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 4, 2021**

Cardiff Oncology™

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 4, 2021, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2021. 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 4, 2021.

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 4, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology™

Cardiff Oncology Reports Third Quarter 2021 Results and Provides Business Updates

- Announced updated clinical data from lead KRAS-mutated metastatic colorectal cancer program showing an objective response rate and median progression free survival that substantially exceed those seen in historical control trials

- Strengthened management team with the appointments of Katherine L. Ruffner, M.D., as CMO and James E. Levine as CFO

- Cash, cash equivalents, and short-term investments of approximately $134 million as of September 30, 2021

SAN DIEGO, November 4, 2021 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need including KRAS-mutated colorectal cancer, pancreatic cancer, and castrate-resistant prostate cancer, today announced recent company highlights and financial results for the third quarter ended September 30, 2021.

“During the third quarter, the data we released from our Phase 1b/2 KRAS-mutated metastatic colorectal cancer trial showed meaningful improvements in treatment response and durability relative to historical controls,” said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. “With radiographic responses achieved across multiple KRAS mutation variants, we believe these findings differentiate onvansertib from agents targeting individual KRAS mutations such as G12C.”

Dr. Erlander added, “Beyond our KRAS-focused programs, we also continue to leverage onvansertib’s broadly applicable mechanism of action to advance its development as a platform molecule. By targeting PLK1, onvansertib inhibits DNA repair and processes that promote mitosis, positioning it to combine synergistically with a range of anti-cancer agents and potentially improve outcomes across a broad array of difficult-to-treat indications.”

Program highlights for the quarter ended September 30, 2021, include:

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:

Announced new data from Phase 1b/2 trial evaluating onvansertib plus FOLFIRI/bevacizumab continuing to show robust objective response rate and progression-free survival

The data were presented as part of a key opinion leader webinar and showed that trial participants treated with onvansertib plus standard-of-care FOLFIRI/bevacizumab had an objective response rate (ORR) and median progression-free survival (mPFS) that substantially exceeded those previously achieved with FOLFIRI/bevacizumab alone. Highlights from the webinar include:

Efficacy data in patients evaluable for disease response as of data cutoff date (July 2, 2021):

- Patients treated per protocol at the recommended Phase 2 dose (RP2D; 15 mg/m^2) across Phase 1b and Phase 2
  - 7 of 19 (37%) achieved a confirmed partial response (PR; based on further follow-up of patients with an initial PR as of data cutoff date)

    - ORRs observed in historical control trials in similar patient populations treated with standard-of-care are 5-13%[1-4]
- Patients evaluable for response treated at all dose levels (12 mg/m^2, 15 mg/m^2, 18 mg/m^2) across Phase 1b and Phase 2
    - 10 of 32 (31%) have achieved a confirmed PR (based on further follow-up of patients with an initial PR as of data cutoff date)

mPFS biomarker, and safety data as of cutoff date

- mPFS across all response-evaluable patients (n = 32) is 9.4 months (95% confidence interval: 7.8 – not yet reached); which favorably compares to ~4.5-5.7 months reported in historical control trials in similar patient populations treated with standard-of-care[1-4]
- PRs were observed across different KRAS mutation variants, including the 3 most common observed in colorectal cancer (G12D, G12V, G13D)
- The combination of onvansertib and FOLFIRI/bevacizumab was shown to be well-tolerated with only 10% (49/490) of reported treatment-emergent adverse events being G3/G4

A replay of the key opinion leader webinar, which featured the clinical trial principal investigator, Heinz-Josef Lenz, M.D., FACP, USC Norris Comprehensive Cancer Center, key clinical advisor Afsaneh Barzi, M.D., Ph.D., City of Hope Comprehensive Cancer Center, and members of the Cardiff Oncology management team, can be viewed here.

Corporate Highlights:

Strengthened management team with the appointments of Katherine L. Ruffner, M.D., as chief medical officer and James E. Levine as chief financial officer

Dr. Ruffner is a US-trained hematologist/oncologist with over 25 years of clinical care, oncology, biotechnology and pharmaceutical drug development experience, most recently serving as vice president, clinical development for ALX Oncology. Mr. Levine was most recently the CFO of Cidara Therapeutics and has over two decades of corporate and investment banking experience in the biotechnology and pharmaceutical sectors.

Third Quarter 2021 Financial Results:

As of September 30, 2021, Cardiff Oncology had approximately $134 million in cash, cash equivalents, and short-term investments.

Total operating expenses were approximately $7.1 million for the three months ended September 30, 2021, an increase of $2.6 million from $4.5 million for the same period in 2020. The increase in operating expenses is attributed to advancing ongoing and new onvansertib clinical development programs and preclinical activities, additional outside services for legal fees mainly related to the expansion of our patent portfolio, recruiting fees and stock compensation expense.

