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): **November 3, 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 November 3, 2022, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 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 November 3, 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: November 3, 2022

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology™

Cardiff Oncology Reports Third Quarter 2022 Results and Provides Business Updates

- *Data from Phase 1b/2 trial in KRAS-mutated metastatic colorectal cancer (mCRC), per September 12th announcement, show durable responses to treatment and support initiation of ONSEMBLE, a randomized Phase 2 trial in KRAS/NRAS-mutated mCRC*

- *Cash, cash equivalents, and short-term investments of approximately $114 million as of September 30, 2022, provide projected runway into 2025*

SAN DIEGO, November 3, 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 financial results and recent highlights for the third quarter ended September 30, 2022.

“We recently announced Phase 1b/2 data that demonstrate onvansertib’s ability to generate durable responses in KRAS-mutated mCRC patients, with various underlying mutations, when combined with standard-of-care FOLFIRI/bevacizumab. In addition, we observed an increase in objective response rate and progression-free survival in the bevacizumab-naïve subgroup of patients, providing key learnings to maximize ovansertib’s therapeutic and commercial potential,” said Mark Erlander, PhD, chief executive officer of Cardiff Oncology. “In the fourth quarter we plan to activate ONSEMBLE, a randomized Phase 2 trial in our lead KRAS/NRAS-mutated mCRC program. This trial is designed to corroborate the robust signal of efficacy provided by the Phase 1b/2 results and position onvansertib for a possible accelerated approval opportunity by demonstrating its contribution over standard-of-care alone.”

Dr. Erlander continued, “With a clear strategic focus and projected cash runway into 2025, we believe we are well positioned to generate value from each of our programs in the coming months and years.”

Recent highlights for the quarter ended September 30, 2022 include:

KRAS/NRAS-mutated mCRC Program:

ONSEMBLE, a Phase 2, open-label, randomized trial for second line treatment of KRAS/NRAS-mutated mCRC, on track for activation in Q4 2022

The Company 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. ONSEMBLE is expected to enroll approximately 150 patients who will be randomized 1:1:1 to receive SoC alone, SoC plus 20 mg onvansertib, or SoC plus 30 mg onvansertib, with onvansertib administered on days 1-5 and 15-19 of 28-day treatment cycles. The primary endpoint of the trial is objective response rate (ORR). Progression-free survival (PFS) and duration of response (DoR) will be key secondary endpoints. Activation of the trial is expected in Q4 2022, and topline data are expected in 2H 2024.

Phase 1b/2 mCRC data show durable response to treatment across multiple KRAS-mutation variants, as well as an objective response rate and median progression-free survival that substantially exceed those observed in historical control trials

Data from the Phase 1b/2 trial of onvansertib plus FOLFIRI/bevacizumab in second line KRAS-mutated mCRC were presented during the European Society for Medical Oncology (ESMO) Congress 2022 and on a company webcast on September 12, 2022. Key data and conclusions featured in these presentations include:

- Objective response rate (ORR) across all evaluable patients was 35% (n=48) as compared to an ORR of 5-13% observed historically[1-4], 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[1-4]

Subgroup analysis from Phase 1b/2 mCRC trial shows improved ORR and mPFS in bevacizumab naïve patients

A recently reported 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[4-9]. The observed increase in ORR in bevacizumab naïve patients in the Phase 1b/2 trial was seen consistently across all patient characteristics and demographics. Based on these findings, the Company plans to stratify for prior bevacizumab exposure within the randomization of the ONSEMBLE trial and conduct preclinical studies to explore the apparent synergy between onvansertib and bevacizumab.

Data presented at the ESMO conference suggest combining onvansertib with irinotecan (a component of FOLFIRI) overcomes irinotecan-resistance in RAS-mutated mCRC

Findings from Cardiff Oncology's 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. Highlights from the presentation include:

- EAP patients with prior irinotecan treatment (43 of 51) showed clinical benefit following treatment
- 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 CRC

Collectively, these results support the observed mDoR in Cardiff Oncology's ongoing Phase 1b/2 trial in KRAS-mutated mCRC and suggest onvansertib may combine with irinotecan to overcome mechanisms driving intrinsic and refractory resistance.

Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Program:

Preliminary data provide early signal of efficacy and compare favorably to historical control trials

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 showed one patient achieving an initial partial response (PR) and three patients achieving stable disease (SD). Based on prior clinical studies, the historical ORR and mPFS for second-line mPDAC patients are 7.7% and 3.1 months, respectively[10,11]. All four patients achieving a PR or SD remained on study without disease progression as of the data cut-off date and all have shown tumor shrinkage from baseline. Additional data from the ongoing Phase 2 trial are expected in mid-2023.

