Cardiff Oncology Reports First Quarter 2024 Results and Provides Business Update

May 2, 2024

- In RAS-mutated mCRC, clinical data from ONSEMBLE trial, and preclinical data presented at AACR, demonstrated strong efficacy signal in bev naïve patients and support ongoing first-line RAS-mutated mCRC lead program -

- In RAS wild-type mCRC, preclinical data presented at AACR demonstrated onvansertib's antitumor activity both as a single agent and in combination, highlighting its broad activity across all mCRC -

- In SCLC and ovarian cancer, preclinical data presented at AACR highlighted onvansertib's activity in combination treatments -

- Cash and equivalents of $67 million as of March 31, 2024, projected runway into Q3 2025 -

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

SAN DIEGO, May 02, 2024 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2024, and provided a business update.

"During the start of 2024, we presented several important new data sets supporting our first-line RAS-mutated mCRC strategy and the broader opportunity for onvansertib," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "The data from the ONSEMBLE trial replicated, in a second independent and randomized dataset, the bev naïve signal from our earlier Phase 1b/2 KRAS-mutated mCRC trial. And the Phase 1b data published in the peer-reviewed journal Clinical Cancer Research, and the additional data we presented in one of our five posters at AACR, further substantiated our lead program in RAS-mutated mCRC. The additional AACR posters also point toward new indications for onvansertib in RAS wild-type mCRC, small cell lung cancer and ovarian cancer. Looking ahead, we believe that our upcoming data readout from our first-line trial in RAS-mutated mCRC has the potential to serve as a key value inflection point for our company and revolutionize the treatment of RAS-mutated mCRC, an area with no new treatments approved in over two decades."

Upcoming expected milestones

- The Company has updated its expectation of the timing for an initial readout from the first-line RAS-mutated metastatic colorectal cancer (mCRC) randomized CRDF-004 trial to 2H 2024, based on the enrollment trends observed from active clinical trial sites.

Company highlights for the quarter ended March 31, 2024 and subsequent weeks include:

- **Presented updated data at AACR Annual Meeting 2024 that supports ongoing first-line RAS-mutated mCRC clinical study.**
  - In a poster titled "A Phase 1b/2 Clinical Study of Onvansertib in Combination with FOLFIRI/Bev Revealed a New Role of PLK1 in regulating the Hypoxia Pathway in KRAS-mutated mCRC," updated clinical and preclinical data further supported the ongoing CRDF-004 Phase 2 trial of onvansertib + chemo/bev for the first-line treatment of RAS-mutated mCRC patients, who by definition are bev naïve.
  - In vitro, onvansertib inhibited activation of the hypoxia pathway through the regulation of transcription factor HIF1α and its downstream targets.
  - Bev naïve patients treated with onvansertib + FOLFIRI/bev demonstrated a significantly greater overall response rate [odds ratio=13.64, p<0.001] and longer PFS [hazard ratio=0.21, p=0.003] compared to bev exposed patients.
- **Announced first patient dosed for lead program in randomized first-line Phase 2 trial, CRDF-004, for patients with RAS-mutated mCRC.**
  - The trial, whose clinical execution is being conducted by our partner, Pfizer Ignite, is designed to confirm the dose of onvansertib for a subsequent registrational trial, and generate safety and efficacy data for onvansertib when added to standard of care (SoC) vs. SoC alone.
  - Interim topline results from CRDF-004 are expected in 2H 2024. Contingent upon the results, Cardiff Oncology will initiate a Phase 3, randomized trial, CRDF-005, with registrational intent.
- **Provided a clinical update on Phase 2 randomized second-line ONSEMBLE trial in mCRC.**
  - New clinical data from second-line randomized ONSEMBLE trial, that closed for enrollment in 2023, provide further evidence of onvansertib's role in improving the efficacy of SoC (FOLFIRI+bev) therapy in bev naïve patients.
  - In the trial (n = 21), patients who were bev naïve and who received onvansertib in combination with SoC demonstrated an objective response rate (ORR) of 50% (2 of 4). No clinical responses were observed in bev naïve patients who received SoC alone (n = 3), or patients who were previously exposed to bev (n = 14).
  - The ONSEMBLE data serves as a second independent, randomized, prospective data set providing evidence of the strong efficacy signal in bev naïve patients.
- **Announced the publication of data from Phase 1b study in second line KRAS-mutated mCRC in the peer-reviewed journal Clinical Cancer Research.**
  - Findings from the Phase 1b portion of company's Phase 1b/2 study in second-line KRAS-mutated mCRC highlight the safety and promising efficacy of onvansertib in combination with SoC.
  - These peer-reviewed published data are part of the Phase 1b/2 data announced in August 2023 and informed the shift to

investigation in first-line RAS-mutated mCRC (CRDF-004).

