UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission File Number: 001-35558

CARDIFF ONCOLOGY, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11055 Flintkote Avenue, San Diego, California	**92121**
(Address of principal executive offices)	(Zip Code)

(858) 952-7570

(Registrant's telephone number, including area code)

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, $0.0001 par value	CRDF	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒	Smaller reporting company ☒	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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on a closing sale price of $1.47 per share, which was the last sale price of the common stock as of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was $64,335,342.

As of February 22, 2024, 44,677,169 shares of the registrant's common stock, $0.0001 par value per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14 A in connection with the registrant's 2023 Annual Meeting of Stockholders (the "Proxy Statement"), are incorporated by reference into Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report, the Proxy Statement is not deemed to be filed as part hereof.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. Our actual results could differ materially from those anticipated in the forward-looking statements for many reasons, including the reasons described in our "Business," "Risk Factors," and "Management Discussion and Analysis of Financial Condition and Result of Operations," sections. In some cases, you can identify these forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "depends," "estimate," "expects," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words.

Our operations and business prospects are always subject to risks and uncertainties including, among others:

- the timing of regulatory submissions;
- our ability to obtain and maintain regulatory approval of our existing product candidate and any other product candidates we may develop, and the labeling under any approval we may obtain;
- approvals for clinical trials may be delayed or withheld by regulatory agencies;
- pre-clinical and clinical studies will not be successful or confirm earlier results or meet expectations or meet regulatory requirements or meet performance thresholds for commercial success;
- risks relating to the timing and costs of clinical trials, the timing and costs of other expenses;
- risks associated with obtaining funding from third parties;
- management and employee operations and execution risks;
- loss of key personnel;
- competition;
- risks related to market acceptance of products;
- intellectual property risks;
- assumptions regarding the size of the available market, benefits of our products, product pricing, timing of product launches;
- risks associated with the uncertainty of future financial results;
- our ability to attract collaborators and partners; and
- risks associated with our reliance on third party organizations.

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of filing of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Risk Factor Summary

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Business

- We will need to raise substantial additional capital to develop and commercialize, our product candidate, onvansertib, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

- Our product candidate is in the early stages of clinical development and its commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed.

- If the results of preclinical studies or clinical trials for our product candidate, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business.

- If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

- We, and our collaborators, must comply with extensive government regulations in order to advance our product candidate through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

- We have limited experience in the development of therapeutic product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.

- 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.

- Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be substantially harmed.

- Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

- If the manufacturers upon whom we rely fail to produce our product candidate, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate.

- Our product candidate, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

- If we materially breach or default under the Nerviano Licensing Agreement, Nerviano will have the right to terminate the agreement and we could lose critical license rights, which would materially harm our business.

- Our common stock price may be volatile and could fluctuate widely in price, which could result in substantial losses for investors.

PART I

ITEM 1. BUSINESS

We are a clinical-stage biotechnology company leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations of onvansertib, our oral and highly selective PLK1 inhibitor, and standard-of-care therapeutics. We are focusing our clinical program in 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"). Our clinical development programs incorporate tumor genomics and biomarker assays to refine assessment of patient response to treatment.

Our Lead Drug Candidate, Onvansertib

Onvansertib is an oral, small molecule drug candidate that is highly specific for PLK1 inhibition with a 24-hour half-life.

We believe the attributes of onvansertib described below, as well as early clinical evidence of favorable safety and efficacy, with expected on-target, manageable and transient side effects, may prove beneficial in addressing clinical therapeutic needs across a variety of cancers:

- Onvansertib is highly potent and highly selective against the PLK1 enzyme (IC_{50} = 2nM; IC_{50} is the concentration for 50% inhibition), compared to prior PLK1 inhibitors that were pan-inhibitors of several PLK targets. Low or no activity of onvansertib was observed on a panel of 63 kinases (IC50>500 nM), including the PLK members PLK2 and PLK3 (IC_{50}>10,000 nM);

- Onvansertib is orally bioavailable, allowing for relative ease and flexibility of dosing;

- Onvansertib has a relatively short drug half-life of 24 hours, allowing for flexible dosing and scheduling which has shown favorable safety and tolerability across multiple clinical trials;

In vitro studies have shown synergistic effects when onvansertib was administered in combination with different cytotoxic agents including microtubule-targeting agents, topoisomerase 1 inhibitors, antimetabolites, alkylating agents, proteasome inhibitors, kinase inhibitors, PARP inhibitors, BCL-2 inhibitors, and androgen biosynthesis inhibitors.

In addition, *in vivo* combination studies have confirmed the positive results obtained *in vitro* and additive or synergistic effects on efficacy have been observed in xenograft models of onvansertib in combination with irinotecan, 5-fluorouracil ("5-FU"), abiraterone, PARP inhibitors, venetoclax, paclitaxel, or bevacizumab. Combining onvansertib with standard-of-care cancer agents provides opportunities for synergy with many cancer therapies.

There are five ongoing and planned clinical trials of onvansertib: one trial (CRDF-004) in first-line treatment in patients with RAS-mutated mCRC, one trial (CRDF-001) in second-line treatment in patients with mPDAC, and three investigator-initiated trials in first-line mPDAC, relapsed SCLC and unresectable locally advanced or metastatic TNBC.

Previously we reported data from two additional trials: one trial (TROV-054) in second-line treatment in patients with KRAS-mutated mCRC, and one trial (CRDF-003), which we refer to as the ONSEMBLE trial, in second-line treatment in patients with RAS-mutated mCRC.

RAS-mutated mCRC Program:

CRDF-004 Randomized Clinical Trial in First-Line RAS-mutated mCRC

CRDF-004 is a Phase 2 open-label, randomized multi-center clinical trial of onvansertib in combination with standard-of-care FOLFIRI and bevacizumab or FOLFOX and bevacizumab for the first-line treatment of patients with RAS-mutated mCRC. The primary objectives of the CRDF-004 trial are to evaluate onvansertib's safety and efficacy in combination with the standard-of-care, as well as to evaluate two doses of onvansertib, 20mg and 30mg, given in combination with standard-of-care, against standard-of-care alone. The primary endpoint of the trial is objective response rate ("ORR"). Progression-free survival and duration of response will be secondary endpoints. We anticipate interim data in mid-2024. Pfizer Ignite is responsible for

the clinical execution of the trial and it is expected to enroll approximately 90 evaluable patients. For more information, please visit NCT06106308 at *www.clinicialtrials.gov*.

Contingent upon the results of CRDF-004, we plan to initiate CRDF-005, a Phase 3, randomized trial with registrational intent. The FDA has agreed that a seamless trial with ORR at an interim point is an acceptable endpoint to pursue accelerated approval, with progression-free survival and trend in overall survival being the endpoints for full approval.

Phase 1b/2 Clinical Trial in Second-Line KRAS-mutated mCRC

TROV-054, a Phase 1b/2 open-label multi-center clinical trial of onvansertib in combination with standard-of-care FOLFIRI and bevacizumab for the second-line treatment of patients with KRAS-mutated mCRC, completed enrollment in October 2022.

The primary objectives of this trial were to evaluate the Dose-Limiting Toxicities ("DLTs"), maximum tolerated dose ("MTD") and recommended Phase 2 dose ("RP2D") of onvansertib in combination with FOLFIRI and bevacizumab (Phase 1b) and to continue to assess the safety and preliminary efficacy of onvansertib in combination with FOLFIRI and bevacizumab patients with KRAS-mutated mCRC (Phase 2). For more information, please visit NCT03829410 at *www.clinicialtrials.gov*.

Data presented on August 7, 2023, provided an update of the ongoing TROV-054 Phase 1b/2 single arm clinical trial in KRAS-mutated metastatic colorectal cancer:

- ORR across all evaluable patients was 29%, with 19 of 66 evaluable patients achieving an objective response. Responses have been observed across multiple KRAS variants;
- Median duration of response ("mDoR") across all evaluable patients was 12.0 months (95% confidence interval ("CI"): 8.9 – not reached);
- Median progression free survival ("mPFS") across all evaluable patients was 9.3 months (95% CI: 7.8 – 14). Historical control trials of different drug combinations, including the standard-of-care of FOLFIRI with bevacizumab, in similar patient populations have shown ORR and mPFS of 5 – 13% and ~4.5 – 6.7 months, respectively.
- A subgroup analysis of patients who were bevacizumab naïve when they entered second-line therapy vs. patients who had received prior bevacizumab in first-line therapy showed that patients who were bevacizumab naïve (n=15) had an ORR of 73% and mPFS of 15 months, which is well above historical controls. In contrast, patients previously treated with bevacizumab (n=51) had an ORR of 16% and mPFS of 7.8 months.
- Data on Treatment Emergent Adverse Events ("TEAEs") on the trial showed that onvansertib is well-tolerated when used in combination with FOLFIRI and bevacizumab. The more severe, grade 4 TEAEs are either neutropenia or leukopenia, which are common events in patients treated with FOLFIRI and bevacizumab. None of the patients with grade 4 TEAEs discontinued treatment due to their condition and all resolved without issue. There were no major or unexpected toxicities seen in the trial.

Based on the interim results of the TROV-054 trial, we previously designed the ONSEMBLE trial (CRDF-003) as the next phase of our mCRC program. Upon further review of the clinical data from the bevacizumab naïve subgroup (those patients who did not receive bevacizumab in their first-line therapy), the preclinical data on the mechanism of action and the feedback from the FDA on our clinical development strategy, we made the decision to discontinue enrollment in the ONSEMBLE trial and to initiate the CRDF-004 clinical trial.

Phase 2 Clinical Trial in Second-Line RAS-mutated mCRC

The ONSEMBLE trial (CRDF-003) is a Phase 2 randomized, open-label multi-center clinical trial of onvansertib in combination with standard-of-care FOLFIRI and bevacizumab for the second-line treatment of patients with RAS-mutated mCRC. The primary objectives of the ONSEMBLE trial are to evaluate onvansertib's safety and efficacy in combination with FOLFIRI and bevacizumab, as well as to evaluate two doses of onvansertib, 20mg and 30mg, given in combination with FOLFIRI and bevacizumab, against FOLFIRI and bevacizumab alone. The primary endpoint of the trial is ORR. For more information, please visit NCT05593328 at *www.clinicialtrials.gov*.

The ONSEMBLE trial was discontinued in August 2023 as part of the company's shift to a first-line mCRC program, and the 23 patients enrolled continued treatment per protocol.

Data presented on February 29, 2024, provided the first update of the ongoing ONSEMBLE Phase 2 randomized clinical trial in RAS-mutated mCRC:

- ORR data for each arm of the trial and for the two experimental arms combined are shown in the table below. The table also presents ORR data for two subgroups of patients: those who were bevacizumab naïve when they entered second-line therapy vs. patients who had received prior bevacizumab in first-line therapy.

Objective Response Rate	Bevacizumab Naïve Patients[1]	Bevacizumab 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)

(1) The two partial responses were confirmed on the patients' subsequent scans.

- Data on TEAEs on the trial showed that onvansertib is well-tolerated when used in combination with FOLFIRI and bevacizumab. No Grade 4 TEAEs were observed for the arms of FOLFIRI and bevacizumab alone and onvansertib 30 mg given in combination with FOLFIRI and bevacizumab. Two Grade 4 TEAEs of neutropenia were seen in patients receiving 20 mg onvansertib given in combination with FOLFIRI and bevacizumab. Both patients recovered within 7 and 10 days after withholding the study treatment and no dose reductions in subsequent treatment cycles were needed. There were no major or unexpected toxicities seen in the trial.

The ORR data from the randomized ONSEMBLE trial validates the findings observed in the company's earlier single-arm Phase 1b/2 KRAS-mutated mCRC trial (TROV-054). In the ONSEMBLE trial, objective responses were observed only in bevacizumab naïve patients versus bevacizumab exposed patients. In addition, these objective responses were present only in bevacizumab naïve patients randomized to the experimental arms of onvansertib in combination with FOLFIRI and bevacizumab versus bevacizumab naïve patients randomized to the FOLFIRI and bevacizumab alone control arm.

mDPAC Program:

Phase 2 Investigator-Initiated Clinical Trial in First-Line mPDAC

A two-cohort, non-randomized Phase 2 trial of onvansertib in combination with first-line standard-of-care Gemzar® and Abraxane® will be conducted at the OHSU Knight Cancer Institute. The enrollment criteria includes patients who are treatment-naïve with an ECOG performance status of 0 to 1, and with unresectable, locally advanced, or metastatic pancreatic cancer with measurable disease per RECIST 1.1.

The first cohort of patients will receive ten days of monotherapy as a lead-in. After the lead-in period, patients will then move to receive a combination regimen of standard-of-care chemotherapy and onvansertib.

The second cohort of patients will not receive the onvansertib monotherapy lead-in, but will move straight to the combination regimen.

This combination regimen consists of Gem-Abraxane on days 1, 8 and 15 of a four-week cycle. Patients will receive daily onvansertib with chemotherapy on days 1 through 5, days 8 through 12, and days 15 through 19. Patients will be monitored with bloodwork on a weekly basis.

