UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): **February 29, 2024**

Cardiff Oncology, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35558**	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	IRS Employer Identification No.)

11055 Flintkote Avenue
San Diego, CA 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: **(858) 952-7570**

(Former name or former address, if changed since last report)

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

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 communication 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 Conditions.

On February 29, 2024, Cardiff Oncology, Inc. (the "Company") issued a press release announcing company highlights and financial results for the fourth quarter and full year ended December 31, 2023.

A copy of the earnings press release is furnished as Exhibit 99.1 to this Form 8-K. On February 29, 2024, members of the Company's management will hold a fourth quarter 2023 earnings conference call to discuss the Company's financial results and the presentation attached hereto as Exhibit 99.4 will accompany management's comments.

Item 7.01 Regulation FD Disclosure

The information set forth in Item 2.02 above is hereby incorporated herein by reference.

On February 29, 2024, the Company issued a press release which provided a clinical update on the first release of data from its second-line RAS-mutated metastatic colorectal cancer (mCRC) ONSEMBLE trial. In addition, on February 29, 2024, the Company announced that the first patient was dosed in its randomized first-line Phase 2 trial, CRDF-004, for patients with RAS-mutated metastatic colorectal cancer. A copy of each press releases is furnished as Exhibits 99.2 and 99.3 to this Form 8-K, respectively.

The information in this report, including the press release and the earnings conference call presentation furnished as Exhibits 99.1, 99.2, 99.3 and 99.4 hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, and shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. In addition, the exhibits furnished herewith contain statements intended as "forward-looking statements" that are subject to the cautionary statements about forward-looking statements set forth in such exhibits.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

99.1	Earnings Press Release of Cardiff Oncology, Inc. dated February 29, 2024.
99.2	Clinical Update Press Release of Cardiff Oncology, Inc. dated February 29, 2024.
99.3	First Patient Dosed Press Release of Cardiff Oncology, Inc. dated February 29, 2024.
99.4	Fourth Quarter 2023 earnings conference call presentation materials, dated February 29, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Dated: February 29, 2024

CARDIFF ONCOLOGY, INC.

By: /s/ Mark Erlander
Mark Erlander
Chief Executive Officer

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

- 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, February 29, 2024 -- 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.

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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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Cardiff Oncology, Inc.

Condensed Statements of Operations

(in thousands, except for per share amounts)

	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	45,900	40,288
Loss from operations	(45,412)	(39,902)
Interest income, net	4,069	1,581
Other expense, net	(98)	(383)
Net loss	(41,441)	(38,704)
Preferred stock dividend	(24)	(24)
Net loss attributable to common stockholders	$ (41,465)	$ (38,728)
Net loss per common share — basic and diluted	$ (0.93)	$ (0.89)
Weighted-average shares outstanding — basic and diluted	44,677	43,600

Cardiff Oncology, Inc.

Condensed Balance Sheets

(in thousands)

	December 31, 2023	December 31, 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	77,412	111,284
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	$ 81,637	$ 116,191
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	10,440	7,808
Operating lease liabilities, net of current portion	1,458	2,040
Total Liabilities	11,898	9,848
Stockholders' equity	69,739	106,343
Total liabilities and stockholders' equity	$ 81,637	$ 116,191

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	(30,887)	(33,820)
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	36,195	38,149
Financing activities:		
Proceeds from exercise of options	—	75
Net cash provided by financing activities	—	75
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	$ 21,655	$ 16,347

Cardiff Oncology Provides Clinical Update on Phase 2 Randomized Second-line ONSEMBLE Trial in Patients with RAS-mutated mCRC

- 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 -

- Company discontinued the ONSEMBLE trial in August 2023 to shift focus of clinical development program to first-line RAS-mutated mCRC in agreement with the FDA -

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

SAN DIEGO, February 29, 2024 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today provided a clinical update on the first release of data from its second-line RAS-mutated metastatic colorectal cancer (mCRC) ONSEMBLE trial. Although the Phase 2 ONSEMBLE trial was discontinued as part of the company's shift to a first-line mCRC program, it enrolled 23 patients randomized across three arms prior to closing the trial to new enrollment. The 23 enrolled patients continued treatment per protocol. The clinical data repeats the efficacy findings of onvansertib in bev naïve patients seen in the company's earlier Phase 1b/2 KRAS-mutated mCRC trial.

"The randomized data from the ONSEMBLE trial further validates the opportunity for onvansertib in the first-line RAS-mutated mCRC setting. The only objective responses observed on the trial occurred in bev naïve patients who received onvansertib plus standard of care, and the combination of onvansertib with standard of care was well-tolerated. By moving our lead program to the first-line setting, all patients on the CRDF-004 trial will be bev naïve," said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. "Importantly, no responses were observed in bev naïve patients randomized to the control arm, suggesting onvansertib improved the efficacy of standard of care therapy. And similarly, no responses were observed in patients who had received bev as part of their first line therapy in the onvansertib or the control arms, providing further evidence in a randomized setting of onvansertib's potential to improve outcomes for patients when added to standard of care in the first-line setting. We look forward to sharing the topline results of our first-line CRDF-004 trial in mid-2024."

Data Release from the Phase 2 randomized second-line ONSEMBLE trial in RAS-mutated mCRC

In August 2023, Cardiff Oncology discontinued enrollment in the second-line ONSEMBLE trial to focus on its new lead program in first-line RAS-mutated mCRC. This decision was driven by the fact that both trials essentially test the same clinical hypothesis, the importance of deploying the company's capital efficiently, and the FDA's suggestion that Cardiff Oncology consider focusing on the first-line RAS-mutated mCRC setting given the lack of any new therapies approved in this large cancer indication in the last 20 years.

At the time enrollment was discontinued, the ONSEMBLE trial had randomized 23 patients across three arms including a control arm of standard of care (SoC) FOLFIRI+bev, an experimental arm with onvansertib (20mg dose) added to SoC FOLFIRI+bev, and an experimental arm with onvansertib (30mg dose) added to SoC FOLFIRI+bev. The trial included patients with mCRC who had a documented KRAS or NRAS mutation and had previously received one prior chemotherapy regimen with or without bev in the first-line metastatic setting.

Patient enrollment populations	
Intent to treat population	23 patients
Patient randomized to control arm withdrew consent prior to initial dose	1 patient
Patient population evaluable for safety	22 patients
Patient randomized to control arm withdrew consent prior to post-baseline scan	1 patient
Patient population evaluable for efficacy	21 patients

Efficacy Data – Objective Response Rates (ORR)			
	Bev Naïve patients	Bev Exposed patients	All patients
FOLFIRI/bev (SoC alone); N=6	0% (0 of 3)	0% (0 of 3)	0% (0 of 6)
Onvansertib 20 mg + SoC; N=8	50% (1 of 2)	0% (0 of 6)	13% (1 of 8)
Onvansertib 30 mg + SoC; N=7	50% (1 of 2)	0% (0 of 5)	14% (1 of 7)
Onvansertib (all doses) + SoC; N=15	50% (2 of 4)	0% (0 of 11)	13% (2 of 15)
The two partial responses were confirmed on the patients' subsequent scans.			

