439	1,708
Other assets	1,271	1,279
Total Assets	\$ 66,051	\$ 81,637
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,108	\$ 1,966
Accrued liabilities	6,712	7,783
Operating lease liabilities	702	691
Total current liabilities	12,522	10,440
Operating lease liabilities, net of current portion	1,141	1,458
Total Liabilities	13,663	11,898
Stockholders' equity		
Total liabilities and stockholders' equity	\$ 66,051	\$ 81,637

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

	Six Months Ended June 30,	
	2024	2023
Operating activities		
Net loss	\$ (21,789)	\$ (22,373)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	207	188
Stock-based compensation expense	2,303	2,645
Accretion of discounts on short-term investments, net	(283)	(405)
Changes in operating assets and liabilities	2,592	4,154
Net cash used in operating activities	<u>(16,970)</u>	<u>(15,791)</u>
Investing activities:		
Capital expenditures	(80)	(259)
Net purchases, maturities and sales of short-term investments	18,731	19,072
Net cash provided by investing activities	<u>18,651</u>	<u>18,813</u>
Financing activities:		
Proceeds from sales of common stock, net of expenses	1,805	—
Proceeds from exercise of options	360	—
Net cash provided by financing activities	<u>2,165</u>	<u>—</u>
Net change in cash and cash equivalents	3,846	3,022
Cash and cash equivalents—Beginning of period	21,655	16,347
Cash and cash equivalents—End of period	<u>\$ 25,501</u>	<u>\$ 19,369</u>