Cardiff Oncology Reports Fourth Quarter and Full Year 2024 Results and Provides Business Update

- Robust initial efficacy signal with onvansertib + chemo/bev in ongoing first-line RAS-mut metastatic colorectal cancer ("mCRC") clinical trial (CRDF-004) -

- Priced oversubscribed $40 million underwritten registered direct offering with participation from new and existing healthcare dedicated investors -

- Issuance of new patent with claims for the use of onvansertib for treating KRAS-mut mCRC -

- Cash and equivalents of $91.7 million as of December 31, 2024, projected runway into Q1 2027 -

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

SAN DIEGO, February 27, 2025 -- 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, 2024, and provided a business update.

"2024 was a significant year for Cardiff Oncology as we shared positive data from the first 30 patients in our lead program in first-line RAS-mut mCRC," said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. "We were excited to report that patients on the 30mg onvansertib dose arm demonstrated a 64% response rate, compared to a 33% response rate in the control arm. In the experimental arm, we observed a dose response relationship with the 30mg dose of onvansertib demonstrating increased ORR and deeper tumor regression compared to the 20mg dose of onvansertib with similar safety profiles for both doses. We believe this correlation between the dose of onvansertib and the magnitude of therapeutic effect serves as validation that onvansertib is a biologically active drug for the treatment of cancer, which we believe may translate to additional oncology indications in our pipeline. In addition to the robust efficacy signal in the CRDF-004 trial, these data suggest that onvansertib could safely be combined with both standard of care first-line chemotherapy options for mCRC in the U.S. With our balance sheet strengthened by a $40M investment from biotech specialist investors, we now look forward to sharing additional clinical updates from CRDF-004 in H1 2025."

Upcoming expected milestones

- Additional clinical data from CRDF-004 trial expected in 1H 2025

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

- **Announced positive initial data from ongoing first-line RAS-mutated mCRC clinical trial (CRDF-004)**
  - Phase 2 trial is currently enrolling patients with mCRC who have a documented KRAS or NRAS mutation. Onvansertib is added to standard-of-care (SoC) consisting of FOLFIRI plus bevacizumab ("bev") or FOLFOX plus bev. Patients will be randomized to either 20mg of onvansertib plus SoC, 30mg of onvansertib plus SoC, or SoC alone.
  - Patients on the 30mg onvansertib dose arm demonstrated 64% objective response rate (ORR) versus 33% ORR in the control arm.
  - The 30mg dose of onvansertib demonstrated a higher ORR and deeper tumor regression compared to the 20mg dose of onvansertib (64% vs. 50%).
  - Onvansertib was well tolerated at both doses.

- **Raised $40 million in an oversubscribed underwritten registered direct offering**
    - The financing included participation from new and existing healthcare dedicated investors.
- **Patent issuance from the United States Patent and Trademark Office (USPTO)**
    - U.S. patent No. 12,144,813 has an expected expiration date of no earlier than 2043. The patent claims cover the method of using onvansertib in combination with bev for the treatment of KRAS mutated mCRC patients who have not previously been treated with bev ("bev naïve"). This patent is supported by the unexpected benefits of the treatment in such bev naïve patients.
- **Presented two posters at the San Antonio Breast Cancer Symposium**
    - Onvansertib demonstrated synergy in combination with paclitaxel in hormone receptor positive (HR+) breast cancer cell lines and robust antitumor activity in patient-derived xenograft (PDX) models resistant to first-line therapies. These data support that onvansertib in combination with paclitaxel represents a promising therapeutic strategy for HR+ breast cancer patients after progression on endocrine therapy and CDK4/6 inhibitors. A phase 1b/2 clinical trial is ongoing to evaluate the safety and efficacy of onvansertib in combination with paclitaxel in advanced triple negative breast cancer (NCT05383196).
    - Onvansertib in combination with trastuzumab deruxtecan (T-DXd) was well tolerated, overcame T-DXd resistance, and displayed enhanced anti-tumor activity compared to monotherapies in drug resistant HR+ breast cancer patient derived xenograft (PDX) models. The combination of T-DXd with onvansertib represents a promising therapeutic strategy for HR+ breast cancer patients resistant to first-line therapies.
- **Published clinical data of the combination of onvansertib with FOLFIRI and bev in second-line KRAS mutant mCRC in the peer-reviewed Journal of Clinical Oncology, the flagship publication of the American Society of Clinical Oncology (ASCO)**
    - Phase 2 clinical trial treating patients with KRAS-mutant mCRC (NCT03829410) demonstrated that onvansertib combined with FOLFIRI and bev was well-tolerated and exhibited clinical activity in the second-line setting.
    - A post hoc analysis revealed a greater clinical benefit in bev naïve patients, who demonstrated an ORR of 77% and mPFS of 14.9 months compared to an ORR of 10% and mPFS of 6.6 months in those previously exposed to bev.