The primary endpoint of this trial will be ORR, disease control rate ("DCR") at 16 weeks. Secondary endpoint will be DoR and PFS.

Phase 2 Clinical Trial in mPDAC

CRDF-001 is a Phase 2 open-label multi-center clinical trial of onvansertib in combination with nanoliposomal irinotecan (Onivyde®), leucovorin, and fluorouracil for 2nd line treatment of patients with mPDAC, which is being conducted at six clinical trial sites across the U.S. – The Mayo Clinic Cancer Centers (Arizona, Minnesota, and Florida), Kansas University Medical Center, Inova Schar Cancer Institute, and the University of Nebraska Medical Center. Enrollment for this trial closed in October 2023.

The objective of this trial is to assess the safety and preliminary efficacy of onvansertib in combination with nanoliposomal irinotecan (Onyvide®), 5-FU and leucovorin as a 2nd line treatment in patients with mPDAC who have failed first-line gemcitabine-based therapy. For more information, please visit NCT04752696 at *www.clinicialtrials.gov*.

Preliminary data presented on September 26, 2023 provided an update of the ongoing CRDF-001 Phase 2 open label clinical trial in mPDAC:

- Preliminary data from 21 patients evaluable for radiographic response showed 1 patient achieving a confirmed partial response (“PR”) and 3 patients achieving unconfirmed partial response that were awaiting confirmatory scans;
- 19% objective response rate (“ORR”) achieved compared to historical control of 7.7% in second-line setting;
- 5.0 months median progression-free survival (“mPFS”) achieved compared to historical control of 3.1 months with standard of care (“SoC”);

An update provided on February 29, 2024 indicated 3 of the 4 PRs are confirmed PRs and 1 of the 4 PRs did not confirm on their subsequent scan.

mPDAC biomarker discovery trial

The investigator-initiated biomarker discovery trial is exploring the impact of onvansertib 10-day monotherapy on tumors in mPDAC patients, and is currently enrolling at the Oregon Health & Science University (OHSU) Knight Cancer Institute. Enrollment for this trial is closed.

Preliminary data were presented on September 26, 2023. One patient demonstrated an 86% decrease in Ki67, a well-established biomarker of tumor proliferation, and a 28% decrease in CA 19-9, a clinically-used biomarker to monitor treatment response.

Other Clinical Programs:

Phase 2 Investigator-Initiated Clinical Trial in SCLC

A single-arm, two-stage, Phase 2 trial of onvansertib monotherapy in patients with relapsed SCLC is open for enrollment at the University of Pittsburgh Medical Center ("UPMC"). The trial is designed to enroll 15 patients in Stage 1, with the study proceeding to Stage 2 if 2 or more Stage 1 patients achieve an objective response. Stage 2 is designed to enroll an additional 20 patients. The primary endpoint of the trial is ORR, while key secondary endpoints include PFS and overall survival. For more information, please visit NCT05450965 at *www.clinicialtrials.gov*.

An examination of the safety data from the first six patients by the institutional review board confirmed the trial can continue to enroll as planned. Preliminary efficacy data for seven patients presented on September 26, 2023, showed one confirmed partial response (“PR”), three stable disease (“SD”) and three progressive disease (“PD”). The disease control rate (“DCR”), including PR and SD, is 57% (4 of 7 patients).

Phase 1b/2 Investigator-Initiated Clinical Trial in TNBC

A single-arm, Phase 1b/2 trial of onvansertib in combination with paclitaxel in patients with unresectable locally advanced or metastatic TNBC is open for enrollment at Dana Farber Cancer Institute ("DFCI"). In Phase 1b, approximately 14-16 patients will be treated with different doses of onvansertib in combination with a fixed dose of paclitaxel to determine the maximum tolerated dose and RP2D of onvansertib. In Phase 2, approximately 34 patients will be treated with the selected onvansertib RP2D in combination with paclitaxel.

The primary endpoint of Phase 2 of the trial is ORR, with PFS included as a secondary endpoint. For more information, please visit NCT05383196 at *www.clinicialtrials.gov*.

Identifying Biomarkers that Predict Patient Benefit

Our laboratory in San Diego, California, enables us to optimize drug development and patient care. In the clinical development of our lead drug candidate, onvansertib, correlative biomarker analyses are being used to help inform decisions in the evaluation of dose-response and optimal regimen for desired pharmacologic effect and safety. Additionally, some biomarkers can be used as a surrogate endpoint for efficacy and/or toxicity, as well as identifying certain patient populations that are more likely to respond to the drug therapy.

In our ongoing CRDF-004 clinical trial in RAS-mutated mCRC, we are quantitatively assessing changes in the RAS mutational burden with a blood test based on ctDNA. In TROV-054, our phase 1b/2 single-arm clinical trial in KRAS-mutated metastatic colorectal cancer, decreases in KRAS Mutant Allelic Frequency ("MAF") in ctDNA after the first cycle of treatment were highly predictive of subsequent radiographic response observed as tumor shrinkage.

Operating Segment and Geographic Information

We operate in one business segment, using one measurement of profitability to manage our business. We do not assess the performance of geographic regions on measures of revenue or comprehensive income or expense. In addition, all of our principal operations, assets and decision-making functions are located in the U.S. We do not produce reports for, or measure the performance of, geographic regions on any asset-based metrics. Therefore, geographic information is not presented for revenues or long-lived assets.

The Market

Metastatic Colorectal Cancer

Colorectal Cancer ("CRC") is a common cause of cancer death in the US. The American Cancer Society's estimates for the number of CRC diagnoses expected in the US in 2024 are 106,590 new cases of colon cancer and 46,220 new cases of rectal cancer, with an estimated 53,010 deaths predicted during 2024. Cancer-specific mortality of CRC is predominantly due to metastatic disease. Despite significant progress in the treatment of mCRC, the majority of patients with mCRC succumb to the disease. RAS mutations in the CRC population are common, with greater than 50% of tumors from CRC patients harboring a RAS mutation (43% KRAS, 9% NRAS).

The efficacy of first-line therapy in terms of response and survival prolongation remains limited. Therefore, improving the treatment options and effectiveness of treatment is critical to changing the outcomes for the RAS-mutated patient population.

Additional Cancer Indications

We and certain investigators are currently conducting signal-finding clinical trials to explore the treatment opportunity for onvansertib in mPDAC, SCLC and TNBC.

Collaborative Relationship

Pfizer, Inc.

In November 2021, we entered into a Securities Purchase Agreement (the “SPA”) with Pfizer Inc., as part of the Pfizer Breakthrough Growth Initiative, pursuant to which Pfizer purchased 2.4 million shares of our common stock at a purchase price per share of $6.22 for gross proceeds of approximately $15.0 million. In connection with the stock purchase, we and Pfizer entered into an Information Rights Agreement pursuant to which Adam Schayowitz, Ph.D., MBA, Vice President & Medicine Team Group Lead for Breast Cancer, Colorectal Cancer and Melanoma at Pfizer joined our Scientific Advisory Board, and until May 17, 2024 we agreed to provide Pfizer with rights of first access to any pre-clinical or final clinical data and results generated as part of the onvansertib development program at least two business days prior to us providing such data to a third party.

In August 2023, we announced that Pfizer Ignite, a new end-to-end service for biotech companies, will be responsible for the clinical activities of our new CRDF-004 trial in first-line RAS-mutated mCRC. This expands the relationship established in November 2021 and extends the term of the Information Rights Agreement through the conclusion of the CRDF-004 clinical trial. Pfizer Ignite is a new end-to-end service for biotech companies with high potential science that leverages Pfizer Inc.'s significant R&D capabilities, scale and expertise to accelerate the development of breakthrough therapies. We are financially responsible for all clinical trial activities performed by Pfizer Ignite and maintain full economic ownership and control of onvansertib.

Intellectual Property

We consider the protection of our proprietary technologies and products, as well as our ability to maintain patent protection that covers the composition of matter of our product candidates, their methods of use, and other related technologies and inventions, to be a critical element in the success of our business. As of December 31, 2023, our owned and licensed intellectual property included 53 issued patents and 43 pending patent applications (one U.S. patent application was recently allowed) in the U.S. and abroad, some of which are related to our legacy patent portfolio. The pending patent applications include multiple international patent applications filed under the Patent Cooperation Treaty that may be used as the basis for multiple additional patent applications worldwide.

We licensed onvansertib from Nerviano Medical Sciences ("NMS" or "Nerviano") pursuant to a license agreement with NMS dated March 13, 2017 which grants us exclusive, worldwide licenses under a portfolio of three patent families of U.S. and foreign patents covering three broad areas: (1) onvansertib (composition of matter), related compounds and processes for making compounds; pharmaceutical compositions and methods of treating diseases characterized by dysregulated protein kinase activity; (2) salts and pharmaceutical compositions of onvansertib; methods of treating mammals in need of PLK inhibition; and (3) synergistic combinations of onvansertib and one or more of a broad range of antineoplastic agents, and pharmaceutical compositions of those combinations. Patents of this licensed portfolio will expire between 2027 and 2030. U.S. patents of this licensed patent portfolio will expire in 2030, with patent term extension up to 2035.

On September 19, 2018, we entered into an Exclusive Patent License Agreement with MIT to a patent family directed to combination therapies including an antiandrogen or androgen antagonist and a polo-like kinase inhibitor (such as onvansertib) for the treatment of cancer. The license agreement as amended covers the rights to develop combination therapies and identified predictive clinical biomarkers across cancer types, expanding potential indications for onvansertib. Under the agreement, we have exclusive rights to develop, make, use, and sell combination therapies that include a PLK inhibitor in combination with an anti-androgen or androgen antagonist, or in combination with a microtubule polymerization inhibitor, for the treatment of cancer. The exclusive license agreement is part of our strategy to explore the efficacy of onvansertib in combination with anti-androgen drugs in cancers including prostate, breast, pancreatic, lung and gastrointestinal.

The licensed MIT patent family includes U.S. Patent Nos. 9,566,280, 10,155,006, and 10,772,898, which will expire in 2035, with patent term extension up to 2040. U.S. Patent No. 9,566,280 encompasses using abiraterone in combination with onvansertib to treat cancer. U.S. Patent Nos. 10,155,006 and 10,772,898 broaden earlier issued U.S. Patent No. 9,566,280, by expanding the use of onvansertib to encompass combination therapies with any anti-androgen and androgen antagonist drug, such as Zytiga®, Xtandi® and Erleada® for the treatment of metastatic and non-metastatic castrate-resistant prostate cancer.

Our owned intellectual property includes twenty patent families related to onvansertib. These families include patent applications directed to treating cancer using PLK1 inhibitors and determining efficacy of the treatment, treating benign prostatic hyperplasia using onvansertib, treating prostate cancer using PLK1 inhibitors, determining or predicting efficacies or responsiveness of PLK1 inhibitor treatments based on biomarkers, and treating cancers with combination therapies of PLK1 inhibitors (including combination therapies of PLK1 inhibitors with B-cell lymphoma 2 inhibitors, poly ADP ribose polymerase inhibitors, fibroblast growth factor receptor inhibitors, lysine-specific demethylase 1 inhibitors, or irinotecan). Any patents issued in these families will expire between 2039 and 2044. One of the patent families includes a patent application directed to selecting and treating cancers with combination therapies of PLK1 inhibitors. MIT and we co-own this family. On November 17, 2021, we amended the Exclusive Patent License Agreement with MIT to include this patent family.

Wherever possible, we seek to protect our inventions by filing U.S. patent applications as well as foreign counterpart applications in select countries. Because patent applications in the U.S. are maintained in secrecy for at least eighteen months after the applications are filed, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications, or that we were the first to file for protection of inventions set forth in such patent applications. Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case continued development and marketing of our products would require a license. Required licenses may not be available to us on

commercially acceptable terms, if at all. If we do not obtain these licenses, we could encounter delays in product introductions while we attempt to design around the patents, or we could find that the development, manufacture or sale of products requiring such licenses are not possible.

In addition to patent protection, we also rely on know-how, trade secrets and the careful monitoring of proprietary information, all of which can be difficult to protect. We seek to protect some of our proprietary technologies and processes by entering into confidentiality agreements with our employees, consultants, and contractors. These agreements may be breached, we may not have adequate remedies for any breach and our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that intellectual property owned by others is used by our employees, consultants or contractors, disputes may arise as to the rights in related or resulting know-how and inventions.

Manufacturing and Distribution

We currently rely on third-party manufacturers and distributors to supply and distribute onvansertib used in our clinical studies and nonclinical development programs.

Government Regulation

We operate in a highly regulated industry that is subject to significant federal, state, local and foreign regulation. Our present and future business has been, and will continue to be, subject to a variety of laws including, the Federal Food, Drug, and Cosmetic Act (“FDC Act”), and the Public Health Service Act, among others.

The FDC Act and other federal and state statutes and regulations govern the testing, manufacturing, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these laws and regulations, product development and product approval processes are very expensive and time-consuming.

