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 5, 2021**

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 5, 2021, Cardiff Oncology, Inc. issued a press release announcing company highlights and financial results for the second quarter ended June 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 August 5, 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: August 5, 2021

CARDIFF ONCOLOGY, INC.

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

Cardiff Oncology Reports Second Quarter 2021 Results and Provides Business Updates

- **Lead clinical program of onvansertib in KRAS-mutated metastatic colorectal cancer continues to generate data showing robust response to treatment and progression-free survival**
- **First patient dosed in Phase 2 study of onvansertib in combination with standard-of-care for the treatment of metastatic pancreatic ductal adenocarcinoma**
- **Newly appointed CMO and CFO, and shareholders elected two new members to Company's Board of Directors, with expertise in drug development, financial strategy, and business development**

SAN DIEGO (August 5, 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 second quarter ended June 30, 2021.

"During the past few months, we have achieved important clinical milestones that have advanced our drug development programs and further highlighted the clinical benefits of onvansertib across indications representing some of the most difficult to treat cancers" said Mark Erlander, Ph.D., chief executive officer of Cardiff Oncology. "The added expertise in drug development, financial strategy and business development brought by our CMO, CFO and new board members comes at a pivotal time for the Company, as our strong cash position and recent progress in our clinical and preclinical programs has us poised for a steady cadence of catalysts over the coming months."

Dr. Erlander continued, "Our clinical progress during the second quarter was highlighted by advancements in our two KRAS-focused programs. In metastatic pancreatic ductal adenocarcinoma (mPDAC), where approximately 95% of patients have a KRAS mutation, we began dosing patients in our Phase 2 trial evaluating onvansertib in combination with nanoliposomal irinotecan, 5-FU and leucovorin. This trial is supported by the promising data from our lead KRAS-mutated metastatic colorectal cancer program presented in April, which showed that treatment with onvansertib plus irinotecan, 5-FU and bevacizumab resulted in an overall response rate and median progression free survival that compare favorably to historical controls. Looking forward, we expect continued progress in these and our castrate-resistant prostate cancer trial as well as advancements in our efforts to expand onvansertib's pipeline of indications."
Program highlights for the quarter ended June 30, 2021, along with recent developments, include:

Corporate Highlights:

Strengthened company leadership with the appointments of Katherine L. Ruffner, M.D., as chief medical officer (CMO) and James E. Levine as chief financial officer (CFO)

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 joins Cardiff Oncology with over two decades of corporate and investment banking experience in the biotechnology and pharmaceutical sectors and was most recently the chief financial officer of Cidara Therapeutics.

Added two new independent members to the Board of Directors

Mani Mohindru, Ph.D., and Renee P. Tannenbaum, Pharm.D., were appointed as independent members of Cardiff Oncology's Board of Directors in June 2021. Dr. Mohindru is an experienced biotech industry executive and is currently the chief executive officer of Novasenta, an early-stage biotechnology company, and a director on the Board of CytomX, Inc., a clinical-stage biopharmaceutical company. Dr. Tannenbaum currently serves as vice president of global partnering at Halozyme, Inc. and has in-depth expertise in business development and in establishing successful strategic partnerships.

Added as a member of FTSE Russell Indexes

As of the market open on June 28, 2021, Cardiff Oncology was included as a member of the small-cap Russell 2000® Index, the all-cap Russell 3000® Index, and the Russell Microcap® Index.

KRAS-mutated Metastatic Colorectal Cancer (mCRC) Program:
Announced the upcoming presentation of new data from lead clinical program in KRAS-mutated mCRC on Wednesday, September 8, 2021

Updated data from the Phase 1b/2 trial evaluating onvansertib in combination with standard-of-care FOLFIRI/bevacizumab for the second-line treatment of patients with KRAS-mutated mCRC will be announced at a webinar on September 8, 2021 at 4:00 p.m. ET featuring the clinical trial principal investigator, Heinz-Josef Lenz, M.D., FACP (USC Norris Comprehensive Cancer Center), and key clinical advisor Afsaneh Barzi, M.D., Ph.D., (City of Hope Comprehensive Cancer Center). To register for the webinar, click here.

