
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 06, 2025

Cardiff Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35558
(Commission File Number)

27-2004382
(IRS Employer
Identification No.)

11055 Flintkote Avenue
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 952-7570

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	CRDF	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2025, Cardiff Oncology, Inc. (the "Company") issued a press release announcing company highlights and financial results for the third quarter ended September 30, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release of Cardiff Oncology, Inc. dated November 6, 2025](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARDIFF ONCOLOGY, INC.

Date: November 6, 2025

By: /s/ Mark Erlander
Mark Erlander

Chief Executive Officer



Cardiff Oncology Reports Third Quarter 2025 Results and Provides Business Update

– Announced positive data from the ongoing Phase 2 CRDF-004 trial evaluating onvansertib + standard of care for the treatment of first-line RAS-mutated metastatic colorectal cancer –

– Expects to report an update from the Phase 2 CRDF-004 trial in Q1 2026 –

– Cash and investments of \$60.6 million as of September 30, 2025, projected runway into Q1 2027 –

SAN DIEGO, November 6, 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 third quarter ended September 30, 2025, and provided a business update.

“This quarter was marked by highly encouraging data from our ongoing CRDF-004 trial evaluating onvansertib in combination with standard of care for first-line RAS-mutated mCRC. At the July 8, 2025 data cutoff, the 30mg onvansertib cohort demonstrated a 19% improvement in confirmed ORR, faster time to response, deeper tumor regression, and early signs of separation in the progression-free survival curves when compared to standard of care alone,” said Mark Erlander, Ph.D., Chief Executive Officer of Cardiff Oncology. “The study is on track for the next clinical update in the first quarter of 2026, where we’ll look for a continuation of onvansertib’s favorable tolerability profile and more mature duration of response and progression-free survival data.”

Continued Dr. Erlander, “Onvansertib is uniquely positioned to address a significant medical need and commercial opportunity, with approximately 150,000 new CRC patients diagnosed annually in the U.S. alone. With median progression-free survival of less than 12 months on standard of care and few promising therapies in development for RAS-mutated mCRC, we are optimistic that onvansertib has the potential to redefine first-line care for patients.”

Company highlights for the quarter ended September 30, 2025:

- **Announced positive data from the ongoing CRDF-004 Phase 2 randomized trial evaluating two doses of onvansertib in combination with standard of care (“SoC”) for the treatment of first-line RAS-mutated metastatic colorectal cancer (“mCRC”)**
 - As of the July 8, 2025 data cut-off, the Phase 2 CRDF-004 trial demonstrated a 19% improvement in confirmed objective response rate (“ORR”) in the 30mg onvansertib arm compared to the control arm in the intent-to-treat population.
 - While the median progression-free survival (“PFS”) has not yet been reached, early PFS data show a trend favoring the 30mg onvansertib arm versus control.
 - Dose dependent responses were observed across all endpoints, including ORR, PFS, early tumor shrinkage, and depth of response.
 - Onvansertib continues to be well-tolerated, with no major or unexpected toxicities observed.
 - **An update from the ongoing Phase 2 CRDF-004 trial in first-line RAS-mutated mCRC is expected in 1Q 2026.**
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Third Quarter 2025 Financial Results:

Liquidity, cash burn, and cash runway

As of September 30, 2025, Cardiff Oncology had approximately \$60.6 million in cash, cash equivalents, and short-term investments.

Net cash used in operating activities for the third quarter of 2025 was approximately \$10.8 million, an increase of \$0.3 million from \$10.5 million for the same period in 2024.

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 \$12.1 million for the three months ended September 30, 2025, a decrease of \$0.7 million from \$12.8 million for the same period in 2024. The decrease in operating expenses was primarily due to a reduction in clinical trial expenses and a decrease in preclinical activities.

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 metastatic triple negative breast cancer (mTNBC). 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)
(unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
Royalty revenues	\$ 120	\$ 165	\$ 350	\$ 532
Costs and expenses:				
Research and development	8,197	9,640	30,254	27,140
Selling, general and administrative	3,897	3,126	11,229	9,471
Total operating expenses	<u>12,094</u>	<u>12,766</u>	<u>41,483</u>	<u>36,611</u>
Loss from operations	<u>(11,974)</u>	<u>(12,601)</u>	<u>(41,133)</u>	<u>(36,079)</u>
Other income (expense), net:				
Interest income, net	716	741	2,492	2,472
Other income (expense), net	—	5	6	(37)
Total other income (expense), net	<u>716</u>	<u>746</u>	<u>2,498</u>	<u>2,435</u>
Net loss	<u>(11,258)</u>	<u>(11,855)</u>	<u>(38,635)</u>	<u>(33,644)</u>
Preferred stock dividend	<u>(6)</u>	<u>(6)</u>	<u>(18)</u>	<u>(18)</u>
Net loss attributable to common stockholders	<u>\$ (11,264)</u>	<u>\$ (11,861)</u>	<u>\$ (38,653)</u>	<u>\$ (33,662)</u>
Net loss per common share — basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.25)</u>	<u>\$ (0.58)</u>	<u>\$ (0.74)</u>
Weighted-average shares outstanding — basic and diluted	<u>66,879</u>	<u>46,865</u>	<u>66,644</u>	<u>45,461</u>

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

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,135	\$ 51,470
Short-term investments	50,456	40,276
Accounts receivable and unbilled receivable	254	773
Prepaid expenses and other current assets	956	2,535
Total current assets	61,801	95,054
Property and equipment, net	666	898
Operating lease right-of-use assets	764	1,169
Other assets	549	69
Total Assets	\$ 63,780	\$ 97,190
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,441	\$ 4,821
Accrued liabilities	11,539	7,897
Operating lease liabilities	726	710
Total current liabilities	14,706	13,428
Operating lease liabilities, net of current portion	284	813
Total Liabilities	14,990	14,241
Stockholders' equity		
Total liabilities and stockholders' equity	\$ 63,780	\$ 97,190