Percentage of patients with Grade 4 Treatment-Emergent Adverse Events (TEAEs)	Grade 4 TEAEs
Control Arm (SoC alone)	0% (0 of 7)
Onvansertib 20 mg + SoC	25% (2 of 8)
Onvansertib 30 mg + SoC	0% (0 of 7)
Onvansertib (all doses) + SoC	13% (2 of 15)

- The combination of onvansertib with SoC FOLFIRI/bev was shown to be well-tolerated and no major / unexpected toxicities were seen
- Two Grade 4 TEAEs of neutropenia were seen in patients receiving 20 mg Onvansertib + SOC
    - Both patients recovered within 7 and 10 days after withholding the study treatment and no dose reductions in subsequent treatment cycles were needed. Both patients are still on trial

Key Baseline Characteristics

- The patients' median age was 53 years (range 35-81), and 54% were male
- 68% patients had previously received bev in their first-line treatment
- 12 of 21 (57%) evaluable patients remain on trial at the data cutoff date

Conference Call and Webcast

Cardiff Oncology will host a 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.

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Forward-Looking Statements

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Cardiff Oncology Announces First Patient Dosed in Randomized First-line RAS-mutated Metastatic Colorectal Cancer Trial (CRDF-004)

- Phase 2 trial in patients with RAS-mutated mCRC will evaluate onvansertib plus SoC versus SoC alone in the first-line setting -

- Pfizer Ignite is responsible for the clinical execution of the trial -

- Initial topline results expected in mid-2024 –

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

SAN DIEGO, February 29, 2024 -- Cardiff Oncology, Inc. (Nasdaq: CRDF), a clinical-stage biotechnology company leveraging PLK1 inhibition to develop novel therapies across a range of cancers, today announced that the first patient was dosed in its randomized first-line Phase 2 trial, CRDF-004, for patients with RAS-mutated metastatic colorectal cancer (mCRC). The trial, whose clinical execution is being conducted by Pfizer Ignite, Pfizer's new end-to-end service for biotech companies, 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.

"Today's announcement represents an important milestone for Cardiff Oncology and for patients with RAS-mutated mCRC, who have had no new therapies approved in almost 20 years," said Fairooz Kabbinavar, MD, FACP, Chief Medical Officer of Cardiff Oncology. "Based on the encouraging results from our Phase 1b/2 trial in second-line KRAS-mutated mCRC and our preclinical data demonstrating the powerful impact of combining onvansertib and bevacizumab, we believe the addition of onvansertib in the first-line setting has the potential to provide a meaningful improvement to the efficacy of SoC for mCRC patients with a RAS-mutation. We are especially pleased with the opportunity to leverage Pfizer Ignite's execution capabilities to advance the development of onvansertib. We strongly believe that we are on the cusp of a transformative advance in the treatment landscape for mCRC."

The Phase 2 trial includes patients with mCRC who have a documented KRAS or NRAS mutation. Onvansertib will be added to SoC FOLFIRI plus bevacizumab or FOLFOX plus bevacizumab. A total of 90 patients will be randomized in a 1:1:1 ratio to either 20mg of onvansertib plus SoC, 30mg of onvansertib plus SoC, or SoC alone. The primary endpoint is objective response rate (ORR), and the secondary endpoints include progression-free survival (PFS), duration of response and safety.

"We are pleased that the CRDF-004 trial is underway and look forward to providing clinical development support to advance onvansertib in RAS-mutated mCRC, which we believe has the potential to make an impact in patients with metastatic colorectal cancer," said Adam Schayowitz, Ph.D., MBA, Head, Product Teams, Portfolio & Program Management at Pfizer Oncology, and member of Cardiff Oncology's Scientific Advisory Board.

Contingent upon the results of CRDF-004, Cardiff Oncology will initiate a Phase 3, randomized trial, CRDF-005, with registrational intent. The FDA has agreed that ORR at an interim point is an acceptable

endpoint to pursue accelerated approval of onvansertib from the CRDF-005 trial, with PFS and trend in overall survival being the endpoints for full approval.

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Cardiff Oncology

Q4 2023 Financial Results and ONSEMBLE Trial Data

February 29, 2024

Forward-looking statements

CERTAIN STATEMENTS IN THIS PRESENTATION ARE FORWARD-LOOKING within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of words such as "anticipate," "believe," "forecast," "estimated" and "intend" or other similar terms or expressions that concern our expectations, strategy, plans or intentions. These forward-looking statements are based on our 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 our 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 we do not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances.

Cardiff Oncology

AGENDA

1. 2023 was a transformational ye
2. New data release from 2nd line ONSEMBLE trial
3. Review of financial position

2023 announcements were transformational for Cardiff Oncology

August: mCRC

Novel MOA for onvansertib	Inhibits vascularization of tumors
First-line CRDF-004 trial with Pfizer Ignite	Based on FDA recommendation
Discontinued second-line trial	First-line has larger patient population than second-line

September: beyond mCRC

New data from mPDAC trial	19% (4 PRs of 21) ORR 3 of 4 confirmed (14% C 7.7% ORR historical contr
New mPDAC clinical program	First-line investigator-initiated trial
New data from SCLC trial	Onvansertib monotherapy 1 cPR, 3 SD and 3 PD of patients

* As of February 29, 2024, three of the four initial partial responses seen on the mPDAC trial confirmed on their subsequent scan, and one initial partial response did not confirm. PR: partial response; cPR: confirmed par response; ORR: objective response rate; mCRC: metastatic colorectal cancer; mPDAC: metastatic pancreatic ductal adenocarcinoma; SCLC: small cell lung cancer; MOA: mechanism of action

Our mCRC journey of discovery led us from second-line to first-line

FIRST LINE

CRDF-004

ENROLLING

RAS-mutated mCR
90 patients, randomized, 3 arms (2 doses + control),
Pfizer Ignite

SECOND LINE

Ph 1b/2
(TROV-054)

COMPLETED

KRAS-mutated mCRC
66 evaluable patients, single arm

CRDF-003
ONSEMBLE
mCRC Clinical Trial

DISCONTINUED

RAS-mutated mCR
23 patients*, randomized, blinded, 3 arms (2 doses + control)

* ONSEMBLE enrolled 23 patients, and 2 patients were not evaluable for efficacy because one withdrew consent prior to their first dose and one withdrew consent before their first post-baseline scan. Both patients were "bev exposed" and randomized to the control arm.