Announced updated data from the Phase 1b/2 trial evaluating onvansertib plus FOLFIRI/bevacizumab that continues to demonstrate robust response to treatment and progression-free survival in KRAS-mutated mCRC

The data were presented as part of a Key Opinion Leader webinar in April featuring Daniel H. Ahn, D.O., M.S. (Mayo Clinic Arizona), and Manish R. Sharma, M.D. (START Midwest), and showed robust patient response and progression-free survival when onvansertib is combined with standard-of-care therapy in second line KRAS-mutated mCRC. Data highlights from the Phase 1b trial, as of April 4, 2021, include:

- 7 of 18 (39%) evaluable patients achieved a partial response (PR)
- Evaluable patients have a median progression free survival (mPFS) of 9.4 months (95% confidence interval: 7.85 months – not reached), more than double the historical 4.5-month mPFS from analysis of 23 randomized trials in second-line metastatic colorectal cancer (data from ~10,800 patients)[1]
- 7 patients remain on treatment
- Clinical responses were observed across different KRAS mutations, including the 3 most common in colorectal cancer (G12D, G12V, G13D)
- The greatest decreases in plasma KRAS mutant allelic frequency (MAF) after 1 cycle of treatment were observed in patients achieving a PR
- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no major or unexpected toxicities attributed to onvansertib

Presented findings from the Expanded Access Program (EAP) for onvansertib in KRAS-mutated mCRC highlighting the clinical benefit of onvansertib in heavily pretreated patients
Findings from 20 evaluable EAP participants who were heavily pre-treated (median of 3 prior lines of treatment) were presented at the American Association for Cancer Research (AACR) Annual Meeting 2021 in April. Participants enrolled in the EAP had failed or progressed on multiple lines of standard-of-care treatment and were treated with the same combination regimen (onvansertib 15 mg/m^2 + FOLFIRI/bevacizumab) and dosing schedule used in the ongoing Phase 1b/2 mCRC clinical trial. Highlights from the AACR presentation included:

- 15 of 20 (75%) evaluable participants received an irinotecan-based regimen as their last therapy prior to enrolling in the EAP.
- 13 of 20 (65%) evaluable participants were progressing prior to enrolling in the EAP
- Median progression free survival (mPFS) was 5.6 months (95% confidence interval: 2.7 months – not reached), which is significantly greater than historical controls (2-3 months)[2]
- 62.5% of participants had a greater than 50% decrease in KRAS MAF after one cycle of treatment and continue to show a durable response and have not reached mPFS
- 11 of 20 of evaluable participants remain on treatment
- Onvansertib in combination with FOLFIRI/bevacizumab has been well tolerated with no serious adverse events (SAEs) reported

Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Program:

Began dosing patients in the Phase 2 trial of onvansertib in metastatic PDAC

The trial is a key component of onvansertib's KRAS-targeted clinical programs and is designed to assess the safety and preliminary efficacy of onvansertib in combination with nanoliposomal irinotecan (Onivyde®), leucovorin and fluorouracil (5-FU) as a second-line treatment in patients with metastatic PDAC who have failed first-line gemcitabine-based therapy. The trial expects to enroll 40 patients at 6 U.S. sites. Onvansertib's potential in mPDAC, where ~95% of patients have a KRAS mutation, is supported by the promising clinical data seen in KRAS-mutated mCRC patients treated with the combination of onvansertib, irinotecan and 5-FU (FOLFIRI).

Metastatic Castrate-Resistant Prostate Cancer (mCRPC) Program:

Identified an androgen-independent mechanism of synergy between onvansertib and abiraterone in mCRPC

Collaborative studies with the Massachusetts Institute of Technology featured in a virtual oral poster presentation at the AACR Annual Meeting 2021 suggest that the androgen receptor signaling inhibitor abiraterone sensitizes certain prostate cancer cells to onvansertib via the induction of a mitosis related gene signature and disruption of mitotic spindle orientation. These results are consistent with previous findings showing that onvansertib and abiraterone synergize in an androgen receptor-independent manner in vitro and in vivo. Data from the studies also suggest that the identified mitosis related gene signature may be predictive of patient response to onvansertib-abiraterone combination therapy, a hypothesis that is being further assessed in the ongoing Phase 2 mCRPC trial.

Second Quarter 2021 Financial Results:

As of June 30, 2021, Cardiff Oncology had approximately $140 million in cash, cash equivalents and short-term investments.