FDA Approval Process

In the United States, pharmaceutical products, including biologics, are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacturing, storage, record keeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications (“NDAs”) or Biologics License Applications (“BLAs”) warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation as well as animal trials to assess the characteristics and potential pharmacology and toxicity of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not objected to the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations and Good Clinical Practices (“GCP”) as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an Institutional Review Board ("IRB") for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs, which are applications for marketing approval, are typically conducted in three sequential Phases, but the Phases may overlap. In Phase 1, the initial introduction of the investigational drug candidate into healthy human subjects or patients, the investigational drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness.

Phase 2 usually involves trials in a limited patient population, to determine the effectiveness of the investigational drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. In the case of product candidates for severe or life-threatening diseases such as cancer, the initial human testing is often conducted in patients rather than in healthy volunteers.

If an investigational drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the investigational drug and to provide adequate information for its labeling.

After completion of the required clinical testing, an NDA or, in the case of a biologic, a BLA, is prepared and submitted to the FDA. FDA approval of the marketing application is required before marketing of the product may begin in the United States. The marketing application must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of marketing applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider new information submitted during the review or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a marketing application, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

Additionally, the FDA will inspect the facility or the facilities at which the drug product is manufactured. The FDA will not approve the NDA or, in the case of a biologic, the BLA unless compliance with CGMPs is satisfactory and the marketing application contains data that provide substantial evidence that the product is safe and effective in the indication studied. Manufacturers of biologics also must comply with FDA's general biological product standards.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed in a resubmission of the marketing application, the FDA will re-initiate their review. If the FDA is satisfied that the deficiencies have been addressed, the agency will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. It is not unusual for the FDA to issue a complete response letter because it believes that the drug product is not safe enough or effective enough or because it does not believe that the data submitted are reliable or conclusive.

An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. As a condition of approval of the marketing application, the FDA may require substantial post-approval testing and surveillance to monitor the drug product's safety or efficacy and may impose other conditions, including labeling restrictions, which can materially affect the product's potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

Other Regulatory Requirements

Once a NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of therapeutic products, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement, before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs. We cannot be certain that the FDA or any other regulatory agency will grant approval for our product candidate for any other indications or any other product candidate for any indication on a timely basis, if at all.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as product manufacturing, packaging, and labeling procedures must continue to conform to CGMPs after approval. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with CGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with CGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

Federal and State Fraud and Abuse Laws

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug and biologic product candidates which obtain marketing approval. In addition to FDA restrictions on marketing of pharmaceutical products, pharmaceutical manufacturers are exposed, directly, or indirectly, through customers, to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which a pharmaceutical manufacturer can market, sell and distribute drug and biologic products. These laws include, but are not limited to:

The federal Anti-Kickback Statute which prohibits, any person or entity from, among other things, knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in-kind, to induce or reward either the referring of an individual for, or the purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable, in whole or in part, under Medicare, Medicaid, or any other federally financed healthcare program. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other hand. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

The federal false claims and civil monetary penalty laws, including the Federal False Claims Act, which imposes significant penalties and can be enforced by private citizens through civil *qui tam* actions, prohibits any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to the

federal government, or knowingly making, using or causing to be made, a false statement or record material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, benefits, items or services.

HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, which impose certain requirements relating to the privacy, security, transmission and breach reporting of individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services ("HHS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.

State and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other healthcare providers, and other federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded

healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Healthcare Reform in the United States

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act ("ACA"), which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, was signed into law and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; expanded manufacturer Medicaid rebate liability to include utilization by beneficiaries enrolled in Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected; increased the number of entities eligible for discounts under the 340B program; and included a discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or "donut hole."

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, an executive order was issued to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's AMP, beginning January 1, 2024.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. There have been several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Regulation in the European Union

Biologics are also subject to extensive regulation outside of the United States. In the European Union, for example, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union, which includes most major countries in Europe. If this procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under two simplified application processes, the mutual recognition procedure, or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, pricing and reimbursement approvals are also required in most countries.

Data Privacy and Security

We are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act(“CCPA”), the California Privacy Rights Act(“CPRA”), and the General Data Protection Regulation(“GDPR”), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances and biological materials. We may incur significant costs to comply with such laws and regulations now or in the future.

Some drugs benefit from additional government incentives. Orphan drugs receive special consideration from the FDA in order to encourage pharmaceutical companies to develop treatments for rare diseases. Incentives for the development of orphan drugs include quicker approval time and potential financial assistance, including waiver of the Prescription Drug User Fee Act (“PDUFA”). Companies are often permitted to charge substantial prices for orphan drugs, making them more profitable than they would be without government intervention. As a result, the development of orphan drugs continues to grow at a faster rate than the development of traditional pharmaceuticals.

Competition

Onvansertib is not the first PLK inhibitor that has entered clinical development; however, we believe it currently is the only oral PLK1 inhibitor in active clinical development that delivers highly selective PLK1 inhibition. Onvansertib is also synergistic in combination with numerous chemotherapies and targeted therapeutics and may enhance and/or extend response to treatment across a number of solid tumor cancers. In six clinical trials with over 250 patients, onvansertib was shown to be well-tolerated when dosed as a single agent or in combination with other therapies.

The PLK inhibitor that reached the latest stage of clinical development (Phase 3), is volasertib, a pan-PLK inhibitor developed by Boehringer Ingelheim. Boehringer Ingelheim was developing volasertib plus LDAC for the treatment of AML which did not meet the primary endpoint of ORR (EHA 2016). The data showed an unfavorable overall survival trend with the safety profile of volasertib plus LDAC considered as the main reason. Volasertib's safety profile may have resulted from the fact that its inhibition of PLK1 is not highly selective and it also inhibits PLK2 and PLK3. By contrast, onvansertib is able to deliver much more selective inhibition of PLK1 than volasertib. Onvansertib also has a half-life of 24 hours vs. volasertib's 135 hours and it is orally administered.

One additional PLK1 inhibitor in early-stage clinical development is plogosertib, which is being developed by Cyclacel. Plogosertib has primary selectivity for PLK1 and secondary selectivity for PLK2 and PLK3.

Human Capital

The human capital objectives we focus on in managing our business include attracting, developing, and retaining key personnel. Our employees are critical to the success of our organization and we are committed to supporting our employees' professional development. We believe our management team has the experience necessary to effectively implement our growth strategy and continue to drive shareholder value. We provide competitive compensation and benefits to attract and retain key personnel, while also providing a safe, inclusive and respectful workplace.

As of February 22, 2024, we had a total of 32 employees, 31 of whom were full-time. Based on self-identification data, 47% of our employees identify as female and 47% of our employees identify as a racial or ethnic minority. None of our employees are covered by a collective bargaining agreement, and we consider our relations with our employees to be good.

Corporation Information

We were originally incorporated under the laws of the State of Florida in April 2002. In January 2010, we re-incorporated under the laws of the State of Delaware and changed our name to Trovagene, Inc. In May 2012, our common stock was listed on The Nasdaq Capital Market ("Nasdaq") under the ticker symbol TROV. In May 2020 we changed our name to Cardiff Oncology, Inc. and our Nasdaq ticker symbol changed to CRDF. Our corporate website address is www.cardiffoncology.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, proxy statements, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge at www.cardiffoncology.com as soon as reasonably practicable after electronically filing such reports with the Securities and Exchange Commission. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Annual Report on Form 10-K. These reports are also available at www.sec.gov.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. An investor should carefully consider the risks described below as well as other information contained in this Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission ("SEC"). The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our securities could decline, and investors in our company may lose all or part of their investment.

Risks Related to Our Business

We are a clinical stage company and may never earn a profit.

We are a clinical stage company and have incurred losses since our formation. As of December 31, 2023, we have an accumulated total deficit of approximately $339.5 million. For the fiscal years ended December 31, 2023 and 2022, we had a net loss attributable to common stockholders of approximately $41.5 million and $38.7 million, respectively. To date, we have experienced negative cash flow from development of our product candidate, onvansertib. We have generated limited revenue from operations, and we expect to incur substantial net losses for the foreseeable future as we seek to further develop and commercialize onvansertib. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all.

If we are unable to generate significant revenue from onvansertib or attain profitability, we will not be able to sustain operations.

Because of the numerous risks and uncertainties associated with developing and commercializing onvansertib, we are unable to predict the extent of any future losses or when we will attain profitability, if ever. We may never become profitable and you may never receive a return on an investment in our common stock. An investor in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of onvansertib. We may never successfully commercialize onvansertib, and our business may not be successful.

We will need to raise substantial additional capital to develop and commercialize onvansertib and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

As of December 31, 2023, our cash, cash equivalents and short-term investments balance was approximately $74.8 million and our working capital was approximately $67.0 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidate. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. In order to raise additional capital, we may seek to sell additional equity and/or debt securities or obtain a credit facility or other loan, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidate, restrict our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital at acceptable terms would result in a material and adverse impact on our operations.

Our product candidate, onvansertib, is in the early stages of clinical development and its commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed.

In the near-term, failure to successfully advance the development of our product candidate may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidate through preclinical studies and clinical trials, have the product candidate approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidate successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidate, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidate.

Our product candidate must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete its clinical development or it can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our product candidate. Despite these efforts, our product candidate may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidate. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidate may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidate demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of an NDA or a Biologics License Application ("BLA") to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Our product candidate will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that our product candidate will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidate to be commercialized by us or collaborators for at least several years.

Our product candidate may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval, or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidate to obtain regulatory approval to further advance clinical development or to market it. Even if our product candidate demonstrates biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. In preclinical studies and clinical trials we have conducted to date, our product candidate's safety profile is based on studies and trials that have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the results of preclinical studies or clinical trials for our product candidate, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business.

In order to further advance the development of, and ultimately receive regulatory approval to sell, our product candidate, we must conduct extensive preclinical studies and clinical trials to demonstrate its safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities, including an IRB or Ethical Committee ("EC"), not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting patients or participants dropping out of our clinical trials at a higher rate than we anticipated;

- our third party contractors, upon whom we rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

- having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks;

- IRBs, ECs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and

- the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidate and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for onvansertib.

As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidate.

We, and our collaborators, must comply with extensive government regulations in order to advance our product candidate through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

The product candidate that we, or our collaborators, are developing requires regulatory approval to advance through clinical development and to ultimately be marketed and sold, and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and

biopharmaceutical products. Our product candidate is also subject to similar regulation by foreign governments to the extent we seek to develop or market it in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidate's safety and efficacy before it can be approved for the targeted indications. Our product candidate has not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidate based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA's or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidate through clinical development, and ultimately commercialize them, may:

- adversely impact our ability to raise sufficient capital to fund the development of our product candidate;
- adversely affect our ability to further develop or commercialize our product candidate;
- diminish any competitive advantages that we or our collaborators may have or attain; and
- adversely affect the receipt of potential milestone payments and royalties from the sale of our products or product revenues.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including:

- delays, suspension or termination of clinical trials related to our products;
- refusal by regulatory authorities to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks.

We have limited experience in the development of therapeutic product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.

We have limited experience in the discovery, development and manufacturing of therapeutic compounds. In order to successfully develop our product candidate, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of a number of responsibilities and key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidate. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel, and directors to develop, implement and execute our business strategy, operate the company and

oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidate, we need to retain or attract certain personnel, consultants or advisors with experience in drug development activities that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems. We are highly dependent upon our senior management and scientific staff, particularly Mark Erlander, our Chief Executive Officer ("CEO"). The loss of services of Dr. Erlander or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidate.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key managers or employees, or are unable to attract and retain qualified key personnel, directors, advisors or consultants, the development of our product candidate could be delayed or terminated and our business may be harmed.

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 product candidate may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidate, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidate for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidate, and if those assumptions are incorrect it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidate may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidate or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

Our product candidate could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidate, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

We have not previously submitted a BLA, or a NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for our product candidate, and we cannot be certain that our product candidate will be successful in clinical trials or receive regulatory approval. Further, our product candidate may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for our product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidate are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval and to commercialize our product candidate, directly or with a collaborator, worldwide including the United States, the European Union and other additional foreign countries which we have not yet

identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidate.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering our product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidate for any or all targeted indications. Ultimately, our product candidate may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients' privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert

management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidate.

We need FDA approval prior to marketing our product candidate in the United States. If we fail to obtain FDA approval to market our product candidate, we will be unable to sell our product candidate in the United States and we will not generate any revenue.

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre-clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for our product candidate currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidate for the claimed intended uses. Following any regulatory approval of our product candidate, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidate in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidate is unable to compete effectively with marketed drugs targeting similar indications as our product candidate, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidate. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, onvansertib would compete with the prescription therapies already approved for treatment within the targeted therapeutic area. To our knowledge, other potential competitors are in earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for onvansertib.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully identify and develop key points of product differentiations from currently available therapies;
- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed drugs, we may never generate meaningful revenue.

If the manufacturers upon whom we rely fail to produce our product candidate, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate.

