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, 2020

☐ **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	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	The NASDAQ Capital Market

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. ☐

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 $5.01 per share, which was the last sale price of the common stock as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was $103,720,151.

As of February 18, 2021, 37,052,129 shares of the registrant's common stock, $0.0001 par value per share, were issued and outstanding.

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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 are a clinical stage company and may never earn a profit**.**
- 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.
- 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.
- 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.
- 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.

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

- The outbreak of the novel coronavirus disease, COVID-19, could materially adversely impact our business, results of operations and financial condition, including our clinical trials.

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.

Risks Related to Ownership of Our Common Stock

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

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

PART I

ITEM 1. BUSINESS

We are a clinical-stage, biotechnology company, developing new treatment options for cancer patients in indications with the greatest medical need, including KRAS-mutated metastatic colorectal cancer ("mCRC"), pancreatic cancer, metastatic castrate-resistant prostate cancer ("mCRPC") and leukemias. By integrating biomarkers into our clinical development programs, we will be able to identify patients who are most likely to respond to treatment across a number of cancer types and associated indications.

Our drug candidate, onvansertib, is a first-in-class, third-generation, oral and highly selective Polo-like Kinase 1 ("PLK1") adenosine triphosphate ("ATP") competitive inhibitor. PLK1 is essential for precisely regulating the cell division and maintaining genome stability in mitosis (cell division), spindle assembly, and DNA damage response. Studies have shown that PLK1 is over-expressed in most cancers, which is associated with poor prognosis in patients. Data has shown that blocking the expression of PLK1 by kinase inhibitors can effectively inhibit proliferation and induce apoptosis (death) of tumor cells.

On March 15, 2017, we announced the licensing of onvansertib from Nerviano Medical Sciences S.r.l. ("Nerviano"), the largest company in Italy committed to innovation and research and development in oncology and a leader in protein kinase drug development (Polo-like Kinase Inhibitors).

We believe onvansertib is the only PLK1 selective ATP competitive inhibitor administered orally with apparent antitumor activity in different preclinical models currently in clinical development. PLK1 is the most well-characterized member of the family of serine/threonine protein kinases and strongly promotes the progression of cells through mitosis. PLK1 performs several important functions throughout the mitotic (M) phase of the cell cycle, including the regulation of centrosome maturation and spindle assembly, the removal of cohesins from chromosome arms, the inactivation of anaphase-promoting complex/cyclosome inhibitors, and the regulation of mitotic exit and cytokinesis. PLK1 is ubiquitously expressed in normal proliferating tissues and is over-expressed in a wide variety of human tumors (including lung, colon, prostate, ovary, breast, and head and neck squamous cell carcinoma). Onvansertib was developed to have high selectivity for PLK1, to be administered orally, and to have a relatively short drug half-life of approximately 24 hours compared to previous pan Polo-like inhibitors.

Onvansertib has been tested in-vivo in different xenograft and transgenic models at times suggesting tumor growth inhibition or tumor regression. Onvansertib has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an IC_{50} (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC_{50} values below 1 uM in 133 out of 148 cell lines.

A Phase 1 safety study was successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs*. We have four active Investigational New Drug ("IND") applications in place with the U.S. Food and Drug Administration ("FDA"), and three ongoing clinical studies. The first study is TROV-052 (ClinicalTrials.gov Identifier NCT03303339), a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care low-dose cytarabine ("LDAC") or decitabine for patients with relapsed or refractory AML. The second study is TROV-053 (ClinicalTrials.gov Identifier NCT03414034), a Phase 2 open-label clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, all administered orally, for patients with metastatic Castration-Resistant Prostate Cancer ("mCRPC"). The third study is TROV-054 (ClincalTrials.gov Identifier NCT03829410), a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI (folinic acid, fluorouracil and irinotecan) and Avastin® (bevacizumab) for patients with mCRC, who have a KRAS mutation. A new Phase 2 trial of onvansertib in combination with nanoliposomal irinotecan, leucovorin and fluorouracil for the second-line treatment of patients with metastatic pancreatic ductal adenocarcinoma (PDAC) is planned for initiation in the first half of 2021 (ClinicalTrials.gov Identifier NCT04752696)

Development of onvansertib, as part of a combination regimen with already approved drugs, has the potential to bring new treatment options to patients across a wide array of cancers. Onvansertib has been evaluated preclinically in combination with several different chemotherapies, including irinotecan, cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, and with targeted therapeutics such as abiraterone, histone deacetylase (HDAC) inhibitors, fms-like tyrosine kinase 3 (FLT3) inhibitors, and bortezomib. These therapies are used clinically for the treatment of many hematologic and solid cancers, including acute myeloid leukemia (AML), non-Hodgkin's lymphoma (NHL), metastatic CRC, metastatic castration resistant prostate cancer (mCRPC), adrenocortical carcinoma (ACC), triple negative breast cancer (TNBC), small cell lung cancer (SCLC), and ovarian cancer.

Our strategy includes integrating a predictive clinical biomarker approach into our onvansertib clinical development programs, which we believe may enable us to tailor treatment to specific sub-populations of patients who are most likely to respond and have a positive clinical impact.

Onvansertib Phase 1 Safety Study in Solid Tumors

A Phase 1 safety study of onvansertib was completed in patients with advanced metastatic solid tumor cancers and published in July 2017, in the peer-reviewed journal *Investigational New Drugs*. Dr. Glen Weiss, Medical Oncologist at Goodyear, AZ and affiliated with Cancer Treatment Centers of America at Western Regional Medical Center, was the principal investigator and first author of the publication, entitled *"Phase 1 Dose-Escalation Study of NMS-1286937, an Orally Available Polo-like Kinase 1 Inhibitor, in Patients with Advanced or Metastatic Solid Tumors"* This study evaluated first-cycle dose limiting toxicities and related maximum tolerated dose with data indicating a manageable safety profile for onvansertib (also known as PCM-075 and NMS-1286937) for the treatment of advanced or metastatic solid tumors, with transient adverse events that were likely related to the drug's mechanism of action. The authors believe that data from preclinical work, coupled with the results of the Phase 1 trial, suggest that onvansertib could become a new therapeutic option for the treatment of solid tumor and hematologic cancers.

In this trial, onvansertib was administered orally, once daily for five consecutive days, every three weeks, to evaluate first cycle dose-limiting toxicities and related maximum tolerated dose in adult subjects with advanced/metastatic solid tumors. The study was also intended to evaluate onvansertib's pharmacokinetic profile in plasma, its anti-tumor activity, and its ability to modulate intracellular targets in biopsied tissue. The study identified thrombocytopenia and neutropenia as the primary toxicities, which is consistent with the expected mechanism of action of onvansertib and results from preclinical studies. These hematologic toxicities were reversible, with recovery usually occurring within 3 weeks. No GI disorders, mucositis, or alopecia was observed, confirming that bone marrow cells are the most sensitive to onvansertib inhibition with the applied dosing schedule.

We are utilizing the existing IND applications to develop onvansertib in solid tumors as part of our clinical development expansion plans, with our initial focus in mCRC and mCRPC.

Onvansertib Phase 2 Study in metastatic Castration-Resistant Prostate Cancer

On December 14, 2017, we announced the submission of our Phase 2 protocol of onvansertib in combination with abiraterone acetate (Zytiga® - Johnson & Johnson) for the treatment of mCRPC, to the FDA and our active solid tumor IND. In this multi-center, open-label, Phase 2 trial, onvansertib in combination with the standard dose of Zytiga® and prednisone, all administered orally, will be evaluated for safety and efficacy. The primary efficacy endpoint is the proportion of patients achieving disease control after 12 weeks of study treatment, as defined by lack of Prostate Specific Antigen ("PSA") progression in patients who are showing signs of early progressive disease (rise in PSA but minimally symptomatic or asymptomatic) while currently receiving androgen deprivation therapy ("ADT"), abiraterone and prednisone.

This ongoing Phase 2 clinical study is being conducted at three Harvard Medical sites: Beth Israel Deaconess Medical Center, Dana Farber Cancer Institute and Massachusetts General Hospital, in Boston Massachusetts. Dr. David Einstein at the Genitourinary Oncology Program at Beth Israel Deaconess Medical Center and Harvard Medical School is the principal investigator for the Phase 2 mCRPC trial.

