Cardiff Oncology Reports Second Quarter 2023 Results and Provides Business Update

August 9, 2023

- New lead program in first-line RAS-mutated metastatic colorectal cancer (mCRC) and expanded Pfizer relationship; interim topline data expected in mid-2024 -

- Advance to first-line mCRC follows strong signal from new clinical and preclinical findings and guidance from FDA, and represents an increased market opportunity -

- Cash, cash equivalents, and short-term investments of approximately $89.4 million as of June 30, 2023, projected runway into 2025 -

SAN DIEGO, Aug. 9, 2023 /PRNewswire/ -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers, today announced financial results for the second quarter ended June 30, 2023, and provided a business update.

"2023 has been transformative for Cardiff Oncology, highlighted by the advancement of our lead program to the first-line mCRC setting and an expansion of our relationship with Pfizer," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "The shifting of our clinical development program to the first-line was a data-driven decision based on a strong signal from new clinical and preclinical findings, with agreement from the FDA. There are 48,000 new patients in the U.S. annually in the first-line RAS-mutated mCRC setting, with no ongoing clinical trials or new treatments approved in the past 20 years. We believe that there is a tremendous opportunity for onvansertib to provide a meaningful benefit to a substantial number of patients who are fighting cancer in challenging indications. Looking ahead, we anticipate commencing enrollment in our first-line trial this fall with interim topline data expected in mid-2024."

Upcoming expected milestones

- mPDAC data readout from Phase 2 trial expected in Q3 '23
- SCLC data readout from Phase 2 trial expected in Q3 '23 (investigator-initiated trial with UPMC)
- First patient dosed in first-line mCRC trial expected fall '23
- TNBC data readout from Phase 1b/2 trial expected Q4 '23/Q1 '24 (investigator-initiated trial with Dana-Farber Cancer Institute)
- First-line mCRC randomized data readout expected in mid-2024

Company highlights for the quarter ended June 30, 2023 and resent announcements

- Announced new lead program in mCRC and expanded Pfizer relationship.
- Cardiff Oncology will initiate a first-line trial, CRDF-004, a Phase 2 randomized trial generating preliminary safety and efficacy data and evaluating two different doses of onvansertib to confirm an optimal dose. Onvansertib will be added to standard-of-care consisting of FOLFIRI plus bevacizumab, or FOLFOX plus bevacizumab.
- Contingent upon the results of CRDF-004, Cardiff Oncology will initiate CRDF-005, a Phase 3, randomized trial with registrational intent. The FDA has agreed that a seamless trial with objective response rate 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.
- Pfizer Ignite will be responsible for the clinical execution of the CRDF-004 trail, leveraging Pfizer's significant R&D capabilities, scale and expertise.
- Our new partnership with Pfizer Ignite expands the relationship established in November 2021 when Pfizer made an equity investment in Cardiff Oncology and nominated Adam Schayowitz, Ph.D., Vice President & Medicine Team Group Lead for Breast Cancer, Colorectal Cancer and Melanoma, Pfizer Global Product Development as a Scientific Advisory Board member.

Second Quarter 2023 Financial Results

Liquidity, cash burn, and cash runway

As of June 30, 2023, Cardiff Oncology had approximately $89.4 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the second quarter of 2023 was approximately $7.1 million, an increase of approximately $0.4 million from $6.7 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 $12.3 million for the three months ended June 30, 2023, an increase of $1.8 million from $10.5 million for the same period in 2022. The increase in operating expenses was primarily due to higher salaries and staff costs primarily due to increased headcount and stock-based compensation for additional grants to employees.

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 triple negative breast cancer (TNBC) and small cell lung cancer (SCLC). 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; 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.

Cardiff Oncology Contact:
James Levine
Chief Financial Officer
858-952-7670
jlevine@cardiffoncology.com

Investor Contact:
Kiki Patel, PharmD
Gilmartin Group
332-895-3225
Kiki@gilmartinir.com

Media Contact:
Richa Kumari
Taft Communications
551 344-5592
richa@taftcommunications.com

View News Release Full Screen

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,	
	2023	**2022**	**2023**	**2022**
Royalty revenues	$ 108	$ 91	$ 191	$ 165
Costs and expenses:				
Research and development	8,020	7,448	17,072	14,656
Selling, general and administrative	4,296	3,086	7,379	7,026
Total operating expenses	12,316	10,534	24,451	21,682
Loss from operations	(12,208)	(10,443)	(24,260)	(21,517)
Interest income, net	1,053	253	1,993	383

Other income (expense), net	5	(253)	(106)	(302)
Net loss	(11,150)	(10,443)	(22,373)	(21,436)
Preferred stock dividend	(6)	(6)	(12)	(12)
Net loss attributable to common stockholders	$ (11,156)	$ (10,449)	$ (22,385)	$ (21,448)
Net loss per common share — basic and diluted	$ (0.25)	$ (0.24)	$ (0.50)	$ (0.50)
Weighted-average shares outstanding — basic and diluted	44,677	43,306	44,677	43,269

View News Release Full Screen

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

(unaudited)

	June 30, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 19,369	$ 16,347
Short-term investments	70,059	88,920
Accounts receivable and unbilled receivable	161	771
Prepaid expenses and other current assets	3,142	5,246
Total current assets	92,731	111,284
Property and equipment, net	1,356	1,269
Operating lease right-of-use assets	1,978	2,251
Other assets	1,390	1,387
Total Assets	$ 97,455	$ 116,191
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$ 2,939	$ 1,956
Accrued liabilities	5,501	5,177
Operating lease liabilities	683	675
Total current liabilities	9,123	7,808
Operating lease liabilities, net of current portion	1,753	2,040
Total Liabilities	10,876	9,848
Stockholders' equity	86,579	106,343
Total liabilities and stockholders' equity	$ 97,455	$ 116,191

View News Release Full Screen

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Operating activities		
Net loss	$ (22,373)	$ (21,436)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	188	69
Stock-based compensation expense	2,645	2,207
Amortization of premiums on short-term investments	(405)	557
Release of clinical trial funding commitment	—	139
Changes in operating assets and liabilities	4,154	1,520
Net cash used in operating activities	(15,791)	(16,944)
Investing activities:		

Capital expenditures	(259)	(412)
Net purchases, maturities and sales of short-term investments	19,072	26,378
Net cash provided by investing activities	18,813	25,966
Financing activities:		
Net cash provided by financing activities	—	—
Net change in cash and cash equivalents	3,022	9,022
Cash and cash equivalents—Beginning of period	16,347	11,943
Cash and cash equivalents—End of period	$ 19,369	$ 20,965

SOURCE Cardiff Oncology, Inc.