Our mCRC journey of discovery led us from second-line to first-line

FIRST LINE

Provided initial signal of efficacy in second-line RAS-mutated mCRC

CRDF-004

ENROLLING

RAS-mutated mCR
90 patients, randomized, 3 arms (2 doses + control)
Pfizer Ignite

SECOND LINE

Ph 1b/2
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Our mCRC journey of discovery led us from second-line to first-line

FIRST LINE

Randomized second-line trial designed to show onvansertib's contribution to SoC that was discontinued

CRDF-004

ENROLLING

RAS-mutated mCR
90 patients, randomized, 3 arms (2 doses + control)
Pfizer Ignite

SECOND LINE

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(TROV-054)

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CRDF-003
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Our mCRC journey of discovery led us from second-line to first-line

FIRST LINE

Shift to 1st-line setting based on:

1. Phase 1b/2 clinical data
2. New mechanism of action
3. FDA recommendation

CRDF-004

ENROLLING

RAS-mutated mCR
90 patients, randomized, 3 arms (2 doses + control)
Pfizer Ignite

SECOND LINE

Ph 1b/2
(TROV-054)

COMPLETED

KRAS-mutated mCRC
66 evaluable patients, single arm

CRDF-003
ONSEMBLE
mCRC Clinical Trial

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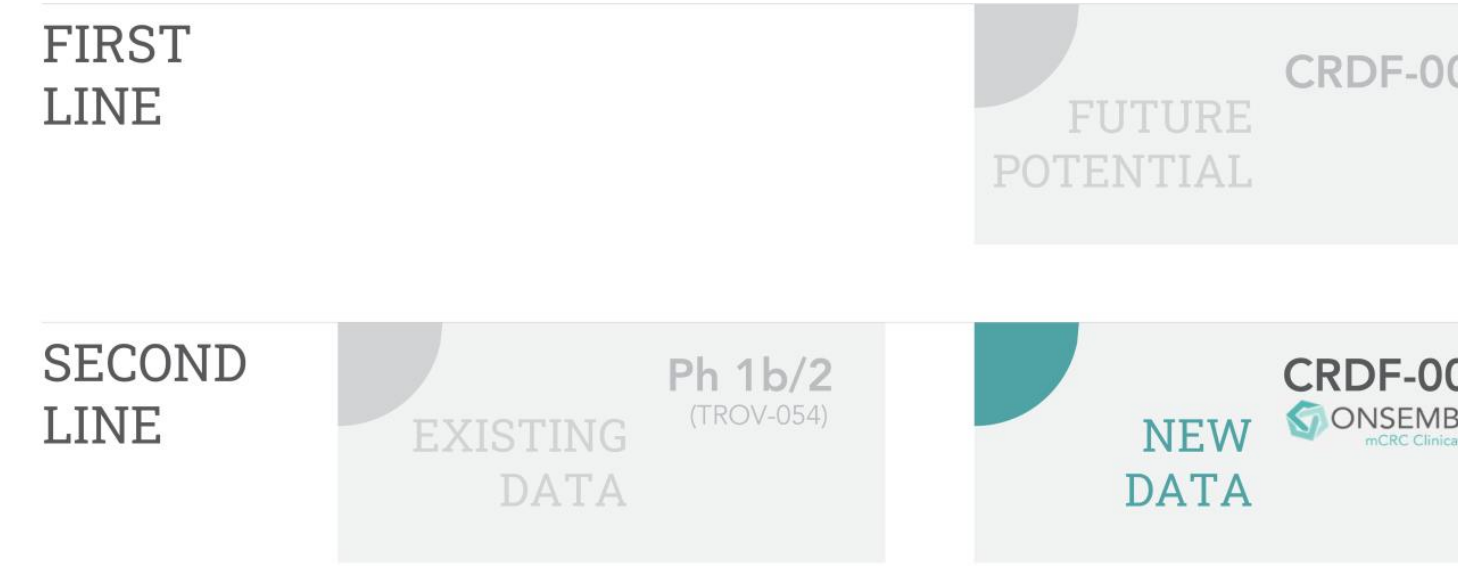
RAS-mutated mCR
23 patients*, randomized, blinded, 3 arms (2 doses + control)

* ONSEMBLE enrolled 23 patients, and 2 patients were not evaluable because one withdrew consent prior to their first dose and one withdrew consent before their first post-baseline scan. Both patients were "bev exposed" and randomized to the control arm.

Today we are announcing new data from the ONSEMBLE trial



ONSEMBLE Phase 2 trial was designed to generate randomized data

NEW DATA
CRDF-003

ENROLLMENT CRITERIA

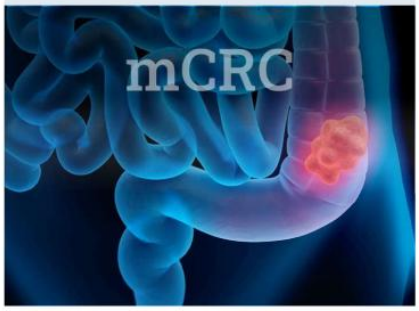
2nd line mCRC

KRAS+/NRAS+

Unresectable

R

N=23
1:1:1

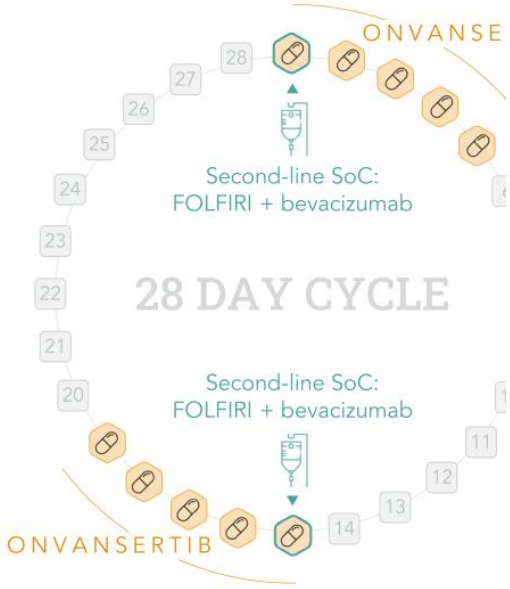


Standard of Care
FOLFIRI/bev

Onvansertib 20mg
+ FOLFIRI+bev

Onvansertib 30mg
+ FOLFIRI+bev

PRIMARY ENDPOINT
Objective Response Rate



ONSEMBLE's patient demographics reflect second-line mCRC populati

NEW DATA
CRDF-003

Enrollment*

Number of Patients (N)	FOLFIRI and bev	FOLFIRI-bev and Onvansertib - 20mg	FOLFIRI-bev and Onvansertib - 30mg	Total Patients All Doses
Intent to Treat	8	8	7	23
Treated (included in safety evaluable patients)	7	8	7	22
Evaluable for efficacy	6	8	7	21

Total Patients N=22	Median [range] or n (%)
Age (years)	53 [35-81]
Sex	
Male	12 (54%)
Female	10 (46%)
ECOG[1]	
0	9 (41%)
1	12 (55%)

Total Patients N=22	Median n (%)
Liver metastasis	
None	5 (23%)
Liver and other	13 (59%)
Liver only	4 (18%)
Number of metastatic organs	
1	7 (32%)
≥2	15 (68%)
Prior bevacizumab treatment	
Yes	15 (68%)
No	7 (32%)

* Data are interim as of January 3, 2024 from an ongoing trial and unlocked database. ONSEMBLE enrolled 23 patients, and 2 patients were not evaluable because one withdrew consent prior to their first dose and one withdrew consent before their first post-baseline scan. Both patients were "bev exposed" and randomized to the control arm.