Onvansertib Phase 1b/2 Study in metastatic Colorectal Cancer

In December 2018, we submitted a new IND application and protocol for our Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for the second-line treatment of mCRC with a KRAS mutation. On January 16, 2019, we received notification from the FDA that the "study may proceed" and on January 29, 2019, we announced an agreement with PoC Capital, LLC to fund the clinical development program. In this open-label, Phase 1b/2 trial, onvansertib in combination with standard-of-care FOLFIRI and Avastin® is being evaluated for safety and efficacy. The trial will enroll up to 44 patients to assess the safety and preliminary efficacy of the combination regimen.

The Phase1b segment of this clinical study has been conducted at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona. Dr. Heinz-Josef Lenz, Associate Director for Clinical Research and Co-Leader of the Gastrointestinal Cancers Program at the USC Norris Comprehensive Cancer Center, is the principal investigator for the Phase 1b/2 mCRC trial. The Phase 2 segment is being conducted at USC Norris Comprehensive Cancer Center, the Mayo Clinic (Arizona, Minnesota and Florida), Kansas University Medical Center and CARTI Cancer Research.

Onvansertib Phase 1b/2 Study in Acute Myeloid Leukemia

In June 2017, we announced the submission of our IND application and our Phase 1b/2 protocol of onvansertib in combination with standard-of-care chemotherapy for the treatment of AML to the FDA. In July 2017, we received notification from the FDA that our Phase 1b/2 clinical trial of onvansertib in patients with AML "may proceed". On October 9, 2017, we announced that the FDA granted Orphan Drug Designation to onvansertib for the treatment of AML. We initiated our Phase 1b/2 AML trial in November 2017 and enrolled our first patient in February 2018. On August 29, 2018, we announced that the European Medicinal Agency granted Orphan Drug Designation to onvansertib for the treatment of AML in the European Union ("EU").

The Phase 1b/2 clinical study is an open-label trial to evaluate the safety and anti-leukemic activity of onvansertib in combination with standard-of-care chemotherapy in patients with AML. Phase 1b is a dose escalation trial to evaluate the safety, tolerability, dose and scheduling of onvansertib, and to determine a recommended clinical treatment dose for the Phase 2 continuation trial. Enrollment of Phase 2 was completed in 2020.

Pharmacokinetics of onvansertib and correlative biomarker activity have been assessed throughout the Phase 1b and Phase 2 segments of the trial. The Phase 2 continuation trial is open-label with administration of the recommended onvansertib clinical dose in combination with standard-of-care chemotherapy to further evaluate safety and assess efficacy.

In 2019, we completed the Phase 1b segment of this trial and enrollment in Phase 2 was completed in October 2020.
A total of eight sites are conducting this trial, which is being led by Hematologist Amer Zeidan, MBBS, MHS, Assistant Professor of Medicine at Yale School of Medicine, Hematology expert at Yale Cancer Center.

Optimizing Drug Development with Correlative Biomarker Analysis using Circulating Tumor DNA

We have significant experience and expertise with biomarkers and technology in cancer. In our ongoing clinical trial in KRAS-mutated mCRC, we are quantitatively assessing changes in the KRAS mutational burden with a simple blood test. Decreases in KRAS mutant allelic frequency (MAF) after the first cycle of treatment are highly predictive of subsequent radiographic response observed as tumor shrinkage.

Technological advancements in the molecular characterization of cancers have enabled researchers to identify an increasing number of key molecular drivers of cancer progression. These discoveries have led to multiple novel anticancer therapeutics and clinical benefit in selected patient populations. As a clinical-stage biotechnology company developing new treatment options for cancer patients in indications with the greatest medical need, our objective is to optimize drug development by using our biomarker strategy as part of our approach.

Our laboratory in San Diego, California, enables us to optimize drug development and patient care. In the clinical development of our 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 predicting patients' response by identifying certain patient populations that are more likely to respond to the drug therapy.

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

Onvansertib

We are a clinical-stage biotechnology company with our primary focus on the development of our drug candidate, onvansertib, a first-in-class, third generation, oral and highly selective PLK1 inhibitor to treat solid tumor cancers and hematologic malignancies.

There have been several drug candidates in this class of targeted oncology therapeutics to enter clinical trials; however, we believe onvansertib is the only oral candidate currently in clinical trials and is differentiated from other ATP competitive inhibitors in that:

- its inhibition of PLK1 is highly-selective and the half maximal inhibitory concentration (IC_{50}) for PLK2 and PLK3 is over 5,000-fold of that for PLK1;
- it has a relatively short half-life of approximately 24 hours;
- it is available in an oral gelcap formulation;
- it allows for flexible dosing and scheduling;
- it has demonstrated safety, tolerability and preliminary efficacy; and
- it is synergistic in combination with numerous chemotherapies and targeted therapeutics, which may enhance efficacy and duration of response.

The unacceptable toxicity of prior PLK inhibitors, such as volasertib from Boehringer Ingelheim, may be due to non-selective inhibition of PLK2 and PLK3 and a much longer half-life (approximately 135 hours) that could result in drug accumulation, which ultimately may have led to unsatisfactory clinical and safety outcomes.

In 2018, we initiated a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy in AML patients to evaluate the safety/tolerability, determine the maximum tolerated dose ("MTD"), and assess preliminary efficacy. This study is on file at ClinicalTrials.gov with the Identifier NCT03303339. We also initiated a Phase 2 open-label clinical trial in patients with mCRPC in combination with Zytiga®. The mCRPC Phase 2 trial is on file at ClinicalTrials.gov with the Identifier NCT03414034. In 2019 we initiated a Phase 1b/2 open-label clinical trial in mCRC in patients with a KRAS mutation in combination with FOLFIRI and Avastin® in the second-line treatment setting. This study is on file at ClinicalTrials.gov with the Identifier NCT03829410. As of December 2020 we have four active IND applications in place with the FDA, one with the hematologic division and three with the solid tumor division. This enables us to quickly initiate additional clinical trials of our drug candidate, onvansertib, in solid tumor cancers and hematologic malignancies.

Drug Development and Monitoring of Therapeutic Outcomes

Cell-free DNA diagnostic technology has significant potential as a simple, quick, noninvasive way of monitoring clinical responses to drugs in clinical development and evaluating patient-specific responses to already approved and marketed therapies. Specific target applications include, but are not limited to, optimizing drug development to identify patients most likely to respond to targeted therapeutics.

One of the largest costs associated with development of a new therapy is the phases and size of human clinical studies required to identify the cohort of responders, and the resulting statistical power required. By measuring specific genetic markers, it may be possible to pre-identify, and subsequently screen for, the most likely responders to the therapy, and to limit patient recruitment to this subset. This strategy could significantly reduce the cost to develop a drug and improve development timelines. We believe that there is significant research potential technology and expertise to be incorporated into ongoing and future clinical trial protocols, and ultimately into post-approval patient identification protocols.

Our Business Strategy

We are a clinical-stage, biotechnology company, developing new treatment options for cancer patients in indications with the greatest medical need, including KRAS-mutated mCRC, pancreatic cancer, mCRPC and leukemia. By integrating

biomarkers into our clinical development programs, we believe we will be able to identify patients who are most likely to respond to treatment. Specifically, we are developing onvansertib, a first-in-class, third generation PLK1 inhibitor that targets mitosis (cell division) to treat a variety of cancers and associated indications.

Research and Development

We have historically made substantial investments in research and development. Our research and development efforts are prioritized on the clinical development of our drug candidate, onvansertib, and our related biomarker assay development and pre-clinical research. Our research and development team is composed of researchers and scientists (PhD's), laboratory associate scientists, and experts in drug development and tumor genomics.

Research and development expenses for the years ended December 31, 2020 and 2019 were approximately $11.2 million and $11.2 million, respectively.

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, 2020, our owned and licensed intellectual property included 57 issued patents and 11 pending patent applications in the U.S. and abroad. 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 plan to protect our intellectual property position by, among other things, licensing or filing our own U.S. and foreign patent applications related to our proprietary technologies and products, and any inventions or improvements that are important to the development and implementation of our business. We also may seek patent protection, if available, with respect to biomarkers and diagnostic methods that may be used to determine optimal patient populations for use of our product candidates.

Our license agreement with Nerviano dated March 15, 2017 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 covers the rights to develop combination therapies and identified predictive clinical biomarkers across cancer types, expanding potential indications for onvansertib. Under the agreement, Cardiff Oncology has exclusive rights to develop, make, use, and sell combination therapies that include an anti-androgen or androgen antagonist and a PLK 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 previously 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 included eight 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 efficacy of PLK1 treatment based on biomarkers, and treating leukemia and lymphoma using combination therapies including a B-cell lymphoma 2 and a PLK1 inhibitor. Any patents issued in these families will expire between 2039 and 2041.