We do not currently possess internal manufacturing capacity. We plan to utilize the services of GMP, FDA validated contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of onvansertib, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We continue to pursue API and drug product supply agreements with other manufacturers. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidate.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We will be responsible for ensuring that each of our future contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with GMP requirements. We will be responsible for regularly assessing a contract manufacturer's compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers of our product candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

While we will oversee compliance by our contract manufacturers, ultimately, we will not have control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or

withdrawal of product approval. If the safety of our product candidate is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of onvansertib or other product candidates, entail higher costs or result in us being unable to effectively commercialize our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidate in commercial quantities, which would prevent us from commercializing our product candidate.

To date, our product candidate has been manufactured in small quantities for preclinical studies and clinical trials. If our product candidate is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for our product candidate in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidate requires precise, high-quality manufacturing. Our failure to achieve and maintain these high-quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition, and results of operations.

Materials necessary to manufacture our product candidate may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidate.

We rely on third party manufacturers to purchase from third-party suppliers the materials necessary to produce bulk APIs, and product candidates for our clinical trials, and we will rely on such manufacturers and any additional similar manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidate, if approved for sale, may not gain acceptance among physicians, patients, and the medical community, thereby limiting our potential to generate revenues.

If our product candidate is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payors and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;

- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payors, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our product.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and healthcare providers could result in decreased use of our proposed product.

If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidate do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidate could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on GMP, FDA validated third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidate according to their own standards, our specifications, CGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidate. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidate. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and foreign agencies to ensure strict compliance with FDA-CGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by

our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidate could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Due to regulatory restrictions inherent in an IND, NDA or BLA, various steps in the manufacture of our product candidate may need to be sole-sourced. In accordance with CGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of our product candidate. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidate.

We do not currently have any internal drug discovery capabilities, and therefore we are dependent on in-licensing or acquiring development programs from third parties in order to obtain additional product candidates.

If in the future we decide to further expand our pipeline, we will be dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third-parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We have product liability insurance coverage for our proposed clinical trials; however, such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us now or in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If we materially breach or default under the Nerviano Licensing Agreement, Nerviano will have the right to terminate the agreement and we could lose critical license rights, which would materially harm our business.

Our business is substantially dependent upon certain intellectual property rights that we license from Nerviano. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under the Nerviano Agreement. The Nerviano Agreement provides the right to terminate for an uncured breach by us, or if we are insolvent or the subject of a bankruptcy proceeding, or potentially other reasons. We expect that other technology in-licenses that we may enter into in the future will contain similar provisions and impose similar obligations on us. If we fail to comply with any such obligations such licensor will likely terminate their out-licenses to us, in which case we would not be able to market products covered by these licenses, including our onvansertib asset. The loss of our license with Nerviano with respect to onvansertib, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business. In addition, our failure to comply with obligations under other material in-licenses we may enter into may cause us to become subject to litigation or other potential disputes under any such license agreements.

In addition, the Nerviano Agreement requires us to make certain payments, including license fees, milestone payments, royalties, and other such terms typically required under licensing agreements and these types of technology in-licenses generally could make it difficult for us to find corporate partners and less profitable for us to develop product candidates utilizing these existing product candidates and technologies.

We may delay or terminate the development of our product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

Even though the results of preclinical studies and clinical trials that have been conducted or may conduct in the future may support further development of our product candidate, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 32 employees as of December 31, 2023. Future growth of our company will impose significant additional responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of our product candidate. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical studies effectively;
- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

There is no guarantee that we will be able to accomplish these tasks, and our failure to accomplish any of them could materially adversely affect our business, prospects and financial condition.

Business disruptions could seriously harm future revenue and financial condition and increase our costs and expenses.

Our corporate headquarters are located in San Diego, California, an area prone to wildfires and earthquakes. These and other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

In addition, we rely on third-party manufacturers to manufacture API for our product candidate. Any disruption in production or inability of our manufacturers to produce or ship adequate quantities to meet our needs, whether as a result of a natural disaster or other causes (such as COVID-19 pandemic), could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidate. In addition, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies in countries our manufactures are located, political unrest or unstable economic conditions in these countries. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidate and impair our competitive position.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our partners' and third party providers proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development and other programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed. While we maintain insurance to cover operational risks, such as cyber risk and technology outages, our insurance may not be sufficient to cover all liability described herein. These risks will likely increase as we store and process more data.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed: notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the HHS. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

General economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. healthcare reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the U.S. and other countries have contributed to increased volatility and diminished expectations for the global economy. If the economic climate does not improve, or if it deteriorates, our business, including our access to patient samples and the addressable market for tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be negatively impacted, which could materially adversely affect our business, prospects and financial condition.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could materially adversely affect our business, prospects and financial condition. Moreover, in the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Healthcare reform measures could adversely affect our business.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, or ACA, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, was signed into law and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; expanded manufacturer Medicaid rebate liability to include utilization by beneficiaries enrolled in Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs; modified the AMP definition under the MDRP for drugs that are inhaled, infused, instilled, implanted or injected; increased the number of entities eligible for discounts under the 340B program; and included a discount on brand name drugs for Medicare Part D beneficiaries in the coverage gap, or "donut hole."

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, an executive order was issued to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's AMP, beginning January 1, 2024.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. There have been several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Catastrophic events, including global pandemics such as the COVID-19 pandemic, could materially adversely impact our business, results of operations and financial condition, including our clinical trials.

Our operations, and those of our Contract Research Organizations ("CROs"), Contract Manufacturing Organizations ("CMOs"), and other contractors, consultants and third parties could be subject to pandemics (including the COVID-19 pandemic), earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires,

extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could materially adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidate. Our ability to obtain clinical supplies of our product candidate could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

The occurrence of regional epidemics or a global pandemic, such as the COVID-19 pandemic, have had and may continue to have an adverse effect on how we and our CROs, CMOs, and other contractors, consultants and third parties are operating our businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID-19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses of our CROs, CMOs, and other contractors, consultants and third parties. To the extent that the pandemic harms our business and results of operations, many of the other risks described in this Part I, Item 1A of this report may be heightened.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, the failures of Silicon Valley Bank, Signature Bank and First Republic Bank in the first half of 2023 resulted in significant disruption in the financial services industry. If any of the banks which hold our cash deposits were to be placed into receivership, we may be unable to access our cash, cash equivalents and available-for-sale marketable securities, which would adversely affect our business. In addition, if any of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to fulfill their obligations to us could be adversely affected.

Geopolitical risks associated with Russia's invasion of Ukraine could result in increased market volatility and uncertainty, which could negatively impact our business, financial condition, and results of operations.

The uncertain nature, scope, magnitude, and duration of hostilities stemming from Russia's military invasion of Ukraine, including the potential effects of such hostilities as well as sanctions, embargoes, asset freezes, cyber-attacks and other actions taken in response to such hostilities on the world economy and markets, have disrupted global markets and contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic and other factors that affect our business and supply chain. There can be no certainty regarding the impacts stemming from the invasion, including the imposition of additional sanctions, embargoes, asset freezes or other economic or military measures resulting from the invasion. The impact of these developments, and additional events that may occur as a result, is currently unknown and could adversely affect our business, supply chain, suppliers and third party providers. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, the availability and cost of materials, supplies, labor, currency exchange rates and financial markets, all of which could negatively impact our business, financial condition and results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidate is being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Volatile and significantly weakened global economic conditions have in the past and may in the future adversely affect our industry, business, and results of operations.

Our overall performance depends in part on worldwide economic and geopolitical conditions. The United States and other key international economies have experienced significant economic and market downturns in the past, and are likely to experience additional cyclical downturns from time to time in which economic activity is impacted by falling demand for a variety of goods and services, restricted credit, poor liquidity, reduced corporate profitability, volatility in credit, equity, and foreign exchange markets, inflation, bankruptcies, and overall uncertainty with respect to the economy. These economic conditions can arise suddenly, as did the conditions associated with the COVID-19 pandemic, and the full impact of such conditions can be difficult to predict. In addition, geopolitical and domestic political developments, such as existing and potential trade wars and other events beyond our control, such as Russia's invasion of Ukraine, can increase levels of political and economic unpredictability globally and increase the volatility of global financial markets. All of these risks and conditions could materially adversely affect our future sales and operating results.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions, to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We may not be successful in defending challenges made in connection with our patents and patent applications. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and our employees are also required to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights. Any failure to protect our intellectual property rights could materially adversely affect our business, prospects and financial condition.

Our currently pending or future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated or held unenforceable. Furthermore, we cannot be certain that we were the first to make the invention claimed in our issued patents or pending patent applications in the U.S., or that we were the first to file for protection of the inventions claimed in our foreign issued patents or pending patent applications. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office ("USPTO"), which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that transitioned the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, we may become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine our entitlement to patents, and these proceedings may conclude that other patents or patent applications have priority over our patents or patent applications. It is also possible that a competitor may successfully challenge our patents through various proceedings and those challenges may result in the elimination or narrowing of our patents, and therefore reduce our patent protection. Accordingly, rights under any of our issued patents, patent applications or future patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes.

The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. Our patents may not protect us against our competitors, and patent litigation is very expensive. We may not have sufficient cash available to pursue any patent litigation to its conclusion because we currently do not generate revenues other than licensing, milestone and royalty income.

We cannot rely solely on our current patents to be successful. The standards that the USPTO and foreign patent offices use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same, are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have been issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries.

We cannot be certain of the level of protection, if any, that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. In addition, the type and extent of any patent claims that may be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using similar technology.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the attention of our technical and management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our potential products or processes. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, we cannot assure you that we would prevail in any of these suits or that the damages or other remedies that we are ordered to pay, if any, would not be substantial. Claims of intellectual property infringement may require us to enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. We may also be subject to injunctions against the further development and use of our technology, which could materially adversely affect our business, prospects and financial condition.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

Certain rights that we in-license from third-parties are not within our control, and we may be negatively impacted if we lose those rights.

We license some of the technology that is necessary for our products and services from third parties. In connection with such in-licenses, we may agree to pay the licensor royalties based on sales of our products, which become a cost of product revenues and impact the margins on our products and services. We may need to in-license other technologies in the future to commercialize on our products and services. We may also need to negotiate licenses after launching our products and services. Our business may suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid, or if we are unable to enter into necessary licenses on acceptable terms.

Risks Related to Ownership of Our Common Stock

Our ability to use our net operating loss carryforwards and certain other tax attributes is limited by Sections 382 and 383 of the Internal Revenue Code.

Net operating loss carryforwards allow companies to use past years' net operating losses to offset against future years' profits, if any, to reduce future tax liabilities. Sections 382 and 383 of the Internal Revenue Code of 1986 limit a corporation's ability to utilize its net operating loss carryforwards and certain other tax attributes (including research credits) to offset any future taxable income or tax if the corporation experiences a cumulative ownership change of more than 50% over any rolling three year period. State net operating loss carryforwards (and certain other tax attributes) may be similarly limited. An ownership change can therefore result in significantly greater tax liabilities than a corporation would incur in the absence of such a change and any increased liabilities could adversely affect the corporation's business, results of operations, financial condition and cash flow.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, President Trump signed into law the TCJA that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact to our projection of minimal cash taxes or to our net operating losses. Further, any eligibility we may have or may someday have for tax credits associated with the qualified clinical testing expenses arising out of the development of orphan drugs will be reduced to 25% as a result of the TCJA; thus, our net future taxable income may be affected. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse.

The rights of the holders of our common stock may be impaired by the potential issuance of preferred stock.

Our certificate of incorporation gives our board of directors the right to create one or more new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights that could adversely affect the voting power and equity interests of the holders of our common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be used to discourage, delay or prevent a change of control of our company, which could materially adversely affect the price of our common stock. Without the consent of the holders of the outstanding shares of our Series A Convertible Preferred Stock, we may not adversely alter or change the rights of the holders of the Series A Convertible Preferred Stock or increase the number of authorized shares of Series A Convertible Preferred Stock, create a class of stock that is senior to or on parity with the Series A Convertible Preferred Stock, amend our certificate of incorporation in breach of these provisions or agree to any of the foregoing.

Our common stock price may be volatile and could fluctuate widely in price, which could result in substantial losses for investors.

The market price of our common stock historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. For example, during the year ended December 31, 2023, the closing price of our common stock ranged from a low of $0.96 to a high of $2.18. These fluctuations may be due to various factors, many of which are beyond our control, including:

- technological innovations or new products and services introduced by us or our competitors;
- clinical trial results relating to our tests or those of our competitors;
- announcements or press releases relating to the industry or to our own business or prospects;
- coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
- regulation and oversight of our product candidates and services, including by the FDA, Centers for Medicare & Medicaid Services and comparable foreign agencies;
- healthcare legislation;
- intellectual property disputes;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;

- loss of any strategic relationship;
- industry developments;
- economic and other external factors;
- catastrophic weather and/or global disease outbreaks, such as the COVID-19 pandemic; and
- period-to-period fluctuations in our financial results.

