Cardiff Oncology Reports Third Quarter 2023 Results and Provides Business Update

November 2, 2023

- Advance to first-line RAS-mutated metastatic colorectal cancer (mCRC) for lead program based on positive clinical and preclinical data and guidance from FDA -

- Expanded relationship with Pfizer, which will provide clinical execution of new Phase 2 randomized first-line mCRC trial of onvansertib + standard-of-care (SoC) versus SoC, with interim topline data expected in mid-2024 -

- Advance to first-line mPDAC with plan to initiate new Phase 2 investigator-initiated trial of onvansertib + SoC -

- Onvansertib monotherapy demonstrates single agent activity in Phase 2 investigator-initiated trial in refractory patients with extensive stage small cell lung cancer -

- Cash, cash equivalents, and short-term investments of approximately $81.4 million as of September 30, 2023, projected runway into 2025 -

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

SAN DIEGO, Nov. 2, 2023 /PRNewswire/ -- 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 third quarter ended September 30, 2023, and provided a business update.

"This has been a transformational quarter for Cardiff Oncology. In August, we presented clinical and pre-clinical data, as well as feedback from the FDA and an expanded Pfizer relationship, all supporting the strategic shift of our lead program in RAS-mutated mCRC to the first-line setting. Looking ahead, we plan to dose the first patient in our first-line mCRC trial this fall and look forward to sharing an update on this trial in the middle of next year," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "In addition, in September we presented data showing single-agent activity for onvansertib in patients with pancreatic and extensive-stage small cell lung cancer. Taken together, these data support our belief that the inhibition of PLK1 has the potential to address large patient populations who have a significant unmet need."

Upcoming expected milestones

- Dosing of first patient in first-line RAS-mutated metastatic colorectal cancer (mCRC) Phase 2 trial expected in 2023
- First-line RAS-mutated mCRC randomized data readout expected in mid-2024

Company highlights for the quarter ended September 30, 2023:

- Announced the shift of lead RAS-mutated mCRC program to the first-line setting and expanded Pfizer relationship. Cardiff Oncology has initiated a new first-line trial, CRDF-004, and Pfizer Ignite, a new end-to-end service for biotech companies with high potential science, is responsible for the clinical execution. The Phase 2 randomized trial is designed to evaluate the safety and efficacy of two different doses of onvansertib added to standard-of-care (SoC) consisting of FOLFIRI/bevacizumab or FOLFOX/bevacizumab to confirm an optimal dose. Patients will be randomized to receive onvansertib plus SoC or SoC alone.
- Contingent upon the results of CRDF-004, Cardiff Oncology plans to initiate CRDF-005, a Phase 3, randomized trial with registrational intent. The FDA has agreed that a seamless trial with objective response rate (ORR) at an interim point is an acceptable endpoint to pursue accelerated approval, with progression-free survival and trend in overall survival being the endpoints for full approval.
- Provided a clinical update on the ongoing Phase 2, open-label, CRDF-001 trial of onvansertib combined with SoC consisting of nanoliposomal irinotecan, leucovorin, and 5-FU in patients with second-line metastatic pancreatic ductal adenocarcinoma (mPDAC). Onvansertib plus SoC demonstrated an ORR of 19% (4 of 21 evaluable patients; 1 confirmed PR, 3 waiting for confirmatory scan) and median progression-free survival (mPFS) of 5.0 months as of the data cutoff of September 13, 2023. Historical control trials in similar patient populations have shown an ORR of 7.7% and mPFS of 3.1 months with SoC.
- Provided a clinical update on the ongoing investigator-initiated biomarker discovery trial at

Oregon Health & Science University (OHSU) Knight Cancer Institute exploring the impact of onvansertib 10-day monotherapy on tumors in mPDAC patients. Two patients have been enrolled to date. One patient demonstrated an 86% decrease in Ki67, a well-established biomarker of tumor proliferation, and a 28% decrease in CA 19-9, a clinically-used biomarker to monitor treatment response.