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 our employees or our consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Manufacturing and Distribution

We have a supply agreement with NerPharMa, S.r.l., a GMP and FDA validated pharmaceutical manufacturing company and a subsidiary of Nerviano, to manufacture drug product for onvansertib. The agreement covers the clinical and commercial supply of onvansertib, and includes both Active Pharmaceutical Ingredients (“API”) and Good Manufacturing Process (“GMP”) production of capsules.

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 biologic 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 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 pneumonia, 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 Current Good Manufacturing Process ("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

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. The Patient Protection and Affordable Care Act ("PPACA") was enacted in March 2010, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price ("AMP");
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. During President Trump's administration, he signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 ("TCJA") includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on a pharmaceutical manufacturer remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure on product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While no one can predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. No one can be sure whether future changes to the regulatory environment will be favorable or unfavorable to business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

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.

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. The FDA granted Orphan Drug Designation ("ODD") to onvansertib in the treatment of AML in October 2017. The European Commission granted ODD to onvansertib in the treatment of AML in Europe in August 2018.

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 and 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 and hematologic malignancies.

A Phase 1 trial in advanced metastatic solid tumor cancers has been completed and published in *Investigational New Drugs*. A Phase 1b/2 trial in AML was initiated in November 2017, with the first patient treated in February, 2018 and a total of eight sites participating. A Phase 2 trial in mCRPC was initiated in June, 2018 with the Harvard Medical Cancer Centers - Beth Israel Deaconess Medical Center, Dana Farber Cancer Institute and Massachusetts General Hospital - with the first patient treated in August, 2018. A Phase 1b/2 trial in mCRC was initiated in July, 2019 with USC Norris Comprehensive Cancer Center and The Mayo Clinic (Arizona) - with the first patient treated in August, 2019. At the end of 2020 and early 2021, five additional sites were added including The Mayo Clinics (Minnesota and Florida), CARTI Cancer Center, Kansas University Medical Center and Inova Schar Cancer Institute.

The most prominent PLK inhibitor tested in late-stage clinical development, thus far, is volasertib, developed by Boehringer Ingelheim. In a randomized Phase 2 trial of volasertib plus LDAC in 87 AML patients not eligible for induction therapy, patients received LDAC 20mg twice-daily subcutaneously on days 1-10 or LDAC plus volasertib 350 mg IV on days 1 + 15 every four weeks. The response rate (complete remission and complete remission with incomplete blood count recovery) was higher for LDAC + volasertib vs LDAC (31.0% vs 13.3%; p=0.052). Median event-free survival was significantly prolonged by LDAC + volasertib compared with LDAC (5.6 vs 2.3 months). The encouraging results led to the Phase 3 POLO-AML-2 study in early 2013, which enrolled 666 elderly patients (65 years or older) with newly diagnosed AML, who were not eligible for intensive induction therapy. However, in June, 2016, Boehringer Ingelheim reported that LDAC + volasertib did not meet the primary endpoint of objective response; although better than LDAC alone, the difference was not statistically significant. The data also showed an unfavorable overall survival trend for the experimental arm, with the safety profile of the LDAC + volasertib dosing regimen considered as the main reason for the trend. The fact that volasertib demonstrated survival benefits in the Phase 2 trial provided proof-of-concept for PLK inhibition as a mechanism of action for an AML therapy; however, its unacceptable safety profile may have resulted from the fact that volasertib's 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.

GSK461364, developed by GSK, appears to have less sensitivity to PLK2 and PLK3 than volasertib, although it is not as specific to PLK1 as onvansertib. GSK461364 was investigated in a Phase 1 study in patients with advanced solid tumor cancers. The best response was prolonged stable disease of more than 16 weeks that occurred in 15% of patients. However, GSK461364 had off target adverse events including grade 4 pulmonary emboli. Venous thrombotic emboli (VTE) and myelosuppression were the most common grade 3-4 drug-related events; and VTE occurred in 20% of patients, which demanded co-administration of anticoagulants. The trial was completed in 2009 and there are no further clinical updates for GSK461364 after the Phase 1 study.

Other PLK inhibitors that have been evaluated include rigosertib (Oncova) and CY140 (Cyclacel). Rigosertib, a non-targeted broad-spectrum multi-kinase inhibitor (RAF, PI3K, PLK), was evaluated for myelodysplastic syndrome ("MDS"), and failed to achieve the primary endpoint of overall survival in a Phase 3 trial (2020). CY140, an inhibitor of PLK1, PLK2 and PLK3, is currently in a phase 1 first-in-human study for advanced leukemias and MDS (2020).

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 18, 2021, we had a total of 12 employees, 11 of whom were full-time. 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 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, 2020, we have an accumulated total deficit of approximately $231.5 million. For the fiscal years ended December 31, 2020 and 2019, we had a net loss attributable to common stockholders of approximately $22.6 million and $16.7 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, 2020, our cash and cash equivalents balance was approximately $131.0 million and our working capital was approximately $127.2 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 a NDA or a 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 several currently approved prescription therapies for the treatment of AML. 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 a competitor markets the same drug for the treatment of AML, before us, we may not receive orphan drug marketing exclusivity.

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 NerPharMa, S.r.l., 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 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. Moreover, we currently do not have any agreements for the production of these materials. 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-mandated current good marketing practices or 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 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 our material in-licenses 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 13 employees as of December 31, 2020. 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 operations, and those of our third-party manufacturers, CROs and other contractors and consultants, could be subject to 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 seriously harm our operations 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 a third-party manufacturer, which is located in Italy, to manufacture API for our product candidate. Any disruption in production or inability of our manufacturer in Italy to produce or ship adequate quantities to meet our needs, whether as a result of a natural disaster or other causes (such as the recent outbreak of the coronavirus in Italy), 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 of the United States or Italian governments, political unrest or unstable economic conditions in Italy. 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 customers' and partners' 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. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

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 U.S. Department of Health and Human Services. 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.

In the United States and foreign jurisdictions, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. In 2010, the PPACA was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the “Physician Payments Sunshine Act”;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the AMP;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers’ Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. During President Trump's administration, he signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on our business remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA to our product candidates. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. It is not certain that we will receive 12 years of biologics marketing exclusivity for any of our products. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation

from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenues. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. We might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

The outbreak of the novel coronavirus disease, COVID-19, could materially adversely impact our business, results of operations and financial condition, including our clinical trials.

In January 2020, the World Health Organization declared the outbreak of COVID-19 as a "Public Health Emergency of International Concern," which continues to spread throughout the world and has adversely impacted global commercial activity and contributed to significant declines and volatility in financial markets. The COVID-19 outbreak and government responses are creating disruption in global supply chains and adversely impacting many industries. The outbreak could have a continued material adverse impact on economic and market conditions and trigger a period of global economic slowdown. We continue to monitor the impact of the COVID-19 outbreak closely. The extent to which the COVID-19 outbreak will impact our operations or financial results is uncertain.

The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material adverse effect on our business, financial condition and results of operations. As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling and retaining patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidate from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- interruption or delays to our sourced clinical activities; and

- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued guidance, which FDA subsequently updated, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all subjects affected by the COVID-19 pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial.

The COVID-19 pandemic continues to evolve rapidly, with the status of operations and government restrictions evolving weekly. The extent to which the outbreak impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain COVID-19 or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

In addition, our business could be materially adversely affected by other business disruptions to us or our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. 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 other global pandemics, 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.

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 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 year 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 "Tax Cuts and Jobs Act" ("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, 2020, the closing price of our common stock ranged from a low of $0.74 to a high of $24.71. 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;
- the establishment of partnerships with clinical reference laboratories;
- 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 recent 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, 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 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 The Nasdaq Capital Market 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 Stock Market LLC ("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 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 December 2021. We (as a sublessor) also sublease portions of our facility to third parties under three separate subleases. 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 18, 2021, 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. SELECTED FINANCIAL DATA

Not applicable.

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

Overview

We are a clinical stage biotechnology company, developing new treatment options for cancer patients in indications with the greatest medical need. Our goal is to overcome resistance, extend duration of response and increase overall survival. We are developing onvansertib, a first-in-class, third-generation Polo-like Kinase 1 ("PLK1") inhibitor, in combination with standard-of-care chemotherapy and targeted therapeutics. Our clinical development programs incorporate tumor genomics and biomarker technology to enable assessment of patient response to treatment.