[1] ECOG was not recorded for one patient

2nd line ONSEMBLE patients may or may not have received bev in 1st

NEW DATA
CRDF-003

Bev exposed vs bev naïve patients

		1st LINE	2nd LINE
"Bev naïve"	patients who did not receive prior bev in first-line	FOLFOX 7 of 21*	FOLFIRI + **bevacizumab** +/- ONVANSERTIB
or			
"Bev exposed"	patients who received bev in first-line	FOLFOX + **bevacizumab** 14 of 21*	

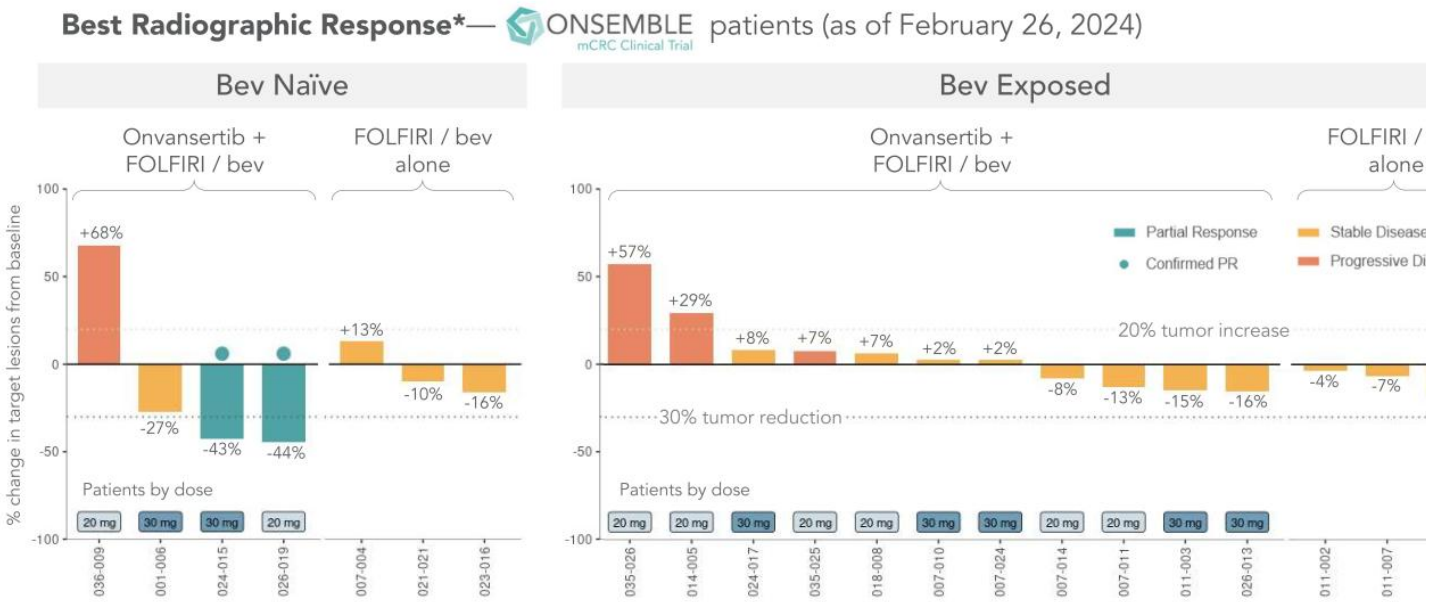
ONSEMBLE mCRC Clinical Trial

In the ONSEMBLE tri all patients received FOLFIRI & bev +/- onvansertib

* Number of the 21 ONSEMBLE patients evaluable for efficacy that were bev naïve or bev exposed.

Bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

NEW DATA
CRDF-003

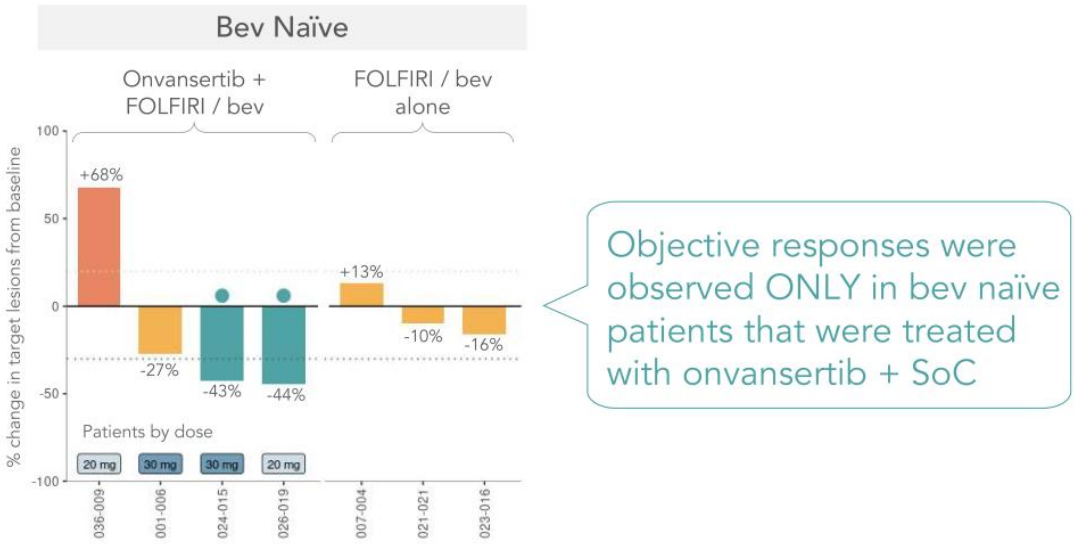


* Radiographic response determined per RECIST 1.1. Waterfall plot reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database.

Bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

NEW DATA
CRDF-003

Best Radiographic Response*— ONSEMBLE mCRC Clinical Trial patients (as of February 26, 2024)



Objective responses were observed ONLY in bev naïve patients that were treated with onvansertib + SoC

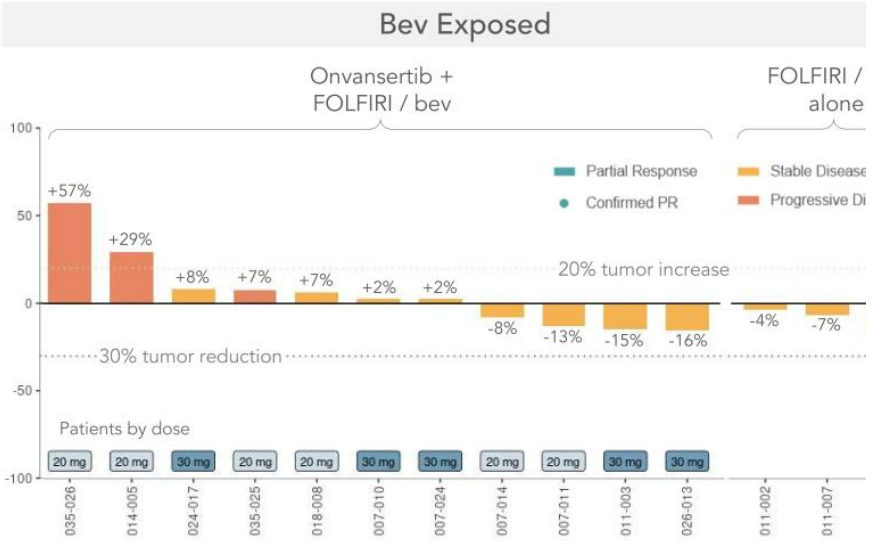
* Radiographic response determined per RECIST 1.1. Waterfall plot reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database.

Bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

NEW DATA
CRDF-003

Best Radiographic Response*— ONSEMBLE mCRC Clinical Trial patients (as of February 26, 2024)

No objective responses observed in bev exposed arms



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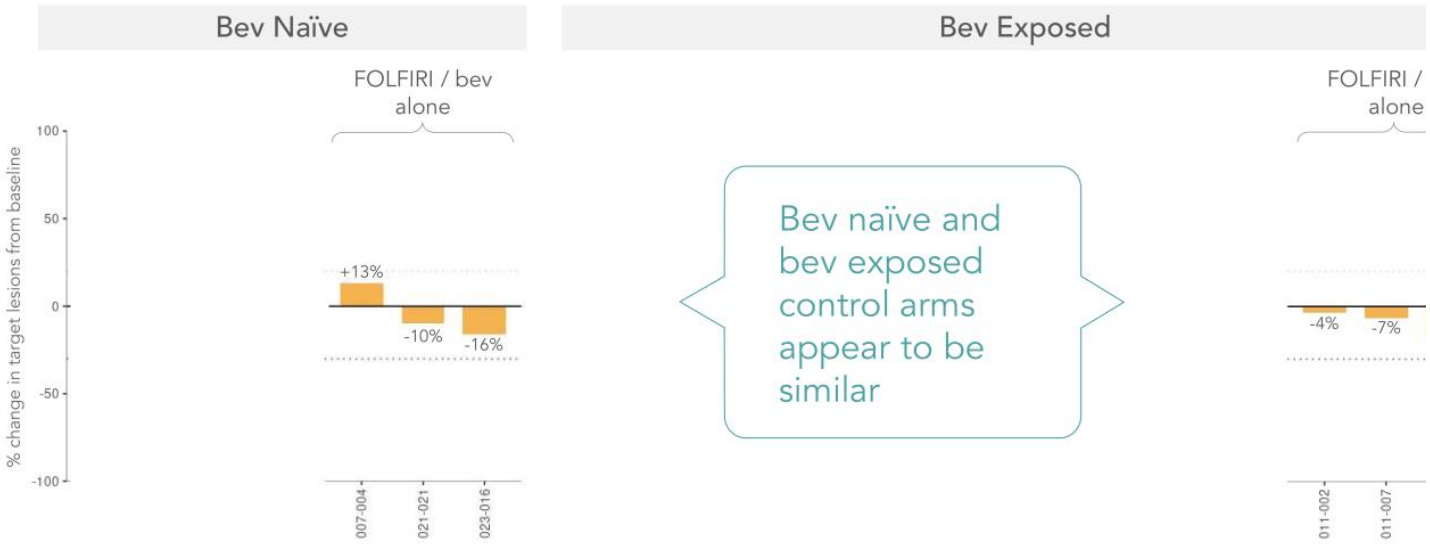
NEW DATA
CRDF-003

Best Radiographic Response*— ONSEMBLE mCRC Clinical Trial patients (as of February 26, 2024)



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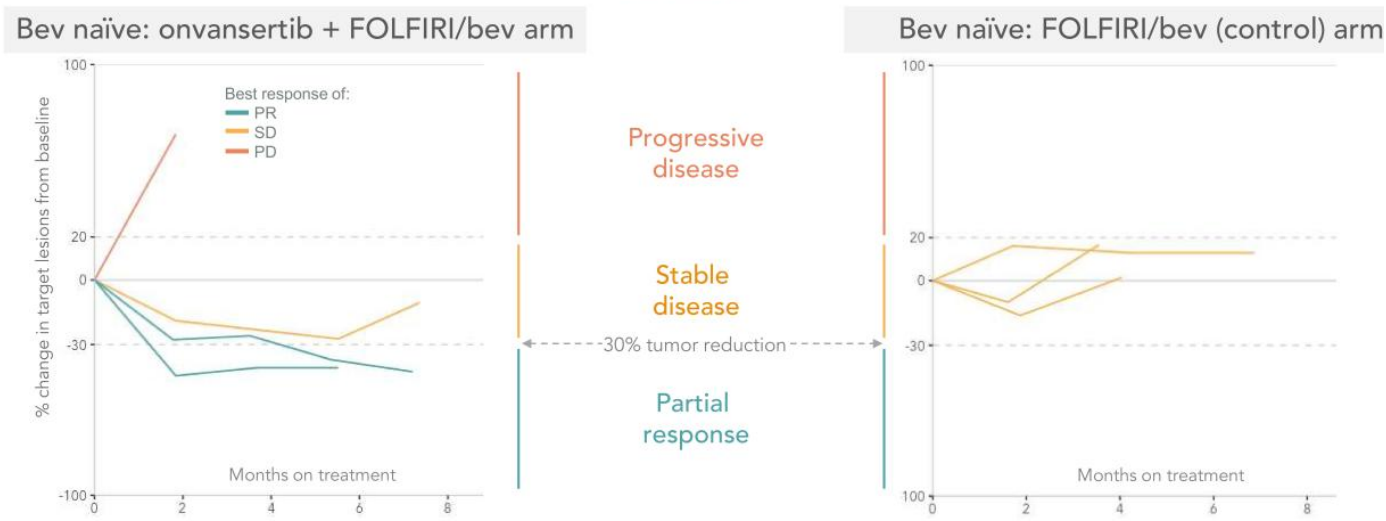
Bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

NEW DATA
CRDF-003

Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev naïve patients (as of February 26, 2024)



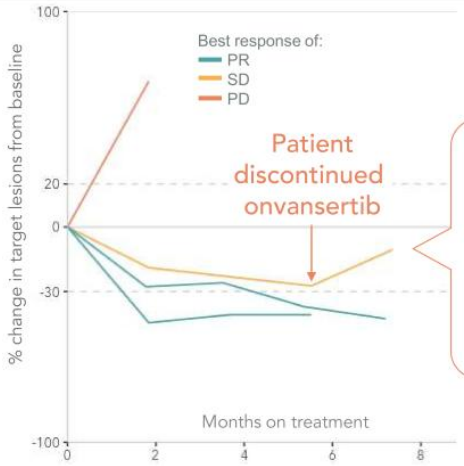
* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database