In addition, market fluctuations, as well as general political and economic conditions, could materially adversely affect the market price of our securities. Because we are a development stage company with no revenue from operations to date, other than licensing, milestone and royalty income unrelated to onvansertib, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the foregoing.

We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid any cash dividends on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors that our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. In addition, the terms of the Series A Convertible Preferred Stock prohibit us from paying dividends to the holders of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid. Investors in our common stock should not rely on an investment in our company if they require dividend income.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Delaware law and our corporate charter and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control of our company or changes in our management. For example, our board of directors has the authority to issue up to 20,000,000 shares of preferred stock in one or more series and to fix the powers, preferences and rights of each series without stockholder approval. The ability to issue preferred stock could discourage unsolicited acquisition proposals or make it more difficult for a third party to gain control of our company, or otherwise could materially adversely affect the market price of our common stock.

Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware. This provision may prohibit or restrict large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us, which could discourage potential takeover attempts, reduce the price that investors may be willing to pay for shares of our common stock in the future and result in our market price being lower than it would without these provisions.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

If our stockholders sell, or the market perceives that our stockholders may sell for various reasons, including the ending of restriction on resale, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We may be subject to stockholder litigation, thereby diverting our resources, which could materially adversely affect our profitability and results of operations.

The market for our common stock is characterized by significant price volatility, and we expect that our share price will continue to be at least as volatile for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price for its securities. In addition, stockholders may bring actions against companies relating to past transactions or other matters. Any such actions could give rise to substantial damages and thereby materially adversely affect our financial position, liquidity or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could materially adversely affect our business, prospects and financial condition. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

If we fail to comply with the continued minimum closing bid requirements of the Nasdaq or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

If we do not maintain compliance with The Nasdaq Capital Market ("Nasdaq") requirements for continued listing or fail to comply with other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

General Risk Factors

If we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act, related to disclosure controls and procedures, or if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important in helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. We previously identified a material weakness in our internal control over financial reporting, which was subsequently remedied. We cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

We incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the Nasdaq. The SEC and other regulators have continued to adopt new rules

and regulations and make additional changes to existing regulations that require our compliance. For example, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") was enacted. There is significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We believe cybersecurity is critical to advancing our technological developments. As a biopharmaceutical company, we face a multitude of cybersecurity threats common to most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our business strategy, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Risk Management

We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. We have established cybersecurity security awareness training and ongoing monitoring.

In the event of an incident, we intend to follow our cybersecurity incident response plan, which outlines the steps to be followed from incident detection to mitigation, and notification. We contract with external firms that have extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks. As a biopharmaceutical company, we must comply with extensive regulations, including requirements imposed by the Federal Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach. We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a clinical site, subcontractor, or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to our IT Incident Response Coordinator who will investigate the direct impact of the incident. Once a potential incident has been confirmed, the Incident Response Coordinator will notify senior management that activation of the incident response plan is required and assign a severity rating, ranging from none to critical, based on the perceived impact.

Governance

The Audit Committee has oversight responsibility for risks and incidents relating to cybersecurity threats, including compliance with disclosure requirements, cooperation with law enforcement, and related effects on financial and other risks, and it reports any findings and recommendations, as appropriate, to the full Board for consideration. Senior management regularly discusses cyber risks and trends and, should they arise, any material incidents with the Audit Committee.

While we have not experienced any material cybersecurity threats or incidents in recent years, there can be no guarantee that we will not be the subject of future threats or incidents. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. While we maintain cybersecurity insurance, the costs related to cybersecurity threats or disruptions may not be fully insured. See "Risk Factors" for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES

We currently lease laboratory and office space for our headquarters in San Diego, California under a lease agreement, as amended from time to time, that expires in February 2027. We believe that our facilities are adequate for our current and near-term needs.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in matters may arise from time to time that may harm our business. As of the date of this report, management believes that there are no claims against us, which it believes will result in a material adverse effect on our business or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market information

Our common stock has traded on The Nasdaq Capital Market under the symbol "CRDF" since May 8, 2020, and was previously traded as "TROV" from May 30, 2012 to May 7, 2020.

Number of Stockholders

As of February 22, 2024, we had approximately 58 stockholders of record of our common stock.

Dividend Policy

Historically, we have not paid any dividends to the holders of shares of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business. Pursuant to the terms of our outstanding shares of Series A Convertible Preferred Stock, dividends cannot be paid to the holders of shares of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

ITEM 6. [Reserved]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Company Overview

We are a clinical-stage biotechnology company, headquartered in San Diego, CA, leveraging PLK1 inhibition, a well-validated oncology drug target, to develop novel therapies across a range of cancers with the greatest unmet medical need. Our goal is to target tumor vulnerabilities with treatment combinations of onvansertib, our oral and highly selective PLK1 inhibitor, and standard-of-care therapeutics. We are focusing our clinical program in indications such as RAS-mutated metastatic colorectal cancer ("mCRC"), as well as in investigator-initiated trials in metastatic pancreatic ductal adenocarcinoma ("mPDAC"), and small cell lung cancer ("SCLC"). Our clinical development programs incorporate tumor genomics and biomarker assays to refine assessment of patient response to treatment. Our common stock is listed on the Nasdaq Capital Market under the ticker symbol "CRDF".

Company Updates

On February 2, 2023 we announced the appointment of Fairooz Kabbinavar, M.D., FACP, as Chief Medical Officer.

Our accumulated deficit through December 31, 2023 is $339.5 million. To date, we have generated minimal revenues, unrelated to onvansertib, and expect to incur additional losses to perform further research and development activities.

Our drug development efforts are in their early stages, and we cannot make estimates of the costs or the time that our development efforts will take to complete, or the timing and amount of revenues related to the sale of our drug. The risk of completion of any program is high because of the many uncertainties involved in developing new drug candidates to market, including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses, and competing technologies being developed by organizations with significantly greater resources.

Critical Accounting Estimate

Our accounting policies are described in Part II, Item 8. Financial Statements—Note 2 *Basis of Presentation and Summary of Significant Accounting Policies* in this Annual Report on Form 10-K. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting estimates.

Accrued Clinical Trial Expenses

We accrue and expense research and development expenditures as incurred, which include costs related to clinical trial activities. We accrue costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the Clinical Research Organizations ("CROs"), professional service providers, and other vendors providing clinical trial services (collectively, the “service providers”). We accrue costs based on estimated work completed in accordance with agreements established with our service providers. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trial activities.

Results of Operations

Years Ended December 31, 2023 and 2022

Revenues

Our total revenues were $488,000 and $386,000 for the years ended December 31, 2023 and 2022, respectively. Revenues are from our sales-based or usage-based royalties on other intellectual property licenses, unrelated to onvansertib. Revenue recognition of the royalty depends on the timing and overall sales activities of the licensees.

Research and Development Expenses

Research and development expenses consisted of the following:

	For the years ended December 31,		
(in thousands)	**2023**	**2022**	**Increase/(Decrease)**
Salaries and staff costs	$ 5,930	$ 4,031	$ 1,899
Stock-based compensation	1,279	1,035	244
Clinical trials, outside services, and lab supplies	23,686	20,556	3,130
Facilities and Other	1,962	1,485	477
Total research and development expenses	$ 32,857	$ 27,107	$ 5,750

Research and development expenses increased by $5.8 million to $32.9 million for the year ended December 31, 2023 from $27.1 million for the year ended December 31, 2022. The overall increase in expenses was primarily due to costs associated with clinical programs and outside service costs related to the development of our lead drug candidate, onvansertib. Salaries and staff costs increased primarily from additional hires in senior management and our clinical operations team (research and development average headcount grew by 39% over the comparative period). The increase in facilities and other costs is primarily due to increased allocation of facilities cost resulting from headcount growth compared to the prior period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

(in thousands)	For the years ended December 31, 2023	2022	Increase/(Decrease)
Salaries and staff costs	$ 3,531	$ 3,134	$ 397
Stock-based compensation	3,230	3,221	9
Outside services and professional fees	4,133	4,192	(59)
Facilities and other	2,149	2,634	(485)
Total selling, general and administrative	$ 13,043	$ 13,181	$ (138)

Selling, general and administrative expenses decreased by $138,000 to $13.0 million for the year ended December 31, 2023, from $13.2 million for the year ended December 31, 2022. Salaries and staff costs increased due to an employee severance agreement. The decrease in facilities and other costs was primarily due to reduced insurance costs compared to the prior period.

Interest Income, Net

Interest income, net was $4.1 million for the year ended December 31, 2023 as compared to $1.6 million for the year ended December 31, 2022. The increase in interest income was primarily due to higher interest rates on our short-term investments portfolio for the year ended December 31, 2023 as compared to the same period of 2022.

Liquidity and Capital Resources

Net cash used in operating activities for the year ended December 31, 2023 was $30.9 million, compared to $33.8 million for the year ended December 31, 2022. Our use of cash was primarily a result of the net loss of $41.4 million for the year ended December 31, 2023, adjusted for non-cash items related to stock-based compensation of $4.5 million. The net change in our operating assets and liabilities was $6.6 million decreasing cash used in operations. Our use of cash was primarily a result of the net loss of $38.7 million for the year ended December 31, 2022, adjusted for non-cash items mainly related to stock-based compensation of $4.3 million, and amortization of premiums on short-term investments of $0.6 million. The net change in our operating assets and liabilities was $0.4 million increasing cash used in operations. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Net cash provided by investing activities was $36.2 million primarily related to sales and maturities in excess of purchases of marketable securities during the year ended December 31, 2023, compared to net cash used in investing activities of $38.1 million primarily related to sales and maturities in excess of purchases of marketable securities during the same period in 2022.

Net cash provided by financing activities was $0.0 million during the year ended December 31, 2023, compared to net cash provided by financing activities of $0.1 million for the same period in 2022.

As of December 31, 2023 and 2022, we had working capital of $67.0 million and $103.5 million, respectively.

We have incurred net losses since our inception and have negative operating cash flows. As of December 31, 2023, we had $74.8 million in cash, cash equivalents and short-term investments and we believe we have sufficient cash to meet our funding requirements for at least the next 12 months following the issuance date of these financial statements. Based on our current projections we expect that our capital resources are sufficient to fund our operations into the third quarter of 2025.

Our drug development efforts are in their early stages, and we cannot make estimates of the costs or the time that our development efforts will take to complete, or the timing and amount of revenues related to the sale of our drug candidates. The risk of completion of any program is high because of the many uncertainties involved in developing new drug candidates to market, including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses, and competing technologies being developed by organizations with significantly greater resources.

For the foreseeable future, we expect to continue to incur losses and require additional capital to further advance our clinical trial programs and support our other operations. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we can raise additional funds by issuing equity securities, our stockholders may experience additional dilution.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

All financial information required by this Item is attached hereto at the end of this report beginning on page F-1 and is hereby incorporated by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2023, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of Stockholders to be held in 2024 (the "2024 Proxy Statement"), under the heading "Election of Directors."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement under the heading "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement under the headings "Family Relationships and other Arrangements."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement under the heading "Proposal 2: Ratification of the Appointment of Our Independent Registered Public Accounting Firm for Fiscal Year Ending December 31, 2024."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description of Exhibit
	(a)(1) ***Financial Statements***
	The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report on Form 10-K.

(b) Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed on March 20, 2012).
3.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Form 10-12G filed on November 25, 2011).
3.4	Certificate of Amendment of Amended and Restated Certificate of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on June 1, 2018).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 12, 2018).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 29, 2019).
3.7	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 31, 2019).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on February 20, 2019).
3.9	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on May 6, 2020).
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 13, 2020).
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 16, 2020).
4.1	Form of Common Stock Certificate of Trovagene, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 10-12G filed on November 25, 2011).
4.2+	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on July 19, 2004)
4.3	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 1, 2014).
4.4+	Trovagene, Inc. 2014 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on July 23, 2014).
4.5	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on July 26, 2016).
4.6	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on June 12, 2018).
4.7	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (Incorporated by reference to Exhibit 4.16 to Form 10-K filed on February 27, 2020).
4.8+	Cardiff Oncology, Inc. 2021 Omnibus Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on April 28, 2021).
10.1	Summary of Terms of Lease Agreement dated as of October 28, 2009 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.3 to the Company's Form 10-12G/A filed on February 15, 2012).