We licensed onvansertib from Nerviano Medical Sciences ("NMS") pursuant to a license agreement with NMS dated March 13, 2017. This exclusive, world-wide license agreement includes 3 issued patents for onvansertib which cover composition of matter, salt forms of onvansertib and combination of onvansertib with other drugs.

Onvansertib is highly potent against the PLK1 enzyme (concentration for 50% inhibition [IC_{50}] = 2nM), whereas low or no activity was observed on a panel of 63 kinases (IC_{50}>500 nM), including the PLK members PLK2 and PLK3 (IC_{50}>10 μM). Onvansertib was developed to have ideal pharmacokinetics, including oral bioavailability and administration and a drug half-life of approximately 24 hours, allowing for flexible dosing and scheduling, and is well tolerated and safe with only mild to moderate side effects reported to-date. A Phase 1 safety study of onvansertib was successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs*.

PLK1, a serine/threonine kinase, is a master regulator of mitotic progression with various roles and localizations during the different mitotic phases. Upon PLK1 depletion in cancer cells by RNA interference ("RNAi"), inhibition of proliferation and decreased viability, resulting from cell cycle arrest with 4N DNA content followed by apoptosis, are observed. PLK1 depletion also results in an increase in the number of cells containing abnormal spindle formation and misaligned chromosomes. Expression of PLK1 is seen in all proliferating normal tissues, and PLK1 is overexpressed in a number of tumors (including breast, prostate, ovary, lung, gastric and colon cancers), as well as in hematologic cancers.

Onvansertib has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an IC_{50} (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC_{50} values below 1 uM in 133 out of 148 cell lines. Onvansertib also appears active in cells expressing multi-drug resistant (“MDR”) transporter proteins and we believe its apparent ability to overcome the MDR transporter resistance mechanism in cancer cells could prove useful in broader drug combination applications. Additionally, onvansertib has been tested in in-vivo xenograft and transgenic models of different cancer types with the demonstration of tumor growth inhibition or tumor regression.

Onvansertib has been evaluated preclinically in combination with several different chemotherapies, including irinotecan, cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, and with targeted therapeutics such as abiraterone, histone deacetylase ("HDAC") inhibitors, fms-like tyrosine kinase 3 ("FLT3") inhibitors, and bortezomib. These therapies are used clinically for the treatment of many hematologic and solid cancers, including acute myeloid leukemia ("AML"), non-Hodgkin’s lymphoma ("NHL"), metastatic CRC, metastatic castration resistant prostate cancer ("mCRPC"), adrenocortical carcinoma ("ACC"), triple negative breast cancer ("TNBC"), small cell lung cancer ("SCLC"), and ovarian cancer.

We believe the high-selectivity of onvansertib to PLK1, its 24-hour half-life and oral bioavailability, as well as its demonstrated safety and tolerability, with expected on-target, easy to manage and reversible side effects, may prove beneficial in addressing clinical therapeutic needs across a variety of cancers.

Clinical Program Updates

We currently have three active clinical trials:

- TROV-054 is a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI and bevacizumab ("Avastin®") for the second line treatment of patients with KRAS-mutated mCRC, which is being conducted at 6 clinical trial sites across the U.S. - USC Norris Comprehensive Cancer Center, The Mayo Clinic Cancer Centers (Arizona, Minnesota and Florida), Kansas University Medical Center ("KUMC") and CARTI Cancer Center;
- TROV-053 is a Phase 2 open-label clinical trial of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients with mCRPC, which is being conducted at Beth Israel Deaconess Medical Center ("BIDMC"), Dana-Farber Cancer Institute ("DFCI"), and Massachusetts General Hospital ("MGH");
- TROV-052 is a Phase 2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy, decitabine, in patients with relapsed or refractory AML, which is being conducted at nine sites across the U.S. The Phase 1b portion of the AML trial was completed in the fourth quarter of 2019 and enrollment in Phase 2 was completed in October 2020.

KRAS-mutated mCRC

TROV-054 is a Phase 1b/2 study of onvansertib for the second-line treatment of patients with KRAS-mutated metastatic colorectal cancer ("mCRC") in combination with standard-of-care FOLFIRI and bevacizumab (Avastin®).

The primary objective of this study is to evaluate the dose-limiting toxicities ("DLTs") and maximum tolerated dose ("MTD") or 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 (Phase 2).

The rationale for this clinical trial is based on three key principles including synthetic lethality, synergy and proof-of-concept clinical benefit. Synthetic lethality arises when a combination of deficiencies in the expression of two genes leads to cell death, whereas a deficiency in only one of these genes does not. The deficiencies can arise through mutations, epigenetic alterations or inhibitors of the protein encoded by one of the genes. In reference to onvansertib, CRC tumor cells harboring KRAS mutations are more vulnerable to cell death with PLK1 inhibition versus KRAS wild-type isogenic cells. Synergy occurs when the combination of two drugs results in an unexpected greater activity than an expected additive effect of the two drugs. Onvansertib in combination with irinotecan and 5-FU (components of FOLFIRI) demonstrate synergy in colorectal cancer cell lines and the combination has demonstrated significantly greater tumor growth inhibition than either drug alone. Proof-of-concept clinical response has been demonstrated in a previously completed Phase 1 trial in solid tumors in which 3 of 5 patients showing stable disease had a KRAS mutation; 2 in colorectal cancer and 1 in pancreatic cancer.

Data presented on January 15, 2021, at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (“ASCO-GI”), demonstrated the safety and efficacy of onvansertib. Of the 12 patients evaluable for efficacy, 5

(42%) achieved a partial response (PR); 4 patients had a confirmed PR; 1 patient went on to curative surgery; 1 patient with a non-confirmed PR went off study due to an unrelated event prior to their 16-week confirmatory scan. 8 (67%) patients showed a durable response to treatment of >6 months with a range from 6.1 to 13.7 months. Time to achieving a PR ranges from 2 to 6 months in patients on treatment. 10 of 12 patients had a KRAS variant detected by ddPCR at baseline (all had a KRAS mutation detected by NGS). Clinical responses were observed across different KRAS variants, including the 3 most common in CRC. The greatest decreases in KRAS mutant allelic frequency (MAF) after 1 cycle of treatment were observed in patients achieving a PR (ranging from -78% to -100%), while the 2 patients who progressed showed a more modest reduction in KRAS MAF (-55% and -26%). Patients with PR and stable disease (SD) tended to have lower on-treatment KRAS MAF than patients with early progressive disease (PD). Onvansertib in combination with FOLFIRI/bevacizumab is safe and well tolerated with only 9% of all adverse events (AEs) being grade 3 or 4. Grade 4 adverse events were attributed to the 5-FU bolus component of the combination regimen, which was eliminated in subsequent cycles of treatment per protocol and institutional guidelines. The only G3/G4 AEs reported in ≥2 patients were neutropenia (n=8), which were managed by dose delay, growth factor therapy and/or discontinuation of the 5-FU bolus; no patients went off trial due to neutropenia. No major or unexpected toxicities were attributed to onvansertib.

Key News Releases

On January 15, 2021, we announced an electronic poster presentation of clinical data further demonstrating the clinical benefit of onvansertib in KRAS-mutate mCRC and initial findings from our Expanded Access Program (EAP) in mCRC.

On September 17, 2020, we announced an electronic poster presentation of clinical data further demonstrating the safety, efficacy and durability of response of onvansertib in KRAS-mutated mCRC patients at the European Society of Medical Oncology ("ESMO") Virtual Congress 2020.

On June 9, 2020, we announced the initiation of our Expanded Access Program ("EAP") for onvansertib, in combination with standard-of-care FOLFIRI and bevacizumab, for second-line treatment of patients with KRAS-mutated mCRC. This announcement followed the FDA granting Fast Track Designation for onvansertib in KRAS-mutated mCRC.

mCRPC

TROV-053 is a Phase 2 study of onvansertib in combination with Zytiga® (abiraterone) and prednisone for the treatment of patients with metastatic castration resistant prostate cancer ("mCRPC").

The primary objective of this study is to observe the effects of onvansertib in combination with abiraterone and prednisone on disease control as assessed by prostate specific antigen ("PSA") decline or stabilization after 12 weeks of study treatment in patients with mCRPC showing early signs of resistance to abiraterone.

The rationale for this trial is based on the mechanism of action ("MOA") of onvansertib and Zytiga® and the synergy of these two drugs when used in combination. Onvansertib inhibits tumor cell division (mitosis) by inducing G2/M arrest of tumor cells and the combination of onvansertib and Zytiga® significantly increases mitotic arrest and is synergistic when used in combination. Additionally, PLK1 inhibition appears to enhance the efficacy of androgen signaling blockade in castration-resistant prostate cancer.