- Announced plans to advance to first-line mPDAC with new Phase 2 investigator-initiated trial at OHSU Knight Cancer Institute. There are two cohorts in this trial. In cohort 1, patients will receive the combination of onvansertib with SoC (Gemzar + Abraxane). In cohort 2, patients will receive 10 days of onvansertib monotherapy followed by onvansertib + SoC to identify biomarkers that predict response to onvansertib.
- Provided a clinical update on the ongoing Phase 2 investigator-initiated trial at University of Pittsburgh Medical Center of onvansertib monotherapy in patients with relapsed extensive stage SCLC who have received up to two prior therapies. An examination of the safety data from the first six patients by the institutional review board confirmed the trial can continue to enroll as planned.

Third Quarter 2023 Financial Results

Liquidity, cash burn, and cash runway

As of September 30, 2023, Cardiff Oncology had approximately $81.4 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the third quarter of 2023 was approximately $8.0 million, an increase of approximately $0.5 million from $7.5 million for the same period in 2022.

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

Operating results

Total operating expenses were approximately $11.0 million for the three months ended September 30, 2023, an increase of $1.9 million from $9.1 million for the same period in 2022. The increase in operating expenses was primarily due to costs associated with clinical programs and outside service costs related to the development of our lead drug candidate, onvansertib, and higher salaries and staff costs primarily due to increased headcount and stock-based compensation for additional grants to employees.

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 November 2, 2023. 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) and metastatic pancreatic ductal adenocarcinoma (mPDAC), as well as in investigator-initiated trials in 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; the need for additional financing to develop and commercialize onvansertib, 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, 2022, 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,	
	2023	**2022**	**2023**	**2022**
Royalty revenues	$ 141	$ 93	$ 332	$ 258
Costs and expenses:				
Research and development	8,022	6,009	25,094	20,665
Selling, general and administrative	2,939	3,077	10,318	10,103
Total operating expenses	10,961	9,086	35,412	30,768
Loss from operations	(10,820)	(8,993)	(35,080)	(30,510)
Interest income, net	1,068	458	3,061	841
Other income (expense), net	21	(36)	(85)	(338)
Net loss	(9,731)	(8,571)	(32,104)	(30,007)
Preferred stock dividend	(6)	(6)	(18)	(18)
Net loss attributable to common stockholders	$ (9,737)	$ (8,577)	$ (32,122)	$ (30,025)
Net loss per common share — basic and diluted	$ (0.22)	$ (0.20)	$ (0.72)	$ (0.69)
Weighted-average shares outstanding — basic and diluted	44,677	43,333	44,677	43,291

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

(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 15,233	$ 16,347
Short-term investments	66,130	88,920
Accounts receivable and unbilled receivable	198	771
Prepaid expenses and other current assets	2,344	5,246
Total current assets	83,905	111,284
Property and equipment, net	1,317	1,269
Operating lease right-of-use assets	1,843	2,251
Other assets	1,387	1,387
Total Assets	$ 88,452	$ 116,191
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,179	$ 1,956
Accrued liabilities	6,151	5,177
Operating lease liabilities	688	675
Total current liabilities	9,018	7,808
Operating lease liabilities, net of current portion	1,607	2,040
Total Liabilities	10,625	9,848
Stockholders' equity	77,827	106,343
Total liabilities and stockholders' equity	$ 88,452	$ 116,191

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

	Nine Months Ended September 30,

	2023	2022
Operating activities		
Net loss	$ (32,104)	$ (30,007)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	295	150
Stock-based compensation expense	3,600	3,244
Amortization of premiums on short-term investments	(716)	672
Release of clinical trial funding commitment	—	139
Changes in operating assets and liabilities	5,177	1,372
Net cash used in operating activities	(23,748)	(24,430)
Investing activities:		
Capital expenditures	(574)	(817)
Net purchases, maturities and sales of short-term investments	23,208	31,946
Net cash provided by investing activities	22,634	31,129
Financing activities:		
Proceeds from exercise of options	—	75
Net cash provided by financing activities	—	75
Net change in cash and cash equivalents	(1,114)	6,774
Cash and cash equivalents—Beginning of period	16,347	11,943
Cash and cash equivalents—End of period	$ 15,233	$ 18,717

SOURCE Cardiff Oncology, Inc.