10.2	Form of First Amendment to Standard Industrial Net Lease dated September 28, 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.4 to the Company's Form 10-12G/A filed on February 15, 2012).
10.3	Form of Second Amendment to Standard Industrial Net Lease dated October 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.5 to the Company's Form 10-12G/A filed on February 15, 2012).
10.4	Form of Third Amendment to Standard Industrial Net Lease dated October 22, 2012 between Trovagene, Inc. and BMR-Sorrento West, LP. (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.5	Form of Fourth Amendment to Standard Industrial Net Lease dated December 2, 2013 between Trovagene, Inc. and BMR-Coast 9 LP. (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.6	Form of Fifth Amendment to Standard Industrial Net Lease dated May 14, 2014 between Trovagene, Inc. and BMR-Coast 9 LP. (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.7	Sixth Amendment to Standard Industrial Net Lease dated June 11, 2015 between Trovagene, Inc. and BMR-Coast 9 LP (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015).
10.8+	Form of Indemnification Agreement to be entered into between the Company and its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 15, 2015).
10.9+	Amended and Restated Employment Agreement, dated February 22, 2021, by and between the Company and Mark Erlander (incorporated by reference to Exhibit 10.9 to Form 10-K filed on February 25, 2021).
10.10	Form of Seventh Amendment to Standard Industrial Net Lease dated April 4, 2016 between Trovagene, Inc. and BMR-Coast 9 LP (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 4, 2016).
10.11*	License Agreement dated as of March 13, 2017 between Nerviano Medical Sciences S.r.l. and Trovagene, Inc. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on March 15, 2017).
10.12	Stock and Warrant Subscription Agreement entered into as of May 8, 2020 by and between Cardiff Oncology, Inc. and POC Capital, LLC. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 13, 2020).
10.13	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.2 to Form 8-K filed on May 13, 2020).
10.14	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 19, 2020).
10.15	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 16, 2020).
10.16+	Employment Agreement, dated July 12, 2021 by and between James Levine and Cardiff Oncology, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 12,2021).
10.17	Securities Purchase Agreement, dated November 17, 2021 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on November 18, 2021).
10.18+	Employment Agreement, dated January 30, 2023 by and between Dr. Fairooz Kabbinavar and Cardiff Oncology, Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 2,2023).
10.19@	Development Agreement between Cardiff Oncology, Inc. and Pfizer, Inc. dated June 30, 2023 (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on August 9, 2023).
23.1	Consent of BDO USA, P.C.
24	Power of Attorney (included on signature page hereto).
31.1	Certification of Principal Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97	Cardiff Oncology, Inc. Clawback Policy.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema.

101.CAL	XBRL Taxonomy Extension Calculation Linkbase.
101.LAB	XBRL Taxonomy Extension Labels Linkbase.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase.
101.DEF	XBRL Taxonomy Extension Definition Linkbase.

+ Indicates a management contract or compensatory plan or arrangement.

* The SEC has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

@ Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CARDIFF ONCOLOGY, INC.

/s/ Mark Erlander

2/29/2024 Chief Executive Officer (Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Mark Erlander as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Mark Erlander Mark Erlander	Chief Executive Officer (Principal Executive Officer)	2/29/2024
/s/ James Levine James Levine	Chief Financial Officer (Principal Financial and Accounting Officer)	2/29/2024
/s/ Rodney S. Markin Rodney S. Markin	Chairman of the Board and Director	2/29/2024
/s/ James O. Armitage James O. Armitage	Director	2/29/2024
/s/ Mani Mohindru Mani Mohindru	Director	2/29/2024
/s/ Gary W. Pace Gary W. Pace	Director	2/29/2024
/s/ Renee Tannenbaum Renee Tannenbaum	Director	2/29/2024
/s/ Lâle White Lâle White	Director	2/29/2024

CARDIFF ONCOLOGY, INC.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Cardiff Oncology, Inc.
San Diego, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Cardiff Oncology, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee of the Company's board of directors and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued clinical trial expenses

As disclosed in Note 2 to the financial statements, the Company expenses research and development expenditures as incurred, which include costs relating to clinical trial activities. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the service providers. As of December 31, 2023, the Company's clinical trial accrual balance of $4.3 million is included in accrued liabilities. The Company's related 2023 clinical trial expenses are included in research and development expense.

We identified accrued clinical trial expenses as a critical audit matter due to the application of management judgment over the estimate of services provided. Specifically, evaluating the progress or stage of completion of the clinical trial activities under the Company's research and development agreements is sensitive to the availability of information from service providers. The Company considers several factors including the key terms of the clinical trial agreements, budgets, contract amendments, and

the progress of clinical trials toward completion (which includes consideration of patient enrollment). Auditing these elements involved especially challenging auditor judgment due to the nature of the audit evidence available to address these matters.

The primary procedures we performed to address the critical audit matter included:

- Testing management's estimation of accrued clinical trial expenses by; (i) obtaining and inspecting certain clinical trial agreements, budgets, and contract amendments, (ii) evaluating the Company's documentation of trial progress and status (including consideration of patient enrollment), (iii) confirming certain amounts invoiced, and amounts paid directly with service providers, and (iv) testing a sample of clinical trial expenses incurred.

- Testing the completeness of the Company's clinical trial accruals by; (i) inspecting board of directors' minutes to identify clinical trials, (ii) evaluating publicly available information (such as press releases, investor presentations and public databases that track clinical trials), (iii) inquiring of clinical staff outside of finance to gain an understanding of the status of certain on-going clinical trials, and (iv) testing a sample of payments subsequent to year end.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2007.

San Diego, California
February 29, 2024

Cardiff Oncology, Inc.
Balance Sheets
(in thousands, except par value)

	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
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000 shares authorized; Series A Convertible Preferred Stock liquidation preference $1,068 and $1,044 at December 31, 2023 and December 31, 2022, respectively; (Note 5)	—	—
Common stock, $0.0001 par value, 150,000 shares authorized; 44,677 shares issued and outstanding at December 31, 2023 and December 31, 2022	4	4
Additional paid-in capital	409,343	404,834
Accumulated other comprehensive loss	(67)	(395)
Accumulated deficit	(339,541)	(298,100)
Total stockholders' equity	69,739	106,343
Total Liabilities and Stockholders' Equity	$ 81,637	$ 116,191

The accompanying notes are an integral part of these financial statements.

Cardiff Oncology, Inc.
Statements of Operations
(in thousands, except 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)
Other income (expense), net:		
Interest income, net	4,069	1,581
Other expense, net	(98)	(383)
Total other income, net	3,971	1,198
Net loss	(41,441)	(38,704)
Preferred stock dividend payable on Series A Convertible Preferred Stock	(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

The accompanying notes are an integral part of these financial statements.

Cardiff Oncology, Inc.
Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2023	2022
Net loss	$ (41,441)	$ (38,704)
Other comprehensive loss:		
Unrealized gain (loss) on securities available-for-sale	328	(253)
Total comprehensive loss	$ (41,113)	$ (38,957)
Preferred stock dividend payable on Series A Convertible Preferred Stock	(24)	(24)
Comprehensive loss attributable to common stockholders	$ (41,137)	$ (38,981)

The accompanying notes are an integral part of these financial statements.

Cardiff Oncology, Inc.
Statements of Stockholders' Equity
(in thousands)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Service Receivable	Accumulated other comprehensive loss	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2021	716	$ 1	41,964	$ 4	$ 400,503	$ (139)	$ (142)	$ (259,810)	$ 140,417
Stock-based compensation	—	—	—	—	4,256	—	—	—	4,256
Issuance of common stock upon exercise of stock options	—	—	29	—	75	—	—	—	75
Issuance of common stock upon conversion of Series E Convertible Preferred Stock	(655)	(1)	2,684	—	—	—	—	—	(1)
Other comprehensive loss	—	—		—	—	—	(253)	—	(253)
Release of clinical trial funding commitment	—	—		—	—	139	—	—	139
Cumulative preferred stock dividend adjustment	—	—	—	—	—	—	—	414	414
Net loss	—	—		—	—	—	—	(38,704)	(38,704)
Balance, December 31, 2022	61	—	44,677	4	404,834	—	(395)	(298,100)	106,343
Stock-based compensation	—	—	—	—	4,509	—	—	—	$ 4,509
Other comprehensive gain	—	—	—	—	—	—	328	—	$ 328
Net loss	—	—	—	—	—	—	—	(41,441)	$ (41,441)
Balance, December 31, 2023	61	$ —	44,677	$ 4	$ 409,343	$ —	$ (67)	$ (339,541)	$ 69,739

The accompanying notes are an integral part of these financial statements.

Cardiff Oncology, Inc.
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 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:		
Other assets	108	(1,148)
Accounts receivable and unbilled receivable	483	(236)
Prepaid expenses and other current assets	3,169	(443)
Operating lease right-of-use assets	543	545
Accounts payable and accrued expenses	2,831	1,348
Operating lease liabilities	(566)	(404)
Other liabilities	—	(42)
Net cash used in operating activities	(30,887)	(33,820)
Investing activities		
Capital expenditures	(582)	(1,006)
Insurance proceeds from casualty loss	—	114
Maturities of short-term investments	86,552	76,445
Purchases of short-term investments	(70,084)	(91,233)
Sales of short-term investments	20,309	53,829
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
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$ 1	$ 2
Acquisition of property and equipment included in accounts payable and accrued liabilities	$ 16	$ 232
Supplemental disclosure of non-cash investing and financing activities:		
Cumulative preferred stock dividend adjustment	$ —	$ (414)

The accompanying notes are an integral part of these financial statements.

Cardiff Oncology, Inc.
Notes to Financial Statements

1. Business Overview and Liquidity

Business Organization and Overview

Cardiff Oncology, Inc. (“Cardiff Oncology” or the “Company”) headquartered in San Diego, California, is a clinical-stage biotechnology company leveraging Polo-like Kinase 1 (“PLK1”) inhibition to develop novel therapies across a range of cancers. The Company’s lead asset is onvansertib, a PLK1 inhibitor that is being evaluated in combination with standard of care therapies in clinical programs targeting indications such as RAS-mutated metastatic colorectal cancer (“mCRC”), as well as 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 standard of care alone. The Company's common stock is listed on the Nasdaq Capital Market under the ticker symbol "CRDF".

Liquidity

The Company has incurred net losses since its inception and has negative operating cash flows. As of December 31, 2023, the Company had $74.8 million in cash, cash equivalents and short-term investments and believes it has sufficient cash to meet its funding requirements for at least the next 12 months following the issuance date of these financial statements.

For the foreseeable future, the Company expects to continue to incur losses and require additional capital to further advance its clinical trial programs and support its other operations. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company’s stockholders may experience additional dilution.

2. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying financial statements of Cardiff Oncology have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker regarding resource allocation and assessing performance. The Company views its operations and manages its business, as one operating segment in the United States.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The most significant estimate involves accrued clinical trial expenses.

Accrued Clinical Trial Expenses

The Company expenses research and development expenditures as incurred, which include costs related to clinical trial activities. The Company accrues costs for clinical trial activities based upon estimates of the services received and related expenses incurred that have yet to be invoiced by the Clinical Research Organizations ("CROs"), investigators, professional service providers, and other vendors providing clinical trial services (collectively, the "service providers"). As of December 31, 2023 the Company's clinical trial accrual balance of $4.3 million is included in accrued liabilities. The Company's related 2023 clinical trial expenses are included in research and development expense.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist of cash in readily available checking and money market accounts.

Investment Securities

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Investments with contractual maturities beyond one year are also classified as short-term due to the Company's ability to liquidate the investment for use in operations within the next 12 months.

Realized gains and losses on investment securities are included in earnings and are derived using the specific identification method for determining the cost of securities sold. The Company has not realized any significant gains or losses on sales of available-for-sale investment securities during any of the periods presented. As all the Company's investment holdings are in the form of debt securities or certificates of deposit, unrealized gains and losses that are determined to be temporary in nature are reported as a component of accumulated other comprehensive loss. A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the establishment of a new cost basis for the security. Interest income is recognized when earned and is included in investment income, as are the amortization of purchase premiums and accretion of purchase discounts on investment securities.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments.

Cash and cash equivalents

The Company maintains deposit accounts at financial institutions that are in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash due to the financial position of the depository institution in which those deposits are held. The Company limits its exposure to credit loss by generally placing its cash in high credit quality financial institutions and investment in non FDIC insured money market funds denominated and payable in U.S. dollars.

Short-term investments

The Company follows an investment policy which requires short-term investments to be diversified across different types of instruments and issuers. The investment policy also requires investments to be in high quality instruments. The diversification and credit quality requirements of the Company's investment policy limits its exposure to credit loss.

Revenues

The Company recognizes revenue when control of its products and services are transferred to its customers in an amount that reflects the consideration it expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of goods or service to the customer, meaning the customer has the ability to use and obtain the benefit of goods or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control. For sales-based royalties, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Royalty and License Revenues

The Company licenses and sublicenses its patent rights to healthcare companies, medical laboratories and biotechnology partners. These patents are from the Company's legacy portfolio and unrelated to onvansertib. Agreements may involve multiple elements such as license fees, minimum royalties, usage-based royalties and milestone payments. Revenue is recognized when the criteria described above have been met as well as the following:

- Up-front nonrefundable license fees pursuant to agreements under which the Company has no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is probable.

- Minimum royalties are recognized as earned, and royalties are earned based on the licensee’s use. The Company estimates and records licensee’s sales based on historical usage rate and collectability.

- For sales-based royalties, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Payment terms and conditions vary by contracts, although terms generally include a requirement of payment within 30 to 45 days after invoice. Royalties are generally due quarterly or annually.