Data presented on February 11, 2021, at the American Society of Clinical Oncology Genitourinary Cancers Symposium (“ASCO-GU”) demonstrated safety and efficacy of onvansertib in combination with abiraterone. Arms A (n=17) and B (n=12) showed similar efficacy with 29% and 25% of patients achieving the primary endpoint and 53% and 42% of patients with SD at 12 weeks, respectively. The more continuous dosing schedule of Arm C (n=8) has shown a higher response rate with 63% of patients, to-date, achieving the primary endpoint and 75% with SD at 12 weeks. Efficacy was observed in patients harboring AR alterations across all 3 arms. ctDNA analysis revealed differences in baseline genomic profiles of patients achieving SD at 12 weeks vs patients progressing before or at 12 weeks. Mutations exclusively present in patients with SD were associated with cell cycle and DNA repair pathways that may result in increased sensitivity to onvansertib and efficacy of the combination. Onvansertib + abiraterone has demonstrated safety across all 3 dosing schedules.

Key News Releases

On February 11, 2021, we announced an electronic poster presentation of clinical data further demonstrating the safety, efficacy and durability of response in patient with mCRPC at the American Society of Clinical Oncology Genitourinary Cancers Symposium (“ASCO-GU”).

AML

TROV-052 is a Phase 2 Study of onvansertib in combination with standard-of-care chemotherapy, decitabine, for the treatment of patients with relapsed or refractory acute myeloid leukemia ("AML"). The Phase 1b portion of this trial was completed in the fourth quarter of 2019.

The objective of this trial is to evaluate the DLTs and MTD or RP2D of onvansertib (Phase 1b – completed in October 2019). In Phase 2, the objective is to assess the safety, tolerability and preliminary efficacy of the combination of onvansertib at the RP2D and decitabine in patients with relapsed or refractory AML (Phase 2 enrollment completed in October 2020). Additionally, as a correlative objective, this trial is evaluating potential pharmacodynamic ("PD") and diagnostic biomarkers of onvansertib in patients with AML. We were granted Orphan Drug Designation ("ODD") for onvansertib for the treatment of AML from the FDA and the European Commission.

Data presented on December 6, 2020 at the 62nd American Society of Hematology ("ASH") conference, demonstrated the safety, tolerability and anti-leukemic activity of onvansertib in combination with decitabine in patients with difficult-to-treat relapsed/refractory AML. Nine of 45 (20%) patients achieved a complete remission with or without hematologic count recovery (CR/CRi – 5 in Phase 1b and 4 in Phase 2); 55% of responders had a mutation in a splicing factor. Two patients proceeded to transplant following CR and four patients remain on treatment with duration of response of 9, 10, 17 and 20 months, respectively. Together with data demonstrating the safety and tolerability of the combination therapy, these findings highlight onvansertib's potential to address critical unmet needs in hematologic malignancies.

Key News Releases

On December 6, 2020, we announced an electronic poster presentation of data from the Phase 1b/2 trial in AML demonstrating the safety and efficacy of onvansertib in relapsed or refractory patients at the annual American Society of Hematology ("ASH") conference.

Financial and Company Updates

Financial

On September 29, 2020 we announced pricing of an underwritten public offering of 6,500,000 shares of our common stock at a price of $13.50 per share. The underwriters had an option to purchase an additional 975,000 shares, which was exercised in full. The offering was completed on October 2, 2020 and the gross proceeds were $100.9 million.

Company

On December 21, 2020 we announced that Dr. Thomas Adams has stepped down from his positions as Executive Chairman and Chairman of the Board of Directors and will continue to serve as a Director. Dr. Rodney Markin was appointed by the Board of Directors as our new Chairman of the Board.

On May 8, 2020 we changed our company name from Trovagene, Inc. to Cardiff Oncology, Inc., and our Nasdaq ticker symbol to 'CRDF.' The web address for the Cardiff Oncology website is www.cardiffoncology.com.

On May 8, 2020 Mark Erlander, PhD, assumed the role of Chief Executive Officer and Thomas Adams, PhD, transitioned from Chief Executive Officer and Chairman to Executive Chairman.

On April 22, 2020, we announced the election of three new independent Directors to our Board of Directors; Dr. James Armitage, Dr. Gary Pace and Ms. Lâle White. Each new Director brings extensive and relevant experience to our company.

Our accumulated deficit through December 31, 2020 is $231,495,279. To date, we have generated minimal revenues 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 drugs. 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 Policies

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 policies.

Accrued Clinical Trial Expenses

We 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), investigators, professional service providers, and other vendors providing clinical trial services (collectively, the “service providers”). As of December 31, 2020 our clinical trial accrual balance of $1,683,195 is included in accrued liabilities and other liabilities. Our related 2020 clinical trial expenses are included in research and development expense of $11,235,396. Certain accrued clinical trial expenses are released from service receivables classified within equity as clinical trial services are performed.

Derivative Financial Instruments—Warrants

We have 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. Such warrants do not meet the exemption that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders’ equity. The warrants contain a feature that could require the transfer of cash in the event a change of control occurs without an authorization of our Board of Directors, and therefore classified as a liability. Changes in fair value of derivative liabilities are recorded in the statement of operations under the caption “gain (loss) from changes in fair value of derivative financial 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. Accordingly, the fair value of the warrants is sensitive to changes in these estimates. At December 31, 2020 and 2019, the fair value of such warrants was $284,971 and $4,127, respectively, and was recorded as a liability under the caption “derivative financial instruments—warrants” on the balance sheet.

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. We estimate the grant date fair value using a Black-Scholes model. Stock-based compensation recorded in our statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. We recognize the value of the awards on a straight-line basis over the awards’ requisite service periods. The requisite service period is generally the time over which our stock-based awards vest. Compensation expense for RSU's is measured at the grant date and recognized ratably over the vesting period in the statement of operations. The fair value of RSU's is determined based on the closing market price of our common stock on the grant date.

Off-Balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

See Item 8. Financial Statements—Note 2 *Basis of Presentation and Summary of Significant Accounting Policies* in this Annual Report on Form 10-K for a discussion of recent accounting pronouncements.

Results of Operations

Years Ended December 31, 2020 and 2019

Revenues

Our total revenues were $365,993 and $244,632 for the years ended December 31, 2020 and 2019, respectively. Total revenues consisted of the following:

	For the years ended December 31,		
	2020	2019	Increase/(Decrease)
Royalty income	$ 365,993	$ 243,137	$ 122,856
Service revenue	—	1,495	(1,495)
Total revenues	$ 365,993	$ 244,632	$ 121,361

The increase in revenues for the year ended December 31, 2020 as compared to the prior period is primarily from fluctuations of 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,		
	2020	2019	Increase/(Decrease)
Salaries and staff costs	$ 1,723,601	$ 1,585,381	$ 138,220
Stock-based compensation	354,692	399,687	(44,995)
Clinical trials, outside services, and lab supplies	8,388,482	8,250,313	138,169
Facilities and Other	768,621	926,855	(158,234)
Total research and development expenses	$ 11,235,396	$ 11,162,236	$ 73,160

Research and development expenses increased by $73,160 to $11,235,396 for the year ended December 31, 2020 from $11,162,236 for the year ended December 31, 2019. The increase in salaries and staff costs is primarily due to promotions, merit increases and increased headcount. The increase in costs associated with clinical programs and outside service costs is primarily related to assay development and recruiting fees. Facilities and other decreased primarily due to decreased travel and conference expenses to present data related to our drug candidate, onvansertib. Due to COVID-19 presentation of data has transitioned to virtual conferences.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted of the following:

	For the years ended December 31,		
	2020	2019	Increase/(Decrease)
Salaries and staff costs	$ 2,430,671	$ 1,955,305	$ 475,366
Stock-based compensation	1,410,112	485,256	924,856
Outside services and professional fees	2,639,403	1,986,039	653,364
Facilities and other	1,736,285	1,334,290	401,995
Total selling, general and administrative	$ 8,216,471	$ 5,760,890	$ 2,455,581

Selling, general and administrative expenses increased by $2,455,581 to $8,216,471 for the year ended December 31, 2020, from $5,760,890 for the year ended December 31, 2019. The increase of stock-based compensation expense and salaries and staff costs is primarily related to the Separation Agreement with Thomas Adams which includes accelerated vesting of

stock options of approximately $583,000 and a one-time severance payment of $300,000. The increase in outside services and professional fees is primarily related to legal and patent fees to analyze our competitive landscape and evergreen patent strategy. The increase in facilities and other cost was due to a decrease in sublease income, an increase in Delaware franchise tax and an increase in insurance costs.

