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 4, 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 August 4, 2022, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the second quarter ended June 30, 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 August 4, 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: August 4, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Reports Second Quarter 2022 Results and Provides Business Updates

- Initial preclinical data in ovarian cancer presented at AACR showed treatment with onvansertib plus olaparib leading to a statistically significant survival benefit compared to treatment with either agent alone

- Data from Phase 2 metastatic castration-resistant prostate cancer (mCRPC) clinical trial presented at AACR showed higher disease control rates with increasing onvansertib dose density

- Biomarker data from Phase 2 mCRPC clinical trial presented at AACR showed treatment response correlating with mutations in *MTOR* and *PTEN,* two key genes in the PI3K signaling pathway

- Cash, cash equivalents, and short-term investments of approximately $122 million as of June 30, 2022

SAN DIEGO, August 4, 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 company highlights and financial results for the second quarter ended June 30, 2022.

“We remain focused on advancing our research and development priorities, in particular our lead clinical trial program in KRAS-mutated metastatic colorectal cancer (mCRC),” said Mark Erlander, PhD, chief executive officer of Cardiff Oncology. “In addition, our recent AACR presentation highlighted preclinical data from patient-derived ovarian cancer xenograft models in which onvansertib was shown to combine synergistically with a PARP inhibitor to overcome PARP inhibitor resistance. Also presented at AACR were updated data from our Phase 2 clinical trial of onvansertib in combination with abiraterone in metastatic castration-resistant prostate cancer that showed clinically meaningful disease control rates in patients showing initial abiraterone resistance. We look forward to building on these preclinical and clinical results and believe our talented leadership team and strong cash position have us well-positioned for continued success.”

Program highlights for the quarter ended June 30, 2022, include:

Ovarian Cancer Preclinical Program:

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 American Association for Cancer Research (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.

Metastatic Castration-resistant Prostate Cancer (mCRPC) Clinical Program:

Reported updated clinical and new biomarker data from Phase 2 clinical trial of onvansertib plus abiraterone/prednisone in mCRPC patients showing initial abiraterone resistance at the AACR Annual Meeting

Data featured in a poster presentation showed clinically meaningful disease control rates that rose with increasing onvansertib dose density. 75% (15 of 20) of evaluable patients in Arm C, which represents the trial's most dose-dense treatment schedule, showed radiographic stable disease (SD) or a radiographic partial response (PR) at 12-weeks, compared to 53% (9 of 17) and 58% (11 of 19) of evaluable patients in the less dose-dense Arms A and B, respectively.

Additional highlights from the announcement include:

- Treatment response (SD/PR) correlated with mutations in PTEN and MTOR, key genes in the PI3K signaling pathway
- Treatment response correlated with gene signatures 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

Second Quarter 2022 Financial Results:

Liquidity and cash burn

As of June 30, 2022, Cardiff Oncology had approximately $122 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the second quarter of 2022 was approximately $6.7 million, an increase of approximately $2.4 million from $4.3 million for the same period in 2021.

Operating Expenses

(in thousands)	Three Months Ended June 30,		
	2022	2021	Increase (Decrease)
Costs and expenses:			
Research and development	$ 7,448	$ 4,119	$ 3,329
Selling, general and administrative	3,086	2,838	248
Total operating expenses	$ 10,534	$ 6,957	$ 3,577

The overall increase in research and development expenses was primarily related to chemistry, manufacturing, and controls ("CMC") and clinical pharmacology studies to support the development of our lead drug candidate, onvansertib. Salaries and staff costs increased primarily due to additional hires in senior management and our clinical operations team.

The overall increase in selling, general and administrative expense was primarily due to higher salaries costs from merit increases and additional new hires. An increase in D&O insurance costs and higher operating lease costs also contributed to higher selling, general and administrative expenses in the current period, offset by a reduction in recruiting fees from the prior period.

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, a PLK1 inhibitor 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 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, 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:
James Levine
Chief Financial Officer
858-952-7670
jlevine@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)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Royalty revenues	$ 91	$ 68	$ 165	$ 140
Costs and expenses:				
Research and development	7,448	4,119	14,656	7,398
Selling, general and administrative	3,086	2,838	7,026	5,073
Total operating expenses	10,534	6,957	21,682	12,471
Loss from operations	(10,443)	(6,889)	(21,517)	(12,331)
Interest income, net	253	71	383	115
Gain (loss) from change in fair value of derivative financial instruments—warrants	—	61	—	268
Other income (expense), net	(253)	—	(302)	12
Net loss	(10,443)	(6,757)	(21,436)	(11,936)
Preferred stock dividend	(6)	(6)	(12)	(12)
Net loss attributable to common stockholders	$ (10,449)	$ (6,763)	$ (21,448)	$ (11,948)
Net loss per common share — basic and diluted	$ (0.24)	$ (0.17)	$ (0.50)	$ (0.31)
Weighted-average shares outstanding — basic and diluted	43,306	38,761	43,269	37,967

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,965	$ 11,943
Short-term investments	101,041	128,878
Accounts receivable and unbilled receivable	551	535
Prepaid expenses and other current assets	4,857	4,771
Total current assets	127,414	146,127
Property and equipment, net	1,138	382
Operating lease right-of-use assets	2,524	2,796
Other assets	185	239
Total Assets	$ 131,261	$ 149,544
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,522	$ 1,439
Accrued liabilities	6,279	4,527
Operating lease liabilities	670	551
Other current liabilities	10	42
Total current liabilities	8,481	6,559
Operating lease liabilities, net of current portion	2,306	2,568
Total Liabilities	10,787	9,127
Stockholders' equity	120,474	140,417
Total liabilities and stockholders' equity	$ 131,261	$ 149,544

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2022	**2021**
Operating activities		
Net loss	$ (21,436)	$ (11,936)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	1
Depreciation	69	228
Stock-based compensation expense	2,207	1,304
Amortization of premiums on short-term investments	557	698
Change in fair value of derivative financial instruments—warrants	—	(268)
Release of clinical trial funding commitment	139	926
Changes in operating assets and liabilities	1,520	(1,138)
Net cash used in operating activities	(16,944)	(10,185)
Investing activities:		
Net capital expenditures	(412)	—
Net purchases, maturities and sales of short-term investments	26,378	(130,703)
Net cash provided by/(used in) investing activities	25,966	(130,703)
Financing activities:		
Proceeds from sales of common stock, net of expenses	—	19,225
Proceeds from exercise of warrants	—	1,263
Net cash provided by financing activities	—	20,488
Net change in cash and cash equivalents	9,022	(120,400)
Cash and cash equivalents—Beginning of period	11,943	130,981
Cash and cash equivalents—End of period	$ 20,965	$ 10,581