Investigator-initiated Trials

Trials in triple negative breast cancer (TNBC) and small cell lung cancer (SCLC) enrolled first patients

A single-arm, Phase 1b/2 trial of onvansertib in combination with paclitaxel in patients with unresectable locally advanced or metastatic TNBC recently enrolled its first patient at Dana Farber Cancer Institute (DFCI). Preliminary data from the trial are expected in late 2023 or early 2024. For more information, please visit NCT05383196.

A single-arm, two-stage, Phase 2 trial of onvansertib monotherapy in patients with relapsed SCLC recently enrolled its first patient at the University of Pittsburgh Medical Center (UPMC). Preliminary data from the trial are expected in mid-2023. For more information, please visit NCT05450965.

Third Quarter 2022 Financial Results:

Liquidity, cash burn and cash runway

As of September 30, 2022, Cardiff Oncology had approximately $114 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the third quarter of 2022 was approximately $7.5 million, an increase of approximately $2.0 million from $5.5 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 Expenses

(in thousands)	Three Months Ended September 30,		
	2022	2021	Increase (Decrease)
Costs and expenses:			
Research and development	$ 6,009	$ 4,154	$ 1,855
Selling, general and administrative	3,077	2,930	147
Total operating expenses	$ 9,086	$ 7,084	$ 2,002

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 also contributed to higher selling, general and administrative expenses in the current period, offset by a reduction in recruiting fees from the prior period.

References

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9. Beretta et al., Med Oncol 2013, 30:486
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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/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 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 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, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Royalty revenues	$ 93	$ 86	$ 258	$ 226
Costs and expenses:				
Research and development	6,009	4,154	20,665	11,552
Selling, general and administrative	3,077	2,930	10,103	8,003
Total operating expenses	9,086	7,084	30,768	19,555
Loss from operations	(8,993)	(6,998)	(30,510)	(19,329)
Interest income, net	458	70	841	185
Gain (loss) from change in fair value of derivative financial instruments—warrants	—	12	—	280
Other income (expense), net	(36)	3	(338)	15
Net loss	(8,571)	(6,913)	(30,007)	(18,849)
Preferred stock dividend	(6)	(6)	(18)	(18)
Net loss attributable to common stockholders	$ (8,577)	$ (6,919)	$ (30,025)	$ (18,867)
Net loss per common share — basic and diluted	$ (0.20)	$ (0.17)	$ (0.69)	$ (0.49)
Weighted-average shares outstanding — basic and diluted	43,333	39,552	43,291	38,501

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 18,717	$ 11,943
Short-term investments	95,586	128,878
Accounts receivable and unbilled receivable	650	535
Prepaid expenses and other current assets	4,802	4,771
Total current assets	119,755	146,127
Property and equipment, net	1,304	382
Operating lease right-of-use assets	2,388	2,796
Other assets	184	239
Total Assets	$ 123,631	$ 149,544
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,425	$ 1,439
Accrued liabilities	6,138	4,527
Operating lease liabilities	674	551
Other current liabilities	8	42
Total current liabilities	8,245	6,559
Operating lease liabilities, net of current portion	2,174	2,568
Total Liabilities	10,419	9,127
Stockholders' equity	113,212	140,417
Total liabilities and stockholders' equity	$ 123,631	$ 149,544

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Operating activities		
Net loss	$ (30,007)	$ (18,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	1
Depreciation	150	338
Stock-based compensation expense	3,244	2,244
Amortization of premiums on short-term investments	672	1,160
Change in fair value of derivative financial instruments—warrants	—	(280)
Release of clinical trial funding commitment	139	1,505
Changes in operating assets and liabilities	1,372	(1,769)
Net cash used in operating activities	(24,430)	(15,650)
Investing activities:		
Net capital expenditures	(817)	(98)
Net purchases, maturities and sales of short-term investments	31,946	(122,556)
Net cash provided by (used in) investing activities	31,129	(122,654)
Financing activities:		
Proceeds from sales of common stock, net of expenses	—	19,225
Proceeds from exercise of options	75	—
Proceeds from exercise of warrants	—	1,263
Net cash provided by financing activities	75	20,488
Net change in cash and cash equivalents	6,774	(117,816)
Cash and cash equivalents—Beginning of period	11,943	130,981
Cash and cash equivalents—End of period	$ 18,717	$ 13,165