Interest Income

Interest income was $89,809 and $234,169 for the years ended December 31, 2020 and 2019, respectively. The decrease of interest income is due to significantly lower average interest rates during 2020 as compared to 2019.

Change in Fair Value of Derivative Financial Instruments—Warrants

We have issued warrants to purchase shares of our common stock that are accounted for as derivative liabilities. As of December 31, 2020, the derivative financial instruments—warrants liabilities related to securities issued were revalued to $284,971, resulting in a increase in fair value of $280,844 from December 31, 2019 based primarily upon the change in our stock price from $1.24 at December 31, 2019 to $17.99 at December 31, 2020, and the changes in the expected term, volatility and risk-free interest rates for the expected term. The increase in value was recorded as non-operating loss for the year ended December 31, 2020.

Net Loss

Net loss and per share amounts were as follows:

	For the years ended December 31,		
	2020	2019	Increase/(Decrease)
Net loss	$ (19,306,672)	$ (16,414,159)	$ 2,892,513
Preferred stock dividend	(24,240)	(24,240)	—
Deemed dividend on preferred stock	(3,266,484)	(268,269)	2,998,215
Net loss attributable to common stockholders	$ (22,597,396)	$ (16,706,668)	$ 5,890,728
Net loss per common share — basic and diluted	$ (1.08)	$ (2.80)	$ (1.72)
Weighted-average shares outstanding — basic and diluted	20,874,665	5,973,906	14,900,759

The increase of $5,890,728 net loss attributable to common stockholders is primarily related to an increase of deemed dividends on preferred stock of $2,998,215, related to the beneficial conversion upon issuance of preferred stock and an increase of net loss of $2,892,513. The increase of 14,900,759 basic and diluted weighted-average shares outstanding primarily resulting from the sales of common stock through public and direct offerings and the issuance of common stock upon exercise of warrants. The $1.72 decrease in basic and diluted net loss per share was impacted by the increase in net loss attributable to shareholders and the increase in basic and weighted average shares outstanding.

Liquidity and Capital Resources

The COVID-19 outbreak in the United States has caused business disruptions. The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, and impact on our clinical trials, employees and vendors, all of which are uncertain and cannot be predicted. The economic effects of the outbreak could also have an adverse effect on our ability to raise additional capital. At this point, the extent to which COVID-19 may impact our future financial condition or results of operations is uncertain. There has not been a material impact on the Company's financial statements for the twelve months ended December 31, 2020.

As of December 31, 2020, we had $130,980,681 in cash and cash equivalents. Net cash used in operating activities for the year ended December 31, 2020 was $16,314,962, compared to $13,267,500 for the year ended December 31, 2019. Our use of cash was primarily a result of the net loss of $19,306,672 for the year ended December 31, 2020, adjusted for items mainly related to stock-based compensation of $1,764,804, release of clinical trial funding commitment of $1,100,415, and depreciation of $466,009. The net change in our operating assets and liabilities was $654,531 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 used by investing activities was $211,880 and $67,622 for the years ended December 31, 2020 and 2019, respectively. Investing activities during the year ended December 31, 2020 and 2019 consisted of the purchase of capital equipment.

Net cash provided by financing activities was $137,312,231 during the year ended December 31, 2020, compared to $12,077,281 provided in financing activities during the year ended December 31, 2019. Financing activities during the year ended December 31, 2020 and 2019 related primarily to sales of Common Stock, Preferred Stock, Warrants and proceeds from exercise of warrants.

As of December 31, 2020 and 2019, we had working capital of $127,237,483 and $6,571,985, respectively. The increase in working capital is primarily due to the increase in cash and cash equivalents from financing activities during the year ended December 31, 2020.

We have incurred net losses since our inception and have negative operating cash flows. As of December 31, 2020, we had $130,980,681 in cash and cash equivalents 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.

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. The economic effects of COVID-19 could also have an adverse effect on our ability to raise additional capital.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs. To date, our sources of cash have been primarily limited to the sale of equity securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. 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 one or more product candidates, all of which may have a material adverse impact on our operations. We may also be required to (i) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (ii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms. We are evaluating all options to raise additional capital, increase revenue, as well as reduce costs, in an effort to strengthen our liquidity position, which may include the following: (1) Raising capital through public and private equity offerings; (2) Introducing operation and business development initiatives to bring in new revenue streams; (3) Reducing operating costs by identifying internal synergies; and (4) Engaging in strategic partnerships. We continually assess our spending plans to effectively and efficiently address our liquidity needs.

Controlled Equity Offerings and Public Offerings

See Note 5 to the financial statements.

Nasdaq Compliance

On September 5, 2017, we received a written notice from Nasdaq notifying us that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market, as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock, and our common stock continued to trade on the Nasdaq Capital Market under the symbol “TROV”. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had until March 5, 2018, to regain compliance with the minimum bid price requirement.

We were eligible for extensions and hearings and ultimately announced on February 12, 2019 that our stockholders approved a reverse stock split of our issued and outstanding shares of common stock and on February 19, 2019, we effected a six for one reverse stock split of our issued and outstanding shares of common stock. On March 11, 2019 we received a letter from Nasdaq, informing us that we had regained compliance with the minimum bid price requirement. We were subject to a Nasdaq Panel Monitor until March 10, 2020. We received a letter from Nasdaq on May 29, 2020 informing us that we are in compliance with applicable Nasdaq Listing Rules.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash and cash equivalents primarily consists of deposits and money market deposits managed by commercial banks as of December 31, 2020. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments were in short-term money marketable funds during the years ended December 31, 2020 and 2019. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

We do not believe our cash and cash equivalents have significant risk of default issues; however, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current stability of financial institutions, we believe that we will not experience losses on these deposits.

Foreign Currency Risk

We face foreign currency risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Changes in foreign currency exchange rates can create foreign exchange gains or losses to us. We did not incur significant foreign currency gains or losses for the years ended December 31, 2020 and 2019.

Effects of Inflation

We do not believe that inflation and changing prices during the years ended December 31, 2020 and 2019 had a significant impact on our results of operations.

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 chief executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, 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, 2020, 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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

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 2021 (the "2021 Proxy Statement"), under the headings "Election of Directors."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2021 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 2021 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 2021 Proxy Statement under the headings "Certain Relationships and Related Transactions."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2021 Proxy Statement under the heading "Proposal 2: Ratification of the Appointment of Our Independent Registered Public Accounting Firm for Fiscal Year Ending December 31, 2021".

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).
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 .
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).
10.12	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.2 to Form 8-K filed on May 13, 2020).
10.13	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 19, 2020).
10.14	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 16, 2020).
10.15+	Separation Agreement between Thomas Adams and Cardiff Oncology, Inc. dated December 21, 2020 (incorporated by reference to Exhibit 10.1 to Form 8-K filed on December 21, 2020).
10.16+	Employment Agreement, dated February 22, 2021 by and between the Company and Vicki Keleman.
10.17+	Employment Agreement, dated February 22, 2021 by and between the Company and Brigitte Lindsay.
23.1	Consent of BDO USA, LLP.
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.
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.

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

2/25/2021

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)	2/25/2021
/s/ Brigitte Lindsay Brigitte Lindsay	VP, Finance (Principal Financial and Accounting Officer)	2/25/2021
/s/ Rodney S. Markin Rodney S. Markin	Chairman of the Board and Director	2/25/2021
/s/ Thomas Adams Thomas Adams	Director	2/25/2021
/s/ James O. Armitage James O. Armitage	Director	2/25/2021
/s/ John Brancaccio John Brancaccio	Director	2/25/2021
/s/ Gary S. Jacob Gary S. Jacob	Director	2/25/2021
/s/ Gary W. Pace Gary W. Pace	Director	2/25/2021
/s/ Lâle White Lâle White	Director	2/25/2021

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, 2020 and 2019, the related statements of operations, stockholders' equity, and cash flows for 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, 2020 and 2019, 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 critical audit matters does not alter in any way our opinion on the consolidated 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 consolidated 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 performed and costs incurred that have not been invoiced by the service providers. The Company's clinical trial accrual balance at December 31, 2020 is $1.69 million, and the Company's related 2020 clinical trial expenses are included in research and development expense of $11.2 million for the year ended December 31, 2020.