- **Presented three posters at AACR Annual Meeting 2024 in therapeutic areas outside of RAS-mutated mCRC**
  - In a poster titled “The PLK1 Inhibitor Onvansertib is Active as Monotherapy and in Combination with Cetuximab in RAS Wild-type mCRC Patient-derived Xenografts,” single agent onvansertib successfully induced tumor stasis or regression in 70% (14/20) of the RAS wild-type mCRC patient-derived xenograft (PDX) models tested which included both models sensitive to cetuximab (5/7, 71%) and resistant to cetuximab (9/13, 69%). Additionally, onvansertib in combination with cetuximab induced tumor stasis or regression in 90% (18/20) of the models tested. The antitumor activity of the combination was superior compared to monotherapy with either agent in both cetuximab sensitive and resistant models.
  - In a poster titled “The PLK1 Inhibitor, Onvansertib, Synergizes with Paclitaxel in Small Cell Lung Cancer (SCLC),” onvansertib in combination with paclitaxel was well-tolerated and demonstrated superior efficacy over monotherapies in cisplatin sensitive and resistant SCLC PDX models. These preclinical findings in SCLC and previous data generated in breast cancer suggest that onvansertib in combination with paclitaxel has the potential to become a highly promising combination strategy across multiple cancer indications.
  - In a poster titled “In vivo anti-tumor activity of onvansertib, a PLK1 inhibitor, combined with gemcitabine or carboplatin in platinum-resistant ovarian carcinoma patient-derived xenograft models,” onvansertib was synergistic in vitro in both combinations in an ovarian cancer cell line. Both combinations demonstrated antitumor activity in vivo in platinum-resistant ovarian cancer PDX models and was well tolerated. These data support the potential of onvansertib to improve SoC treatments for platinum-resistant ovarian cancer patients.

First Quarter 2024 Financial Results

Liquidity, cash burn, and cash runway

As of March 31, 2024, Cardiff Oncology had approximately $67.2 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the first quarter of 2024 was approximately $7.7 million, a decrease of approximately $1.0 million from $8.7 million for the same period in 2023.

Based on its current expectations and projections, the Company believes its current cash resources are sufficient to fund its operations into Q3 of 2025.

Operating results

Total operating expenses were approximately $11.1 million for the three months ended March 31, 2024, a decrease of $1.0 million from $12.1 million for the same period in 2023. The decrease in operating expenses was primarily due to a reduction in chemistry, manufacturing and controls costs compared to the prior period.

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 May 2, 2024. 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), as well as in investigator-initiated trials in metastatic pancreatic ductal adenocarcinoma (mPDAC), 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; results of preclinical studies or clinical trials for our product candidate could be unfavorable or delayed; our need for additional financing; risks related to business interruptions, including the outbreak of an epidemic or pandemic such as the COVID-19 coronavirus and cyber-attacks on our information technology infrastructure, 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 our product candidate 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, 2023, 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 March 31,	
	2024	**2023**
Royalty revenues	$ 205	$ 83
Costs and expenses:		
Research and development	8,008	9,052
Selling, general and administrative	3,130	3,083
Total operating expenses	11,138	12,135
Loss from operations	(10,933)	(12,052)
Interest income, net	926	940
Other income (expense), net	(4)	(111)
Net loss	(10,011)	(11,223)
Preferred stock dividend	(6)	(6)
Net loss attributable to common stockholders	$ (10,017)	$ (11,229)
Net loss per common share — basic and diluted	$ (0.22)	$ (0.25)
Weighted-average shares outstanding — basic and diluted	44,678	44,677

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

	March 31, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 18,658	$ 21,655
Short-term investments	48,529	53,168
Accounts receivable and unbilled receivable	393	288
Prepaid expenses and other current assets	2,410	2,301
Total current assets	69,990	77,412
Property and equipment, net	1,199	1,238
Operating lease right-of-use assets	1,574	1,708
Other assets	1,275	1,279
Total Assets	$ 74,038	$ 81,637
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,191	$ 1,966
Accrued liabilities	5,956	7,783
Operating lease liabilities	696	691
Total current liabilities	11,843	10,440
Operating lease liabilities, net of current portion	1,301	1,458
Total Liabilities	13,144	11,898
Stockholders' equity	60,894	69,739
Total liabilities and stockholders' equity	$ 74,038	$ 81,637

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

	Three Months Ended March 31,	
	2024	**2023**
Operating activities		
Net loss	$ (10,011)	$ (11,223)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	102	90
Stock-based compensation expense	1,124	1,064
Accretion of discounts on short-term investments, net	(156)	(163)
Changes in operating assets and liabilities	1,201	1,573
Net cash used in operating activities	(7,740)	(8,659)
Investing activities:		
Capital expenditures	(80)	(8)
Net purchases, maturities and sales of short-term investments	4,716	7,337
Net cash provided by investing activities	4,636	7,329
Financing activities:		
Proceeds from exercise of options	107	—
Net cash provided by financing activities	107	—
Net change in cash and cash equivalents	(2,997)	(1,330)
Cash and cash equivalents—Beginning of period	21,655	16,347
Cash and cash equivalents—End of period	$ 18,658	$ 15,017