Derivative Financial Instruments—Warrants

The Company has issued common stock warrants in connection with the execution of certain equity financings. Such warrants are classified as derivative liabilities and are recorded at their fair market value as of each reporting period as they do not meet the criteria for equity classification. Changes in fair value of derivative liabilities are recorded in the statement of operations under the caption “Change in fair value of derivative instruments—warrants.”

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding the historical volatility of Cardiff Oncology’s common stock price, the remaining life of the warrants, and the risk-free interest rates at each period end. The Company thus uses model-derived valuations where inputs are observable in active markets to determine the

fair value. The use of the Black-Scholes model classifies such warrants as Level 3 (See "*Fair Value of Financial Instruments"* below). These warrants expired during the first quarter of 2023. At December 31, 2022, the fair value of these warrants was $0.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date based on the estimated fair value of the award and is recognized straight-line over the requisite service period of the individual grants, which typically equals the vesting period.

Fair Value of Financial Instruments

Financial instruments consist of cash equivalents, accounts receivable, and accounts payable. The Company applies ASC 820 for financial assets and liabilities that are required to be measured at fair value and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature as they reflect current market interest rates.

The authoritative guidance establishes a fair value hierarchy that is based on the extent and level of judgment used to estimate the fair value of assets and liabilities. In general, the authoritative guidance requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. An asset or liability's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the measurement of its fair value. The three levels of input defined by the authoritative guidance are as follows:

The Company measures certain assets and liabilities at fair value on a recurring basis using the three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers include:

- Level 1 — Quoted prices for identical instruments in active markets.
- Level 2 — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 — Instruments where significant value drivers are unobservable to third parties.

Long-Lived Assets

Long-lived assets consist of property, equipment and lease right-of-use assets. The Company records property and equipment at cost. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful life of the asset. Depreciation of leasehold improvements is computed based on the shorter of the life of the asset or the term of the lease. The estimated useful lives of the major classes of property and equipment are as follows:

	Estimated Useful Lives
Furniture and office equipment	3 to 5 years
Leasehold improvements	4 to 6 years
Laboratory equipment	5 years

Impairment losses on long-lived assets used in operations are recorded when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets carrying amount. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease Right-of-Use ("ROU") assets, current operating lease liabilities and non-current operating lease liabilities in the Company's balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at

commencement date based on the present value of lease payments over the lease term. None of the Company's operating leases provide an implicit rate, therefore the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow on a collateralized and fully amortizing basis over a similar term an amount equal to the lease payments in a similar economic environment. The operating lease ROU asset also includes any lease payments made less lease incentives received. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease term. Our facilities lease agreement contains lease and non-lease components, such as common area maintenance. We have elected to account for these lease and non-lease components of this agreement as a single lease component.

Leases with an initial term of 12 months or less are not recorded on the Company's balance sheets. These short-term leases are expensed on a straight-line basis over the lease term.

Income Taxes

Income taxes are determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial statement and tax bases of Cardiff Oncology's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, stockholder lawsuits, product and environmental liability, and tax matters. In accordance with FASB ASC Topic 450, *Contingencies*, the Company records such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. The Company, in accordance with this guidance, does not recognize gain contingencies until realized.

Research and Development

Research and development expenses include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, clinical trials, purchased in-process research and development and regulatory and scientific consulting fees, as well as contract research and insurance. Also, patent filing and patent maintenance expenses are considered legal in nature and therefore classified as general and administrative expense, if any.

Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense.

Upfront and milestone payments to acquire contractual rights to licensed technology are expensed when incurred if there is uncertainty in the Company receiving future economic benefit from the acquired contractual rights. Certain contractual rights may require the Company to make additional milestone payments based on development and commercial milestones, and royalties based on sales volume. See Note 10 - *Commitments and Contingencies*, for further details.

These potential development milestones include: (a) dosing of the first subject in the first Phase III Clinical Trial for the first Product, a registration enabling Phase II Clinical Trial, or after completion of a Phase II Clinical Trial that is used as the basis for an NDA submission; and (b) upon filing of the first NDA or equivalent for the first product candidate.

Net Loss Per Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. The accretion of Series A Convertible Preferred Stock dividends and deemed dividends recognized in connection with certain preferred share issuances are included in net loss attributable to common stockholders in the computation of basic and diluted earnings per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as inclusion of the potentially dilutive securities would be antidilutive. Shares used in calculating diluted net loss per common share exclude as anti-dilutive the following share equivalents:

	December 31,	
	2023	2022
Options to purchase Common Stock	6,650,954	5,069,458
Warrants to purchase Common Stock	2,807,948	4,360,968
Series A Convertible Preferred Stock	877	877
	9,459,779	9,431,303

Recently Adopted Accounting Pronouncement

In May 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2021-04 ("ASU 2021-04"), Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force). The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company has prospectively adopted this standard as of January 1, 2022 for periods presented after the adoption. The adoption of ASU 2021-04 did not have a material impact on the Company's financial statements.

Recent Accounting Pronouncement Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06"), Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted EPS computation. The amendments in this update are effective for the Company on January 1, 2024. The amendment is to be adopted through either a fully retrospective or modified retrospective method of transition. Early adoption is permitted. The Company will adopt this standard as of January 1, 2024 using the modified-retrospective method. The Company is currently evaluating the adoption of ASU 2020-06, but does not expect it to have a material impact on the Company's financial statements.

In December 2023, the FASB issued ASU No. 2023-09 ("ASU 2023-09"), "Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024 and for private businesses for annual periods beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statement disclosures.

3. Supplementary Balance Sheet Information

Short-term investments available-for-sale securities consist of the following:

	As of December 31, 2023			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Maturity less than 1 year:				
Certificate of deposit	$ 8,317	$ 16	$ —	$ 8,333
Corporate debt securities	10,948	8	(16)	10,940
Commercial paper	6,193	9	—	6,202
U.S. government agencies	835	—	(1)	834
Total maturity less than 1 year	26,293	33	(17)	26,309
Maturity 1 to 2 years:				
Corporate debt securities	8,437	6	(10)	8,433
U.S. treasury securities	18,505	—	(79)	18,426
Total maturity 1 to 2 years	26,942	6	(89)	26,859
Total short-term investments	$ 53,235	$ 39	$ (106)	$ 53,168

	As of December 31, 2022			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Maturity less than 1 year:				
Certificate of deposit	$ 16,101	$ 3	$ (81)	$ 16,023
Corporate debt securities	44,806	8	(275)	44,539
Commercial paper	13,203	4	(20)	13,187
U.S. government agencies	2,284	4	—	2,288
U.S. treasury securities	7,905	—	(18)	7,887
Total maturity less than 1 year	84,299	19	(394)	83,924
Maturity 1 to 2 years:				
Corporate debt securities	5,016	1	(21)	4,996
Total maturity 1 to 2 years	5,016	1	(21)	4,996
Total short-term investments	$ 89,315	$ 20	$ (415)	$ 88,920

For the year ended December 31, 2023 the net realized loss recorded within the Company's statement of operations from the sale of short-term investments was $0.1 million. The amount of gains and losses reclassified out of other comprehensive income for the period related to the sales of short-term investments was not material for the year ended December 31, 2023.

The Company periodically reviews the portfolio of debt securities to determine if any investment is impaired due to credit loss or other potential valuation concerns. For debt securities where the fair value of the investment is less than the amortized cost basis, the Company has assessed at the individual security level for various quantitative factors including, but not limited to, the nature of the investments, changes in credit ratings, interest rate fluctuations, industry analyst reports, and the severity of impairment. Unrealized losses in investments available for sale debt securities at December 31, 2023, were substantially due to increases in interest rates, not due to increased credit risks associated with specific securities. Accordingly, the Company has not recorded an allowance for credit losses. It is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity.

Investments available for sale that have been in a continuous unrealized loss position for greater than one-year consist of the following:

(in thousands)	As of December 31, 2023	
	Fair Market Value	Gross Unrealized Loss
Corporate debt securities	$ 397	$ (3)
Total short-term investments	$ 397	$ (3)

(in thousands)	As of December 31, 2022	
	Fair Market Value	Gross Unrealized Loss
Corporate debt securities	$ 17,084	$ (161)
U.S. treasury securities	3,666	(14)
Total short-term investments	$ 20,750	$ (175)

Accrued Interest from short-term investments

Accrued interest from short-term investments contained within prepaid expenses and other current assets as of December 31, 2023 and 2022 was $0.6 million and $0.5 million, respectively.

Property and Equipment

Fixed assets consist of furniture and office equipment, leasehold improvements and laboratory equipment. Depreciation expense for property and equipment for the years ended December 31, 2023 and 2022 was $0.4 million and $0.2 million, respectively. Property and equipment consisted of the following:

(in thousands)	As of December 31,	
	2023	2022
Furniture and office equipment	$ 1,067	$ 1,066
Leasehold improvements	2,568	2,560
Laboratory equipment	1,355	1,056
Property and equipment, gross	4,990	4,682
Less—accumulated depreciation	(3,752)	(3,413)
Property and equipment, net	$ 1,238	$ 1,269

Accrued Liabilities

Accrued liabilities consisted of the following:

(in thousands)	As of December 31,	
	2023	2022
Accrued compensation	$ 2,737	$ 1,849
Clinical trials	4,309	2,333
Research agreements and services	530	509
Other accrued liabilities	207	486
Total accrued liabilities	$ 7,783	$ 5,177

4. Leases

As a lessee, the Company's current lease includes its master facility lease which is considered an operating lease.

Master Facility Lease

The Company currently leases office and lab space in San Diego that expires on February 28, 2027. The lease currently requires monthly payments of approximately $63,000 per month with 3% annual escalation.

The components of lease expense were as follows:

(in thousands)	Twelve Months Ended December 31, 2023	Twelve Months Ended December 31, 2022
Operating lease cost	$ 714	$ 754
Net operating lease cost	$ 714	$ 754

Supplemental balance sheet information related to leases was as follows:

(in thousands)	As of December 31, 2023	As of December 31, 2022
Operating lease ROU assets	$ 1,708	$ 2,251
Current operating lease liabilities	$ 691	$ 675
Non-current operating lease liabilities	1,458	2,040
Total operating lease liabilities	$ 2,149	$ 2,715
Weighted-average remaining lease term–operating leases	3.2 years	4.2 years
Weighted-average discount rate–operating leases	7 %	7 %

Supplemental cash flow and other information related to leases was as follows:

(in thousands)	Twelve Months Ended December 31, 2023	Twelve Months Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Cash paid included in operating cash flows	$ 737	$ 612

Total remaining annual commitments under non-cancelable operating lease agreements as of December 31, 2023, are summarized are as follows:

(in thousands)

Year Ending December 31,	Operating Leases
2024	$ 691
2025	775
2026	796
2027	136
Thereafter	—
Total future minimum lease payments	$ 2,398
Less imputed interest	(249)
Total	$ 2,149

5. Stockholders' Equity

Warrants

A summary of warrant activity and changes in warrants outstanding, including both liability and equity classifications, is presented below:

	Number of Warrants	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term
Balance outstanding, December 31, 2021	4,490,159	$ 5.80	3.0 years
Expired	(129,191)	$ 21.60	
Balance outstanding, December 31, 2022	4,360,968	$ 5.33	2.1 years
Expired	(1,553,020)	$ 10.54	
Balance outstanding, December 31, 2023	2,807,948	$ 2.45	1.9 years

Series A Convertible Preferred Stock

The material terms of the Series A Convertible Preferred Stock consist of:

1) *Dividends.* Holders of the Company's Series A Convertible Preferred Stock are entitled to receive cumulative dividends at the rate per share of 4% per annum, payable quarterly on March 31, June 30, September 30 and December 31, beginning with September 30, 2005. Dividends are payable, at the Company's sole election, in cash or shares of common stock. As of December 31, 2023 and 2022, the Company had $462,000 and $438,000, respectively in cumulative unpaid preferred stock dividends, included in the liquidation preference of the Series A Convertible Preferred Stock, and $24,000 and $24,000 of cumulative dividends were added to the liquidation preference of the Series A Convertible Preferred Stock during the years ended December 31, 2023 and 2022, respectively.

2) *Voting Rights.* Shares of the Series A Convertible Preferred Stock have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of the shares of Series A Convertible Preferred Stock then outstanding, (a) adversely change the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend its certificate of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.

3) *Liquidation.* Upon any liquidation, dissolution or winding-up of the Company, the holders of the Series A Convertible Preferred Stock are entitled to receive an amount equal to the Stated Value per share, which is currently $10 per share plus any accrued and unpaid dividends.

4) *Conversion Rights.* Each share of Series A Convertible Preferred Stock is convertible at the option of the holder into that number of shares of common stock determined by dividing the Stated Value, currently $10 per share, by the conversion price, which at the time of issuance was $928.80 per share, and subsequently adjusted to $691.20 per share.

5) *Subsequent Equity Sales.* The conversion price is subject to adjustment for dilutive issuances for a period of 12 months beginning March 17, 2006 and the conversion price was adjusted to $691.20 per share.