Full Year 2024 Financial Results:

Liquidity, cash burn, and cash runway

As of December 31, 2024, Cardiff Oncology had approximately $91.7 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the full year 2024 was approximately $37.7 million, an increase of approximately $6.8 million from $30.9 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 Q1 2027.

Operating results

Total operating expenses were approximately $49.3 million for the full year ended December 31, 2024, an increase of $3.4 million from $45.9 million for the same period in 2023. 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 today at 4:30 p.m. ET/1:30 p.m. PT. 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 ongoing and planned 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 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, 2024, 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)

	Year Ended December 31,	
	2024	2023
Royalty revenues	$ 683	$ 488
Costs and expenses:		
Research and development	36,852	32,857
Selling, general and administrative	12,482	13,043
Total operating expenses	49,334	45,900
Loss from operations	(48,651)	(45,412)
Other income (expense), net:		
Interest income, net	3,259	4,069
Other expense, net	(39)	(98)
Total other income, net	3,220	3,971
Net loss	(45,431)	(41,441)
Preferred stock dividend	(24)	(24)
Net loss attributable to common stockholders	$ (45,455)	$ (41,465)
Net loss per common share — basic and diluted	$ (0.95)	$ (0.93)
Weighted-average shares outstanding — basic and diluted	47,650	44,677

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 51,470	$ 21,655
Short-term investments	40,276	53,168
Accounts receivable and unbilled receivable	773	288
Prepaid expenses and other current assets	2,535	2,301
Total current assets	95,054	77,412
Property and equipment, net	898	1,238
Operating lease right-of-use assets	1,169	1,708
Other assets	69	1,279
Total Assets	$ 97,190	$ 81,637
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,821	$ 1,966
Accrued liabilities	7,897	7,783
Operating lease liabilities	710	691
Total current liabilities	13,428	10,440
Operating lease liabilities, net of current portion	813	1,458
Total Liabilities	14,241	11,898
Stockholders' equity	82,949	69,739
Total liabilities and stockholders' equity	$ 97,190	$ 81,637

Cardiff Oncology, Inc.

Condensed Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2024	**2023**
Operating activities		
Net loss	$ (45,431)	$ (41,441)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	404	398
Stock-based compensation expense	4,760	4,509
Accretion of discounts on short-term investments, net	(598)	(921)
Changes in operating assets and liabilities	3,172	6,568
Net cash used in operating activities	(37,693)	(30,887)
Investing activities		
Capital expenditures	(80)	(582)
Net purchases, maturities and sales of short-term investments	13,808	36,777
Net cash provided by investing activities	13,728	36,195
Financing activities		
Proceeds from sales of common stock, net of expenses	53,407	—
Proceeds from exercise of options	373	—
Net cash provided by financing activities	53,780	—
Net change in cash and cash equivalents	29,815	5,308
Cash and cash equivalents—Beginning of period	21,655	16,347
Cash and cash equivalents—End of period	$ 51,470	$ 21,655