Bev naïve patients treated with onvansertib + SoC achieved deeper responses than SoC alone

NEW DATA
CRDF-003

Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev naïve patients (as of February 26, 2024)

Bev naïve: onvansertib + FOLFIRI/bev arm



Patient 006 discontinued onvansertib but remained on FOLFIRI/bev at their 6-month scan due to a suspicious new lung lesion.
Lesion was later biopsy-confirmed as a Valley fever (fungal) infection, not a new tumor lesion

* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database

Two independent clinical trials demonstrate the bev naïve finding

NEW DATA
CRDF-003

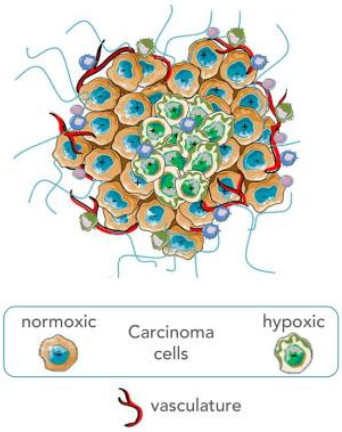
			Objective Response Rate (ORR) by Cohort*	
		N	Bev Naïve	Bev Exposed
ONSEMBLE mCRC Clinical Trial Randomized	Onvansertib + SoC	15	50% (2 of 4)	0% (0 of 11)
	Control (SoC alone)	6	0% (0 of 3)	0% (0 of 3)
Phase 1b/2 Single-arm	Onvansertib + SoC	66	73% (11 of 15)	16% (8 of 51)

* Radiographic response determined per RECIST 1.1. ONSEMBLE data reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database. Onvansertib + SoC includes patients at both the 20mg and 30mg dose of onvansertib. Phase 1b/2 data reflects interim data as of June 16, 2023 from an ongoing trial and unlocked database.

HIF1α plays a critical role in a tumor's response to hypoxia

Tumor growth → Hypoxia → HIF1α

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…



… low oxygen levels lead to elevated HIF1α protein expression

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes

VEGF-A

- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

Onvansertib and bev independently inhibit tumor response to hypoxi in bev naïve tumors

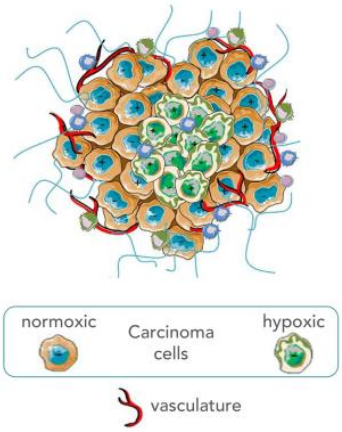
Tumor growth → **Hypoxia** → **HIF1α** ⊣ **onvanseri**

The tumor cells outgrow the blood supply and become starved of oxygen and nutrients…

… low oxygen levels lead to elevated HIF1α protein expression

… turns on VEGF-A expression and secretion to recruit new vasculature as well as turning on a multitude of downstream survival genes

inhibits H
expres



bevacizumab ⊣ VEGF-A

neutralizes VEGF-A

- Angiogenesis: Vascularization of the tumor
- Tumor cell survival
- Proliferation

https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2017.01625/full

Each step of our journey has reinforced the next step

FIRST LINE

FUTURE POTENTIAL

CRDF-00

ENROLLING

SECOND LINE

EXISTING DATA

Ph. 1b/2

(TROV-054)

COMPLETED

NEW DATA

CRDF-00

ONSEMB

mCRC Clinica

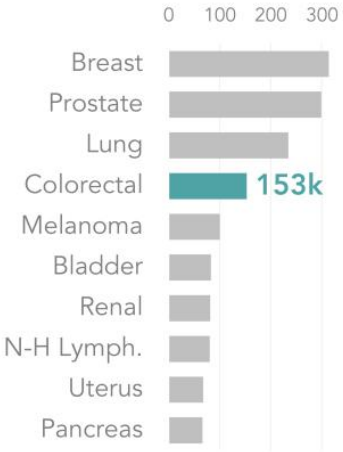
DISCONTINU

Our lead program targets first-line RAS-mutated mCRC

FUTURE POTENTIAL
CRDF-004

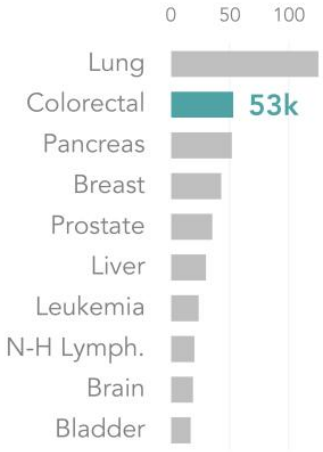
mCRC is common…

2024 new US cases ('000s)*

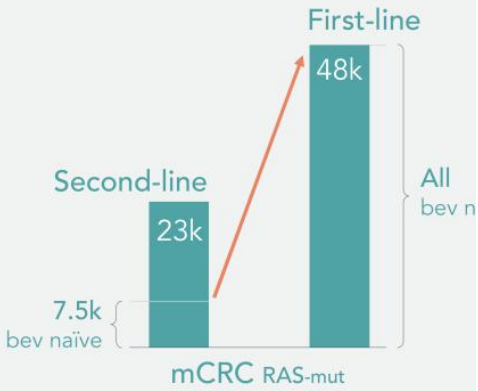


…and challenging to treat

2024 US deaths ('000s)*



Annual eligible US patients



* American Cancer Society Cancer Facts and Figures 2024, and company estimates of first-line and second-line mCRC population with KRAS- and NRAS-mutated cancers.

There is a significant unmet need in RAS-mutated mCRC first-line SoC

FUTURE POTENTIAL
CRDF-004

Standard of Care for first-line RAS-mutated mCRC includes chemo + bevacizumab

Chemotherapy	FOLFOX FOLFIRI	(approved 1996) (approved 2002)
✚		
Antiangiogenic	Bevacizumab (Avastin®)	(approved 2004)
Targeted therapy	None	

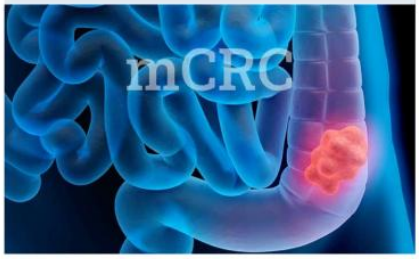
Trial design of CRDF-004: first-line RAS-mutated mCRC Phase 2 trial