We identified accrued clinical trial expenses as a critical audit matter. When estimating clinical trial expenses, the Company considers several factors including clinical trial budgets, contract amendments and the progress toward completion. Auditing these elements involves especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters and a high degree of auditor subjectivity.

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

- Testing management's process for estimating accrued clinical trial expenses by (i) obtaining and inspecting significant agreements, clinical trial budgets, and contract amendments, (ii) evaluating the Company's documentation of trial progress and status (including consideration of patient enrollment and milestones achieved), (iii) confirming clinical trial progress with third party service providers, and (iv) testing a sample of transactions by comparing the costs against the related invoices and agreements.

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

/s/ BDO USA, LLP

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

San Diego, California
February 25, 2021

Cardiff Oncology, Inc.
Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 130,980,681	$ 10,195,292
Accounts receivable and unbilled receivable	320,458	203,480
Prepaid expenses and other assets	2,055,321	954,957
Total current assets	133,356,460	11,353,729
Property and equipment, net	623,694	877,823
Operating lease right-of-use assets	343,001	697,418
Other assets	404,232	157,576
Total Assets	$ 134,727,387	$ 13,086,546
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,366,008	$ 656,304
Accrued liabilities	3,850,763	3,260,061
Operating lease liabilities	860,206	865,379
Other current liabilities	42,000	—
Total current liabilities	6,118,977	4,781,744
Derivative financial instruments—warrants	284,971	4,127
Operating lease liabilities, net of current portion	9,291	860,963
Other liabilities	156,266	128,368
Total liabilities	6,569,505	5,775,202
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized; (Note 5)	716	60
Common stock, $0.0001 par value, 150,000,000 shares authorized; 36,780,805 and 8,593,633 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	3,678	8,312
Additional paid-in capital	361,820,025	217,172,528
Service receivables	(2,171,258)	(971,673)
Accumulated deficit	(231,495,279)	(208,897,883)
Total stockholders' equity	128,157,882	7,311,344
Total Liabilities and Stockholders' Equity	$ 134,727,387	$ 13,086,546

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

Cardiff Oncology, Inc.
Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Revenues:		
Royalties	$ 365,993	$ 243,137
Services	—	1,495
Total revenues	365,993	244,632
Costs and expenses:		
Research and development	11,235,396	11,162,236
Selling, general and administrative	8,216,471	5,760,890
Total operating expenses	19,451,867	16,923,126
Loss from operations	(19,085,874)	(16,678,494)
Interest income	89,809	234,169
Interest expense	(1,519)	—
Other gain (loss), net	(28,244)	1,978
Gain (loss) from changes in fair value of derivative financial instruments—warrants	(280,844)	28,188
Net loss	(19,306,672)	(16,414,159)
Preferred stock dividend payable on Series A Convertible Preferred Stock	(24,240)	(24,240)
Deemed dividend recognized on beneficial conversion features of Series C Convertible Preferred Stock issuance	—	(268,269)
Deemed dividend recognized on beneficial conversion features of Series D Convertible Preferred Stock issuance	(601,767)	—
Deemed dividend recognized on beneficial conversion features of Series E Convertible Preferred Stock issuance	(2,664,717)	—
Net loss attributable to common stockholders	$ (22,597,396)	$ (16,706,668)
Net loss per common share — basic and diluted	$ (1.08)	$ (2.80)
Weighted-average shares outstanding — basic and diluted	20,874,665	5,973,906

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

Cardiff Oncology, Inc.
Statements of Stockholders' Equity

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Service Receivable	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2018	60,600	$ 60	3,831,879	$ 7,742	$ 202,267,605	$ —	$ (192,191,215)	$ 10,084,192
Sale of common stock and warrants, net of expenses	—	—	1,994,929	199	8,817,573	—	—	8,817,772
Issuance of common stock, preferred stock and warrants for clinical trial funding commitment, net of expenses and discount	200,000	200	183,334	110	1,634,690	(1,675,000)	—	(40,000)
Stock-based compensation	—	—	—	—	884,942	—	—	884,942
Issuance of common stock upon exercise of warrants	—	—	2,221,635	223	3,299,287	—	—	3,299,510
Issuance of common stock upon vesting of restricted stock units	—	—	22,057	5	(5)	—	—	—
Deemed dividend recognized on beneficial conversion features of Series C Convertible Preferred Stock issuance	—	—	—	—	268,269	—	(268,269)	—
Issuance of common stock upon conversion of Series C Convertible Preferred Stock	(200,000)	(200)	333,333	33	167	—	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	—	(24,240)	(24,240)
Issuance of common stock for share rounding as a result of reverse stock split	—	—	6,466	—	—	—	—	—
Release of clinical trial funding commitment	—	—	—	—	—	703,327	—	703,327
Net loss	—	—	—	—	—		(16,414,159)	(16,414,159)
Balance, December 31, 2019	60,600	$ 60	8,593,633	$ 8,312	$ 217,172,528	$ (971,673)	$ (208,897,883)	$ 7,311,344
Sale of common stock, preferred stock and warrants, net of expenses[(1)]	865,824	866	12,964,313	1,297	112,297,786	—	—	112,299,949
Issuance of common stock, preferred stock and warrants for clinical trial funding commitment	154,670	15	602,833	60	2,292,425	(2,300,000)	—	(7,500)
Stock-based compensation	—	—		—	1,764,804	—	—	1,764,804
Issuance of common stock upon exercise of warrants	—	—	12,138,469	1,214	24,870,372	—	—	24,871,586
Issuance of common stock upon vesting of restricted stock units	—	—	10,810	1	(1)	—	—	—
Deemed dividend recognized on beneficial conversion features of Series D Convertible Preferred Stock issuance	—	—	—	—	601,767	—	(601,767)	—
Deemed dividend recognized on beneficial conversion features of Series E Convertible Preferred Stock issuance	—	—	—	—	2,664,717	—	(2,664,717)	—
Issuance of common stock upon conversion of Series D Convertible Preferred Stock	(154,670)	(15)	1,546,700	155	(140)	—	—	—
Issuance of common stock upon conversion of Series E Convertible Preferred Stock	(210,780)	(210)	863,852	86	124	—	—	—
Preferred stock dividend payable on Series A Convertible Preferred Stock	—	—	—	—	—	—	(24,240)	(24,240)
Release of clinical trial funding commitment	—	—	—	—	—	1,100,415		1,100,415
Common Stock par value adjustment	—	—	—	(7,453)	7,453	—	—	—
Issuance of common stock upon exercise of stock options	—	—	60,195	6	148,190	—	—	148,196
Net loss	—	—	—	—	—	—	(19,306,672)	(19,306,672)
Balance, December 31, 2020	715,644	$ 716	36,780,805	$ 3,678	$ 361,820,025	$ (2,171,258)	$ (231,495,279)	$ 128,157,882

(1) Net of expenses of $7,507,123, and fair value of warrants issued as a transaction advisory fee as of the date of issuance of $370,666

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

Cardiff Oncology, Inc.
Statements of Cash Flows

	Year ended December 31,	
	2020	2019
Operating activities		
Net loss	$ (19,306,672)	$ (16,414,159)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment loss	34,169	—
Depreciation	466,009	494,232
Stock-based compensation expense	1,764,804	884,943
Change in fair value of derivative financial instruments—warrants	280,844	(28,188)
Release of clinical trial funding commitment	1,100,415	703,327
Changes in operating assets and liabilities:		
Other assets	(246,656)	(54,778)
Accounts receivable and unbilled receivable	(116,978)	(35,725)
Prepaid expenses and other current assets	(1,100,364)	115,459
Operating lease right-of-use assets	320,248	302,491
Accounts payable and accrued expenses	1,276,166	1,455,336
Operating lease liabilities	(856,845)	(776,806)
Other liabilities	69,898	86,368
Net cash used in operating activities	(16,314,962)	(13,267,500)
Investing activities		
Capital expenditures	(211,880)	(67,622)
Net cash used in investing activities	(211,880)	(67,622)
Financing activities		
Proceeds from sale of common stock, preferred stock and warrants, net of expenses of $7,507,123 and $158,678 respectively	112,299,949	8,817,772
Costs related to the clinical trial funding commitment	(7,500)	(40,000)
Proceeds from exercise of warrants	24,871,586	3,299,509
Proceeds from exercise of options	148,196	—
Borrowings under note payable	305,000	—
Repayments of note payable	(305,000)	—
Net cash provided by financing activities	137,312,231	12,077,281
Net change in cash and cash equivalents	120,785,389	(1,257,841)
Cash and cash equivalents—Beginning of period	10,195,292	11,453,133
Cash and cash equivalents—End of period	$ 130,980,681	$ 10,195,292
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	$ 800	$ 800
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividend payable on Series A Convertible Preferred Stock	$ 24,240	$ 24,240
Deemed dividend recognized for beneficial conversion features of Series C Convertible Preferred Stock issuance	$ —	$ 268,269
Deemed dividend recognized for beneficial conversion features of Series D Convertible Preferred Stock issuance	$ 601,767	$ —
Deemed dividend recognized for beneficial conversion features of Series E Convertible Preferred Stock issuance	$ 2,664,717	$ —
Common stock, Series C Convertible Preferred Stock and warrants issued in connection with clinical trial funding commitment, net of discount of $235,640	$ —	$ 1,675,000