6) *Automatic Conversion.* If the price of the Company's common stock equals $1,857.60 per share for 20 consecutive trading days, and an average of 116 shares of common stock per day are traded during the 20 trading days, the Company will have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, requesting the holders to convert any portion of the shares of Series A Convertible Preferred Stock into shares of common stock at the applicable conversion price. As of the date of these financial statements, such conditions have not been met.

The components of the liquidation preference for the Series A Convertible Preferred Stock were as follows:

(in thousands)	As of December 31, 2023	2022
Stated Value per share liquidation	$ 606	$ 606
Cumulative unpaid preferred stock dividends	462	438
Liquidation preference - Series A Convertible Preferred Stock	$ 1,068	$ 1,044

6. Stock-Based Compensation

2021 Equity Incentive Plan

In June 2021 the Company's stockholders approved the 2021 Omnibus Equity Incentive Plan ("2021 Plan"). The number of authorized shares in the 2021 plan is equal to the sum of (i) 3,150,000 shares, plus (ii) the number of shares of Common Stock reserved, but unissued under the 2014 Plan; and (iii) the number of shares of Common Stock underlying forfeited awards under the 2014 Plan. On June 9, 2022 the shareholders approved an increase of shares authorized in the 2021 Plan to 5,150,000. As of December 31, 2023, there were 2,013,871 shares available for issuance under the 2021 Plan.

2014 Equity Incentive Plan

Subsequent to the adoption of the 2021 Plan, no additional equity awards can be made under the terms of the 2014 Plan.

Inducement Grants

In July 2021, the Company began issuing equity awards to certain new employees as inducement grants outside of its 2021 Plan. As of December 31, 2023, an aggregate of 1,435,256 shares were issuable upon the exercise of inducement grant stock options approved by the Company.

Modification of Stock Options

In June 2023 the Company modified stock options for a departing employee. The modification resulted in an incremental stock-based compensation expense of $0.6 million during the year ended December 31, 2023.

In June 2022 one of the Company's directors did not seek another term on the Board of Directors. At the time of departure, the Compensation Committee passed a resolution to extend the expiration date of the vested stock options, and to immediately accelerate the vesting of the unvested options. The Company recorded incremental reduction to stock compensation expense of $0.1 million during the year ended December 31, 2022, related to the modifications.

Stock-based compensation has been recognized in operating results as follows:

(in thousands)	Years ended December 31,	
	2023	2022
Research and development expenses	$ 1,279	$ 1,035
Selling, general and administrative expenses	3,230	3,221
Total stock-based compensation	$ 4,509	$ 4,256

Stock Options

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following assumptions during the years indicated below:

	Years ended December 31,	
	2023	2022
Risk-free interest rate (range)	3.56% - 4.06%	1.62% - 3.75%
Dividend yield	0%	0%
Expected volatility (range)	105% - 110%	98% - 110%
Expected volatility (weighted-average)	109%	106%
Expected term (in years)	5.2 years	6.0 years

Risk-free interest rate — Based on the daily yield curve rates for U.S. Treasury obligations with maturities that correspond to the expected term of the Company’s stock options.

Dividend yield — Cardiff Oncology has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility — Based on the historical volatility of Cardiff Oncology's common stock.

Expected term — The expected term for options granted after January 1, 2023 is estimated based on the Company's historical employee data. Prior to January 1, 2023, the Company used the "simplified method" to estimate expected term.

Forfeitures — The Company estimates forfeitures based on its historical experience.

The weighted-average fair value per share of all options granted during the years ended December 31, 2023 and 2022, estimated as of the grant date using the Black-Scholes option valuation model, was $1.35 and $2.55 per share, respectively.

The unrecognized compensation cost related to non-vested stock options outstanding at December 31, 2023 was $6.6 million. The weighted-average remaining amortization period at December 31, 2023 for non-vested stock options was 2.1 years.

The total fair value of shares vested during the years ended December 31, 2023 and 2022 was $4.8 million and $4.7 million, respectively.

A summary of stock option activity and of changes in stock options outstanding is presented below:

	Number of Options	Weighted-Average Exercise Price Per Share	Intrinsic Value	Weighted-Average Remaining Contractual Life
Balance outstanding, December 31, 2022	5,069,458	$ 5.92	$ 19,322	7.4 years
Granted	2,138,624	$ 1.70		
Forfeited and expired	(557,128)	$ 9.43		
Balance Outstanding, December 31, 2023	6,650,954	$ 4.27	$ 23,926	7.9 years
Vested and exercisable, December 31, 2023	3,124,492	$ 5.66	$ 22,456	6.9 years
Vested and expected to vest, December 31, 2023	6,462,464	$ 4.33	$ 23,853	7.8 years

7. Derivative Financial Instruments — Warrants

Certain warrants issued in connection with the Company's equity financings are accounted for as derivative liabilities. Accordingly, the warrants are remeasured at each balance sheet date based on their estimated fair value using the Black-Scholes option pricing model. These warrants expired during the first quarter of 2023. Changes in fair value are recorded within Company's statements of operations.

The assumptions used to determine the fair value of the warrants using the Black-Scholes option pricing model were:

	As of December 31, 2022
Fair value of Cardiff Oncology common stock	$1.40
Expected warrant term	0.1 years
Risk-free interest rate	4.12 %
Expected volatility of Cardiff Oncology common stock	54 %
Dividend yield	0 %

Expected volatility is based on the historical volatility of Cardiff Oncology's common stock. The warrants have a transferability provision and based on guidance for instruments issued with such a provision, Cardiff Oncology used the remaining contractual term as the expected term of the warrants. The risk-free interest rate is based on the U.S. Treasury security rates consistent with the expected remaining term of the warrants at each balance sheet date.

The following table sets forth the components of changes in the Company's derivative financial instruments—warrants liability balance, valued using the Black-Scholes option pricing method, for the periods indicated.

(in thousands, except for number of warrants) Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2021	Balance of derivative financial instruments—warrants liability	64,496	$ 285
	Change in fair value of derivative financial instruments—warrants during the year recognized as a gain in the statement of operations	—	(285)
December 31, 2022	Balance of derivative financial instruments—warrants liability	64,496	—
	Expiration of Derivative Financial Instruments	(64,496)	—
	Change in fair value of derivative financial instruments—warrants during the year recognized as a loss in the statement of operations	—	—
December 31, 2023	Balance of derivative financial instruments—warrants liability	—	$ —

8. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2023 and 2022:

	Fair Value Measurements at December 31, 2023			
(in thousands)	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund	$ 21,606	$ —	$ —	$ 21,606
Total included in cash and cash equivalents	$ 21,606	$ —	$ —	$ 21,606
Available for sale investments:				
Certificate of deposit	$ —	$ 8,333	$ —	$ 8,333
Corporate debt securities	—	19,373	—	19,373
Commercial paper	—	6,202	—	6,202
U.S. government agencies	—	834		834
U.S. treasury securities	18,426	—	—	18,426
Total available for sale investments	$ 18,426	$ 34,742	$ —	$ 53,168
Total assets measured at fair value on a recurring basis	$ 40,032	$ 34,742	$ —	$ 74,774

	Fair Value Measurements at December 31, 2022			
(in thousands)	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund	$ 15,722	$ —	$ —	$ 15,722
Total included in cash and cash equivalents	$ 15,722	$ —	$ —	$ 15,722
Available for sale investments:				
Certificate of deposit	$ —	$ 16,023	$ —	$ 16,023
Corporate debt securities	—	49,535	—	49,535
Commercial paper	—	13,187	—	13,187
U.S. government agencies	—	2,288	—	2,288
U.S. treasury securities	7,887	—	—	7,887
Total available for sale investments	$ 7,887	$ 81,033	$ —	$ 88,920
Total assets measured at fair value on a recurring basis	$ 23,609	$ 81,033	$ —	$ 104,642

The Company's policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 3 during the years ended December 31, 2023 and 2022.

9. Income Taxes

At December 31, 2023, Cardiff Oncology had federal net operating loss carryforwards ("NOLs") of approximately $5.1 million which, if not used, will continue to expire through 2037, and federal net operating loss carryforwards of approximately $99.2 million, which do not expire. Cardiff Oncology also has California NOLs of approximately $22.2 million which, if not used, will begin to expire in 2029. Cardiff Oncology also has research and development tax credits available for federal and California purposes of approximately $1.6 million and $2.6 million, respectively. The federal research and development tax credits will begin to expire on January 31, 2025. The California research and development tax credits do not expire.

Pursuant to the Internal Revenue Code of 1986, as amended (the "Code") Sections 382 and 383, annual use of a company's NOL and research and development credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. If limited, the related tax asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. The Company has established a valuation allowance as the realization of such deferred tax assets has not met the more likely than not threshold requirement. Due to the existence of the valuation allowance, further changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

The provision for income taxes based on losses from continuing operations consists of the following at December 31:

	Years ended December 31,	
(in thousands)	**2023**	**2022**
Current:		
State	$ —	$ —
Total current provision	—	—
Deferred:		
Federal	(8,300)	19,054
State	(789)	4,902
Total deferred (benefit) expense	(9,089)	23,956
Valuation allowance	9,089	(23,956)
Total income tax provision	$ —	$ —

Significant components of the Company's taxes and the rates as of December 31 are shown below:

	Years ended December 31,			
(in thousands, except percentages)	**2023**		**2022**	
Tax computed at the federal statutory rate	$ (8,703)	21 %	$ (8,128)	21 %
State tax, net of federal tax benefit	(645)	2 %	(518)	1 %
Permanent items	(2)	— %	32,369	(84)%
Stock based compensation	902	(2)%	553	(1)%
Research and development credits	(515)	1 %	(319)	1 %
Other	(126)	— %	(1)	— %
Valuation allowance increase (decrease)	9,089	(22)%	(23,956)	62 %
Provision for income taxes	$ —	— %	$ —	— %

Significant components of the Company's deferred tax assets and liabilities from federal and state income taxes as of December 31 are shown below (in thousands):

(in thousands)	Years ended December 31, 2023	2022
Deferred tax assets:		
Tax loss carryforwards	$ 23,441	$ 20,289
Research and development credits and other tax credits	3,611	2,743
Stock-based compensation	1,407	1,317
Capitalized research and development	9,687	4,794
Other	1,400	1,431
Total deferred tax assets	39,546	30,574
Deferred tax liabilities:		
Operating lease right-of-use assets	(375)	(492)
Total deferred tax liabilities	(375)	(492)
Net deferred tax assets before valuation allowance	39,171	30,082
Valuation allowance	(39,171)	(30,082)
Net deferred tax asset	$ —	$ —

Since inception the Company has incurred continuing losses and expects to continue to incur losses for the foreseeable future. The Company has recorded a full valuation allowance against its net deferred tax assets as it is more likely than not they will not be realized.

Cardiff Oncology does not have any unrecognized tax benefits. Cardiff Oncology's practice is to recognize interest and/or penalties related to income tax matters in income tax expense, and none have been incurred to date. The Company does not anticipate a significant change in unrecognized tax benefits over the next 12 months. The Company is subject to taxation in the U.S. and California. Due to net operating losses all tax years since inception remain open to examination.

10. Commitments and Contingencies

Executive Agreements

Certain executive agreements provide for severance payments in case of terminations without cause or certain change of control scenarios.

Research and Development and Clinical Trial Agreements

In March 2017, the Company entered into a license agreement with Nerviano which granted the Company development and commercialization rights to NMS-1286937, which Cardiff Oncology refers to as onvansertib. Terms of the agreement also provide for the Company to pay development and commercial milestones, and royalties based on sales volume. These potential development milestones include: (a) dosing of the first subject in the first Phase III Clinical Trial for the first Product, a registration enabling Phase II Clinical Trial, or after completion of a Phase II Clinical Trial that is used as the basis for an NDA submission; and (b) upon filing of the first NDA or equivalent for the first product candidate. During the years ended December 31, 2023 and 2022, no milestone or royalty payments were made.

The Company is a party of various agreements under which it licenses technology on an exclusive basis in the field of oncology therapeutics. These agreements include License fees, Royalties and Milestone payments. The company also has a legacy license agreement in the field of oncology diagnostics under which royalty payments are due. These royalty payments are calculated as a percent of revenue. During the years ended December 31, 2023 and 2022 payments have not been material.

Litigation

Cardiff Oncology does not believe that it has legal liabilities that are probable or reasonably possible that require either accrual or disclosure. From time to time, the Company may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in matters may arise from time to time that may harm the Company's business. As of the date of this report, management believes that there are no claims against the Company, which it believes will result in a material adverse effect on the Company's business or financial condition.

11. Employee Benefit Plan

The Company has a defined contribution retirement plan under Section 401(k) of the Internal Revenue Service ("IRS") Code covering its employees. The plan allows employees to defer, up to the maximum allowed, a percentage of their income through contributions to the plan as allowed by IRS Code. The Company does not currently make matching contributions.