FUTURE POTENTIAL
CRDF-004

ENROLLMENT CRITERIA

- First-line mCRC
- KRAS+/NRAS+
- Unresectable
- No prior bev treatment

R
N=90
1:1:1



Standard of Care (n=30)
FOLFIRI/bev or FOLFOX/bev

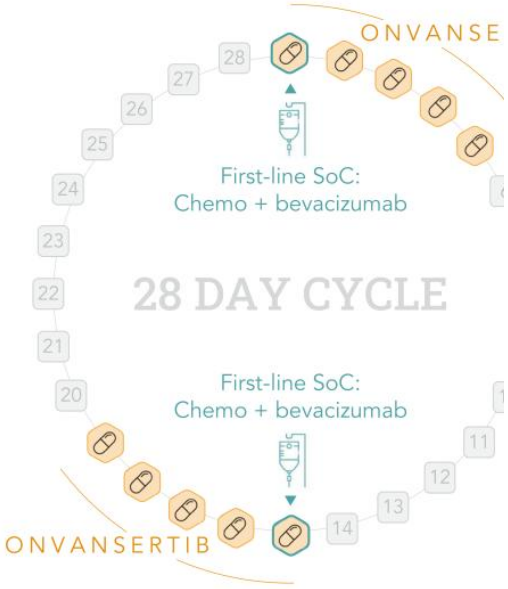
Onvansertib 20mg (n=30)
+FOLFIRI/bev or FOLFOX/bev

Onvansertib 30mg (n=30)
+FOLFIRI/bev or FOLFOX/bev

ENDPOINTS

Primary	ORR
Secondary	DoR and PFS

PFIZER IGNITE is providing clinical execution for CRDF-004



In CRDF-004, each arm will have an equal number of FOLFIRI/bev and FOLFOX/bev patients.

Our financial position is strong as of Q4 2023

Summary financial information as of December 31, 2023	
December 31, 2023 cash and investments*	$74.8M
Q4 2023 net cash used in Operating Activities*	$7.1M
Runway with current cash extends into 3Q 2025	

We expect to release data from our first-line RAS mutated mCRC trial (CRDF-004) in mid-2024

* Financial information above is derived from our audited financials in Form 10K filed on 2/29/24 and unaudited financials in Form 10Q filed on 11/2/23.

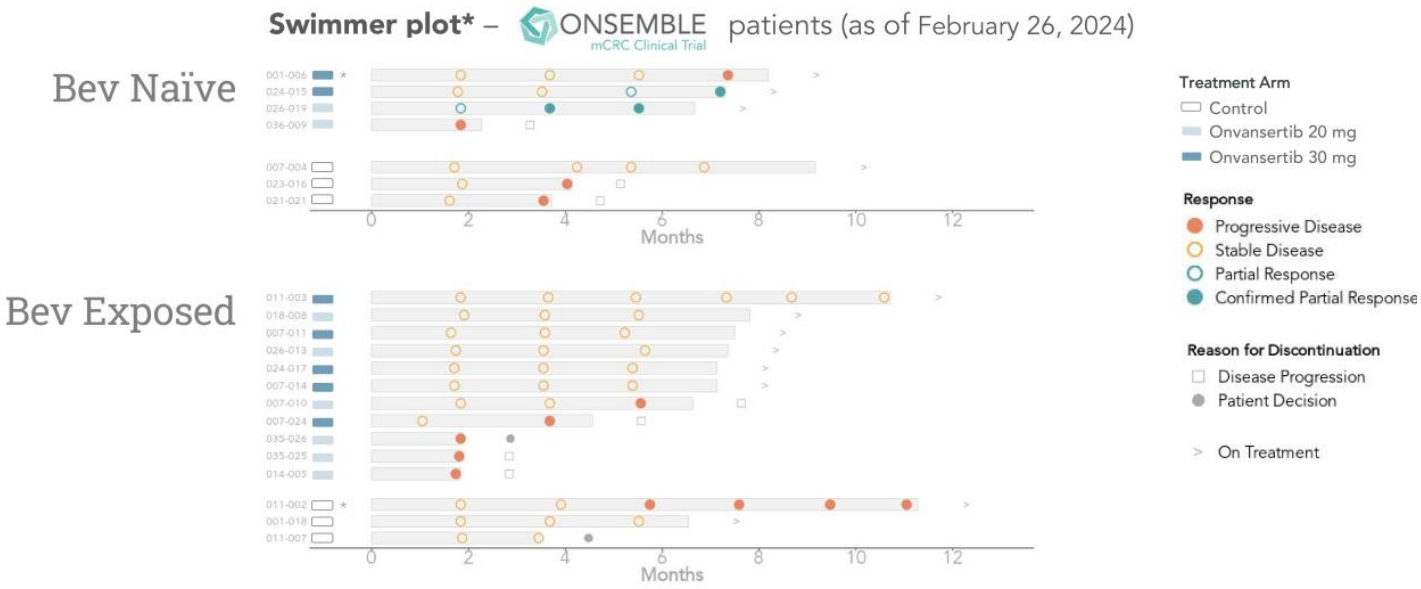
ONSEMBLE second-line data support our CRDF-004 first-line strateg

	Results from ONSEMBLE Second-line RAS-mut mCRC	Implications for CRDF-004 First-line RAS-mut mCRC
Efficacy signal in bev naïve patients	Objective responses observed only in bev naïve patients that received onvansertib with SoC	All first-line mCRC patients are bev naïve
No SoC signal in the control arm	No objective responses observed in bev naïve patients randomized to the control arm (SoC only)	Addition of onvansertib may improve efficacy of SoC chemo/be
Signal in both 20mg & 30mg dose	1 partial response observed in each dose of onvansertib (20mg and 30mg)	Data from 20mg and 30mg arms could be combined for earlier efficacy evaluation

