



Cardiff Oncology Reports Fourth Quarter and Full Year 2023 Results and Provides Business Update

February 29, 2024

- First patient dosed in Phase 2 first-line trial in patients with RAS-mutated mCRC for new lead program with the support of FDA and clinical execution from Pfizer Ignite -

- Interim topline data from first-line RAS-mutated mCRC trial is expected in mid-2024 -

- New clinical data from second-line randomized ONSEMBLE trial provides further evidence of the efficacy of onvansertib in combination with FOLFIRI/bev in bev naïve RAS-mutated mCRC patients -

- Cash and equivalents of \$75 million as of December 31, 2023, 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, Feb. 29, 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 fourth quarter and full year ended December 31, 2023, and provided a business update.

"2024 is a pivotal year for Cardiff Oncology and we are excited for our upcoming randomized data readout from our lead program in first-line mCRC later this year," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "The mCRC data we shared in August 2023, and the ONSEMBLE data we are disclosing today, demonstrates onvansertib's contribution to the standard of care of bevacizumab (bev) and chemotherapy in treating RAS-mutated mCRC. Given there have been no new therapies approved in this large cancer indication in the last 20 years, 2024 marks a critical step in realizing onvansertib's potential to provide clinical benefit to the large number of newly-diagnosed RAS-mutated mCRC patients, and create value for the stakeholders in our company."

Upcoming expected milestones

- First-line RAS-mutated mCRC randomized data readout expected in mid-2024

Company highlights for the quarter ended December 31, 2023, and subsequent weeks include:

- **Provided a clinical update on Phase 2 randomized second-line ONSEMBLE trial in mCRC.** New clinical data from discontinued second-line randomized ONSEMBLE trial provides further evidence of onvansertib's improvement of the efficacy for standard of care therapy in bev naïve patients. In the trial, patients who were bev naïve demonstrated an objective response rate (ORR) of 50% on onvansertib. No clinical responses were observed in patients who received standard of care with FOLFIRI/bev or patients who were previously exposed to bev. For additional information, please refer to the press release issued by the Company today which provided an update on the ONSEMBLE trial.
- **Announced first patient dosed in its randomized first-line Phase 2 trial, CRDF-004, for patients with RAS-mutated metastatic colorectal cancer.** The trial, whose clinical execution is being conducted by 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 mid-2024. Contingent upon the results, Cardiff Oncology will initiate a Phase 3, randomized trial, CRDF-005, with registrational intent.
- **Announced the publication of data from Phase 1b study in second line KRAS-mutated mCRC in [Clinical Cancer Research](#).** The findings of the Phase 1b portion of the Phase 1b/2 study for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer disclosed by Cardiff Oncology in August 2023 have been published in the peer-reviewed journal *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

Full Year 2023 Financial Results:

Liquidity, cash burn, and cash runway

As of December 31, 2023, Cardiff Oncology had approximately \$75 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the full year 2023 was approximately \$30.9 million, a decrease of approximately \$2.9 million from \$33.8 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 Q3 2025.

Operating results

Total operating expenses were approximately \$45.9 million for the full year ended December 31, 2023, an increase of \$5.6 million from \$40.3 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 February 29, 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) 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; 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 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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	Year Ended December 31,	
	2023	2022
Royalty revenues	\$ 488	\$ 386
Costs and expenses:		
Research and development	32,857	27,107
Selling, general and administrative	13,043	13,181
Total operating expenses	<u>45,900</u>	<u>40,288</u>
Loss from operations	<u>(45,412)</u>	<u>(39,902)</u>
Interest income, net	4,069	1,581
Other expense, net	(98)	(383)
Net loss	<u>(41,441)</u>	<u>(38,704)</u>
Preferred stock dividend	(24)	(24)
Net loss attributable to common stockholders	<u>\$ (41,465)</u>	<u>\$ (38,728)</u>
Net loss per common share — basic and diluted	<u>\$ (0.93)</u>	<u>\$ (0.89)</u>
Weighted-average shares outstanding — basic and diluted	<u>44,677</u>	<u>43,600</u>

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

	December 31,	December 31,
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,655	\$ 16,347
Short-term investments	53,168	88,920
Accounts receivable and unbilled receivable	288	771
Prepaid expenses and other current assets	2,301	5,246
Total current assets	<u>77,412</u>	<u>111,284</u>
Property and equipment, net	1,238	1,269
Operating lease right-of-use assets	1,708	2,251
Other assets	1,279	1,387
Total Assets	<u>\$ 81,637</u>	<u>\$ 116,191</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,966	\$ 1,956
Accrued liabilities	7,783	5,177
Operating lease liabilities	691	675
Total current liabilities	<u>10,440</u>	<u>7,808</u>
Operating lease liabilities, net of current portion	1,458	2,040
Total Liabilities	<u>11,898</u>	<u>9,848</u>
Stockholders' equity	69,739	106,343
Total liabilities and stockholders' equity	<u>\$ 81,637</u>	<u>\$ 116,191</u>

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

	Year ended December 31,	
	2023	2022
Operating activities		
Net loss	\$ (41,441)	\$ (38,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	1
Depreciation	398	236
Stock-based compensation expense	4,509	4,256

(Accretion) amortization of (discounts) and premiums on short-term investments, net	(921)	632
Release of clinical trial funding commitment	—	139
Changes in operating assets and liabilities	6,568	(380)
Net cash used in operating activities	<u>(30,887)</u>	<u>(33,820)</u>
Investing activities:		
Net capital expenditures	(582)	(892)
Net purchases, maturities and sales of short-term investments	36,777	39,041
Net cash provided by investing activities	<u>36,195</u>	<u>38,149</u>
Financing activities:		
Proceeds from exercise of options	—	75
Net cash provided by financing activities	<u>—</u>	<u>75</u>
Net change in cash and cash equivalents	5,308	4,404
Cash and cash equivalents—Beginning of period	16,347	11,943
Cash and cash equivalents—End of period	<u>\$ 21,655</u>	<u>\$ 16,347</u>