Research and development expenses increased by approximately $1.3 million to $4.2 million for the three months ended September 30, 2021, from $2.9 million for the same period in 2020. The increase in research and development expenses was primarily due to advancing the onvansertib clinical and preclinical programs and recruitment fees to fill critical medical and clinical operations positions.

Selling, general and administrative expenses increased by approximately $1.3 million to $2.9 million for the three months ended September 30, 2021, from $1.6 million for the same period in 2020. The increase is attributed to increased outside services for legal fees related to the expansion of our patent portfolio, recruitment fees, and stock compensation expense.

Net cash used in operating activities for the third quarter of 2021 was approximately $5.5 million, an increase of approximately $2.0 million from $3.5 million for the same period in 2020.

References

1. Giessen et al., Acta Oncologica 2015, 54: 187-193
2. Cremolini et al., Lancet Oncol 2020, 21: 497–507
3. Antoniotti et al., Correspondence Lancet Oncol June 2020
4. Bennouna et al., Lancet Oncol 2013; 14: 29–37

About Cardiff Oncology, Inc.

Cardiff Oncology is a clinical-stage oncology company, developing new precision medicine treatment options for cancer patients in indications with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations that overcome disease resistance and improve disease response to standard treatment regimens and to increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 (PLK1) inhibitor, in combination with standard-of-care anti-cancer therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to refine assessment of patient response to treatment. We have three clinical programs currently ongoing: a Phase 1b/2 study of onvansertib in combination with FOLFIRI/Avastin® (bevacizumab) in KRAS-mutated metastatic colorectal cancer (mCRC); a Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (mPDAC); and a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castrate-resistant prostate cancer (mCRPC). 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 any of our technology or products 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, 2020, 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,	
	2021	2020	2021	2020
Revenues:				
Royalties	$ 86	$ 136	$ 226	$ 247
Total revenues	86	136	226	247
Costs and expenses:				
Research and development	4,154	2,855	11,552	8,036
Selling, general and administrative	2,930	1,644	8,003	4,800
Total operating expenses	7,084	4,499	19,555	12,836
Loss from operations	(6,998)	(4,363)	(19,329)	(12,589)
Interest income, net	70	16	185	67
Gain (loss) from change in fair value of derivative financial instruments—warrants	12	(144)	280	(186)
Other income (expense), net	3	(6)	15	(2)
Net loss	(6,913)	(4,497)	(18,849)	(12,710)
Preferred stock dividend	(6)	(6)	(18)	(18)
Deemed dividend on preferred stock	—	—	—	(3,267)
Net loss attributable to common stockholders	$ (6,919)	$ (4,503)	$ (18,867)	$ (15,995)
Net loss per common share — basic and diluted	$ (0.17)	$ (0.19)	$ (0.49)	$ (1.00)
Weighted-average shares outstanding — basic and diluted	39,552	23,341	38,501	15,942

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 13,165	$ 130,981
Short-term investments	120,882	—
Accounts receivable and unbilled receivable	395	320
Prepaid expenses and other current assets	3,327	2,055
Total current assets	137,769	133,356
Property and equipment, net	383	624
Operating lease right-of-use assets	3,017	343
Other assets	143	404
Total Assets	$ 141,312	$ 134,727
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 396	$ 1,366
Accrued expenses	4,010	3,851
Operating lease liabilities	594	860
Other current liabilities	42	42
Total current liabilities	5,042	6,119
Derivative financial instruments—warrants	5	285
Operating lease liabilities, net of current portion	2,691	9
Other Liabilities	30	156
Total Liabilities	7,768	6,569
Stockholders' equity	133,544	128,158
Total liabilities and stockholders' equity	$ 141,312	$ 134,727

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net loss	$ (18,849)	$ (12,710)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	1	—
Impairment loss	—	34
Depreciation	338	349
Stock-based compensation expense	2,244	821
Amortization of premiums on short-term investments	1,160	—
Change in fair value of derivative financial instruments—warrants	(280)	186
Release of clinical trial funding commitment	1,505	868
Changes in operating assets and liabilities	(1,769)	(739)
Net cash used in operating activities	(15,650)	(11,191)
Investing activities:		
Capital expenditures	(98)	(154)
Net purchases, maturities and sales of short-term investments	(122,556)	—
Net cash used in investing activities	(122,654)	(154)
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	19,225	18,279
Costs related to the clinical trial funding commitment	—	(8)
Proceeds from exercise of options	—	7
Proceeds from exercise of warrants	1,263	18,972
Borrowings under note payable	—	305
Net cash provided by financing activities	20,488	37,555
Net change in cash and cash equivalents	(117,816)	26,210
Cash and cash equivalents—Beginning of period	130,981	10,195
Cash and cash equivalents—End of period	$ 13,165	$ 36,405