Total operating expenses were approximately $7.0 million for the three months ended June 30, 2021, an increase of $2.9 million from $4.1 million for the same period in 2020. The increase in operating expenses is attributed to 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 $1.6 million to $4.1 million for the three months ended June 30, 2021, from $2.5 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 the critical position of chief medical officer.
Selling, general and administrative expenses increased by approximately $1.1 million to $2.8 million for the three months ended June 30, 2021, from $1.7 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 in the second quarter of 2021 was approximately $4.3 million, which is comparable to the $4.3 million for the same period in 2020.

References

1. Giessen et al, Acta Oncologica, 2015; 54:187-193
2. Bekaii-Saab et al., Clin. Colorectal Cancer, 2019

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 study of onvansertib in combination with Zytiga® (abiraterone)/prednisone in metastatic castrate-resistant prostate cancer (mCRPC); and 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 (PDAC). A Phase 2 study of onvansertib in combination with decitabine in relapsed or refractory acute myeloid leukemia (AML) completed enrollment in 2020. 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 by the use of 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 a number of 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; our ability to develop tests, kits and systems and the success of those products; regulatory, financial and business risks related to our international expansion 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Royalties	$ 68	$ 43	$ 140	$ 110
Total revenues	68	43	140	110
Costs and expenses:				
Research and development	4,119	2,476	7,398	5,181
Selling, general and administrative	2,838	1,669	5,073	3,155
Total operating expenses	6,957	4,145	12,471	8,336
Loss from operations	(6,889)	(4,102)	(12,331)	(8,226)
Interest income, net	71	16	115	51
Gain (loss) from change in fair value of derivative financial instruments—warrants	61	(44)	268	(42)
Other income (expense), net	—	6	12	4
Net loss	(6,757)	(4,124)	(11,936)	(8,213)
Preferred stock dividend	(6)	(6)	(12)	(12)
Deemed dividend on preferred stock	—	(3,267)	—	(3,267)
Net loss attributable to common stockholders	$ (6,763)	$ (7,397)	$ (11,948)	$ (11,492)
Net loss per common share — basic and diluted	$ (0.17)	$ (0.51)	$ (0.31)	$ (0.94)
Weighted-average shares outstanding — basic and diluted	38,761	14,492	37,967	12,201

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 10,581	$ 130,981
Short-term investments	129,470	—
Accounts receivable and unbilled receivable	308	320
Prepaid expenses and other current assets	2,512	2,055
Total current assets	142,871	133,356
Property and equipment, net	422	624
Operating lease right-of-use assets	178	343
Other assets	263	404
Total Assets	$ 143,734	$ 134,727
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 543	$ 1,366
Accrued expenses	3,592	3,851
Operating lease liabilities	402	860
Other current liabilities	42	42
Total current liabilities	4,579	6,119
Derivative financial instruments—warrants	17	285
Operating lease liabilities, net of current portion	6	9
Other Liabilities	214	156
Total Liabilities	4,816	6,569
Stockholders' equity	138,918	128,158
Total liabilities and stockholders' equity	$ 143,734	$ 134,727

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2021	**2020**
Operating activities		
Net loss	$ (11,936)	$ (8,213)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	1	—
Impairment loss	—	34
Depreciation	228	234
Stock-based compensation expense	1,304	459
Amortization of premiums on short-term investments	698	—
Change in fair value of derivative financial instruments—warrants	(268)	42
Release of clinical trial funding commitment	926	506
Changes in operating assets and liabilities	(1,138)	(727)
Net cash used in operating activities	(10,185)	(7,665)
Investing activities:		
Net purchases, maturities and sales of short-term investments	(130,703)	—
Net cash used in investing activities	(130,703)	—
Financing activities:		
Proceeds from sales of common stock, preferred stock and warrants, net of expenses	19,225	18,802
Costs related to the clinical trial funding commitment	—	(8)
Proceeds from exercise of warrants	1,263	6,126
Borrowings under note payable	—	305
Net cash provided by financing activities	20,488	25,225
Net change in cash and cash equivalents	(120,400)	17,560
Cash and cash equivalents—Beginning of period	130,981	10,195
Cash and cash equivalents—End of period	$ 10,581	$ 27,755