Appendix
Additional ONSEMBLE data

ONSEMBLE trial swimmer plot

NEW DATA
CRDF-003

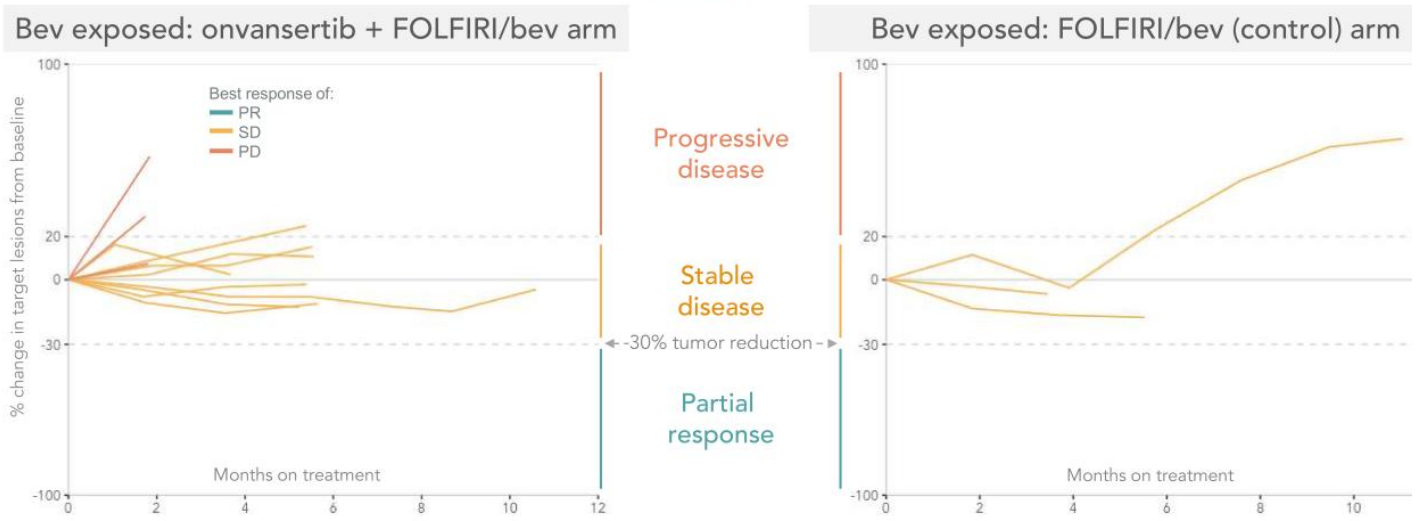


* Swimmer plot reflects interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database. Patient 001-006 discontinued onvansertib at their 6-month scan due to a suspicious new lung lesion which was later biopsy-confirmed as a Valley fever (fungal) infection. Patient 011-002 continues on trial in the control arm despite progressive disease, as the treating physician believes the patient continues to have clinical benefit from second-line standard of care treatment..

Bev exposed patients, with or without onvansertib, showed no response

NEW DATA
CRDF-003

Change in tumor size from baseline* – ONSEMBLE mCRC Clinical Trial bev exposed patients (as of February 26, 2024)



* Spider plots reflect interim data as of February 26, 2024 from an ongoing, discontinued trial and unlocked database

Control Arm: Treatment Emergent Adverse Effects (TEAEs)

NEW DATA
CRDF-003

Control arm
(N=7)

Patients received FOLFIRI+bev

No major/unexpected toxicity seen

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Tota
Any Adverse Events	6 (85.7)	6 (85.7)	3 (42.9)	0 (0.0)	6 (85
Diarrhea	3 (42.9)	1 (14.3)	0 (0.0)	0 (0.0)	4 (57
Nausea	2 (28.6)	1 (14.3)	1 (14.3)	0 (0.0)	4 (57
Fatigue	3 (42.9)	0 (0.0)	1 (14.3)	0 (0.0)	4 (57
Neutropenia	0 (0.0)	3 (42.9)	0 (0.0)	0 (0.0)	3 (42
Stomatitis	1 (14.3)	1 (14.3)	1 (14.3)	0 (0.0)	3 (42
Vomiting	1 (14.3)	0 (0.0)	1 (14.3)	0 (0.0)	2 (28
Alopecia	1 (14.3)	2 (28.6)	0 (0.0)	0 (0.0)	3 (42
Constipation	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42
Decreased appetite	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0
Insomnia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Hypokalaemia	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28
Anaemia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Cough	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14
Dysgeusia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0
Dyspepsia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Hypertension	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	1 (14
Lymphopenia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Pyrexia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14

* Data consists of all adverse events entered into the EDC as of January 3, 2024, from an ongoing trial and unlocked database. N: number of patients; events shown occurred in ≥10% of patients; numbers indicate number of patients experiencin the event, (regardless of causality); each patient is only counted once and only for the highest grade of a given event. TEAEs: Treatment Emergent Adverse Events; Columns show the absolute # of patients and (%) of the population.

Onvansertib 30mg Arm TEAEs: Onvansertib in combination with FOLFIRI+bev is well-tolerated

NEW DATA
CRDF-003

Experimental arm

Onv 30mg (N=7)

Patients received FOLFIRI+bev +30 mg dose of onvansertib

No major/unexpected toxicity seen

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Tota
Any Adverse Events	7 (100.0)	7 (100.0)	4 (57.1)	0 (0.0)	7 (100
Diarrhea	1 (14.3)	1 (14.3)	2 (28.6)	0 (0.0)	4 (57
Nausea	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42
Fatigue	3 (42.9)	1 (14.3)	0 (0.0)	0 (0.0)	4 (57
Neutropenia	0 (0.0)	1 (14.3)	2 (28.6)	0 (0.0)	3 (42
Stomatitis	2 (28.6)	1 (14.3)	0 (0.0)	0 (0.0)	3 (42
Vomiting	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28
Alopecia	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28
Constipation	1 (14.3)	1 (14.3)	0 (0.0)	0 (0.0)	2 (28
Decreased appetite	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	2 (28
Insomnia	3 (42.9)	0 (0.0)	0 (0.0)	0 (0.0)	3 (42
Hypokalaemia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.
Anaemia	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14
Cough	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28
Dysgeusia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Dyspepsia	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14
Hypertension	0 (0.0)	1 (14.3)	1 (14.3)	0 (0.0)	2 (28
Lymphopenia	2 (28.6)	0 (0.0)	0 (0.0)	0 (0.0)	2 (28
Pyrexia	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	1 (14
Thrombocytopenia	0 (0.0)	2 (28.6)	0 (0.0)	0 (0.0)	2 (28

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Onvansertib 20mg Arm TEAEs: Onvansertib in combination with FOLFIRI+bev is well-tolerated

NEW DATA
CRDF-003

Experimental arm

Onv 20mg (N=8)

Patients received FOLFIRI+bev +20 mg dose of onvansertib

No major/unexpected toxicity seen

2 Grade 4 TEAEs of neutropenia seen in patients (008 and 019) receiving 20mg onvansertib+SoC

- Both patients recovered after delaying their next cycle of treatment for 7 and 10 days, respectively
- Both patients are still on-trial

N (% of total)	Grade 1	Grade 2	Grade 3	Grade 4	Total
Any Adverse Events	8 (100.0)	7 (87.5)	2 (25.0)	2 (25.0)	8 (100
Diarrhea	4 (50.0)	3 (37.5)	0 (0.0)	0 (0.0)	7 (87.
Nausea	3 (37.5)	3 (37.5)	0 (0.0)	0 (0.0)	6 (75.
Fatigue	2 (25.0)	0 (0.0)	1 (12.5)	0 (0.0)	3 (37.
Neutropenia	1 (12.5)	0 (0.0)	1 (12.5)	2 (25.0)	3 (37.
Stomatitis	1 (12.5)	1 (12.5)	0 (0.0)	0 (0.0)	2 (25.
Vomiting	2 (25.0)	2 (25.0)	0 (0.0)	0 (0.0)	4 (50.
Alopecia	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (25.
Constipation	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.
Decreased appetite	2 (25.0)	2 (25.0)	0 (0.0)	0 (0.0)	4 (50.
Insomnia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.
Hypokalaemia	1 (12.5)	0 (0.0)	1 (12.5)	0 (0.0)	2 (25.
Anaemia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.
Cough	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.
Dysgeusia	2 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (25.
Dyspepsia	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	1 (12.
Hypertension	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.
Lymphopenia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.
Pyrexia	1 (12.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (12.
Thrombocytopenia	0 (0.0)	1 (12.5)	0 (0.0)	0 (0.0)	1 (12.

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