	Year ended December 31,	
	2020	2019
Common stock, Series D Convertible Preferred Stock and warrants issued in connection with clinical trial funding commitment, net of discount of $488,270	$ 2,300,000	$ —
Common stock issued upon conversion of Series C Convertible Preferred Stock	$ —	$ 33
Common stock issued upon conversion of Series D Convertible Preferred Stock	$ 155	$ —
Common stock issued upon conversion of Series E Convertible Preferred Stock	$ 86	$ —

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 with the singular mission of developing new treatment options for cancer patients in indications with the greatest medical need, including KRAS-mutated metastatic colorectal cancer, pancreatic cancer, Zytiga®-resistant metastatic castration-resistant prostate cancer and leukemias. Our goal is to overcome resistance, improve response to treatment and increase overall survival. Through the integration of tumor genomics and biomarker technology, we are able to assess patient response to treatment.

Liquidity

The Company has incurred net losses since its inception and has negative operating cash flows. As of December 31, 2020, the Company had $131.0 million in cash and cash equivalents 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. The economic effects of COVID-19 could also have an adverse effect on the Company's ability to raise additional capital. See Note 13 to the financial statements for further information.

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").

The Company made a reverse split of its common stock, $0.0001 par value, at a ratio of 1 for 6, effective February 19, 2019. All share and per share information in the financial statements and the accompanying notes have been retroactively adjusted to reflect the reverse stock split for all periods presented.

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 in making decisions regarding resource allocation and assessing performance. The Company views its operations as, and manages its business in, one operating segment.

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 estimates involve accrued clinical trial expenses and determining the assumptions made for stock-based compensation.

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, 2020 the Company's Clinical trial accrual balance of $1,683,195 is included in accrued liabilities and other liabilities. The Company's related 2020 clinical trial expenses are included in research and development expense of $11,235,396. Certain accrued clinical trial expenses are released from service receivables classified within equity (see Note 5) as clinical trial services are performed.

Cash and Cash Equivalents

Cash and cash equivalents consist of operating and money market accounts as of December 31, 2020 and 2019 on deposit. Cash equivalents are considered by the Company to be highly liquid investments purchased with original maturities of three months or less from the date of purchase.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of 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. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity.

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 agreements may involve multiple elements such as license fees, 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. Minimum 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. Such warrants do not meet the exemption that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. The warrants contain a feature that could require the transfer of cash in the event a change of control occurs without an authorization of the Company's Board of Directors, and therefore classified as a liability. 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). At December 31, 2020 and 2019, the fair value of these warrants was $284,971 and $4,127, respectively, and was recorded as a liability under the caption "derivative financial instruments—warrants" on the balance sheets.

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, accounts payable and derivative liabilities. 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 and equipment. The Company records property and equipment at cost, and records other intangible assets based on their fair values at the date of acquisition. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful life of five years for laboratory equipment and three to five years for furniture and office equipment. Depreciation of leasehold improvements is computed based on the shorter of the life of the asset or the term of the lease.

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. As most of the Company's operating leases do not provide an implicit rate, 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, Cardiff Oncology 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*, Cardiff Oncology records such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. Cardiff Oncology, 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 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.

Net Loss Per Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Preferred 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,	
	2020	2019
Options to purchase Common Stock	1,860,507	1,015,418
Warrants to purchase Common Stock	5,260,992	10,589,482
Restricted Stock Units	491	11,301
Series A Convertible Preferred Stock	877	877
Series E Convertible Preferred Stock	2,684,607	—
	9,807,474	11,617,078

Recently Adopted Accounting Pronouncement

In August 2018, the FASB issued ASU No. 2018-13 ("ASU 2018-13"), *Changes to the Disclosure Requirements for Fair Value Measurement*. This ASU eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. The standard is effective for all entities for financial statements issued for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company has prospectively adopted ASU 2018-13 as of January 1, 2020 for periods presented after adoption. The adoption of ASU 2018-13 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 public business entities for fiscal years beginning after December 15, 2021 (or December 15, 2023 for companies who meet the SEC definition of Smaller Reporting Companies), and interim periods within those fiscal years. The amendment is to be adopted through either a fully retrospective or modified retrospective method of transition. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

3. Supplementary Balance Sheet Information

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, 2020 and 2019 was $466,009 and $494,232, respectively. Property and equipment consisted of the following:

	As of December 31,	
	2020	2019
Furniture and office equipment	$ 797,739	$ 775,030
Leasehold improvements	1,962,230	1,962,230
Laboratory equipment	867,750	744,856
	3,627,719	3,482,116
Less—accumulated depreciation	(3,004,025)	(2,604,293)
Property and equipment, net	$ 623,694	$ 877,823

Accrued Liabilities

Accrued liabilities consisted of the following:

	As of December 31,	
	2020	2019
Accrued compensation	$ 1,523,321	$ 1,003,383
Preferred stock dividend	389,495	365,255
Clinical trials	1,557,134	1,504,660
Research agreements and services	66,593	181,408
Director fees	92,500	67,500
Professional fees and outside services	38,180	21,000
Patent, license and other fees	117,440	69,950
Other accrued liabilities	66,100	46,905
Total accrued liabilities	$ 3,850,763	$ 3,260,061

4. Leases

As a lessee, the Company's current leases include its master facility lease and immaterial equipment leases, all of which are considered operating leases.

The Company (as a sublessor) also subleases portions of its facility to third parties under three separate subleases. All of these subleases have been determined to be operating leases and are accounted for separately from the head lease.

Master Facility Lease

The Company leases a building in San Diego under an operating lease that expires on December 31, 2021. The lease currently requires fixed monthly rent payments of approximately $78,000, with 3% annual escalation.

Facility Subleases

As a result of corporate restructurings in previous years, the Company vacated a portion of its facility and has subleased space to third parties under three separate sublease agreements, which all expire December 31, 2021. Income is recognized on a straight-line basis over the term of the sublease.

Impairment of Right-of-Use Assets

The Company recorded an impairment loss of $34,169 and $0 for the twelve months ending December 31, 2020 and 2019, respectively. The loss related to a vacated portion of the facility that was no longer being subleased. The Company determined that the prolonged loss of sublease income and an adverse commercial real estate market caused by COVID-19 were indicators of impairment. A fair value approach using quoted prices for similar assets was used to determine the impairment loss. The loss was recorded within operating expenses in the statement of operations.

The components of lease expense were as follows:

	Twelve Months Ended December 31, 2020	Twelve Months Ended December 31, 2019
Operating lease cost	$ 441,529	$ 444,878
Operating sublease income	(291,173)	(381,653)
Net operating lease cost	$ 150,356	$ 63,225

Supplemental balance sheet information related to leases was as follows:

	As of December 31, 2020	As of December 31, 2019
Operating lease ROU assets	$ 343,001	$ 697,418
Current operating lease liabilities	$ 860,206	$ 865,379
Non-current operating lease liabilities	9,291	860,963
Total operating lease liabilities	$ 869,497	$ 1,726,342
Weighted-average remaining lease term–operating leases	1.0 year	2.0 years
Weighted-average discount rate–operating leases	6.5 %	6.5 %

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

	Twelve Months Ended December 31, 2020	Twelve Months Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 943,959	$ 916,762

Total remaining annual commitments under non-cancelable lease agreements for each of the years ended December 31 are as follows:

Year Ending December 31,	Operating Leases	Sublease Income	Net Operating Leases
2021	$ 889,586	$ (403,345)	$ 486,241
2022	5,868	—	5,868
2023	3,423	—	3,423
Total future minimum lease payments	898,877	$ (403,345)	$ 495,532
Less imputed interest	(29,380)		
Total	$ 869,497		

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, 2018	3,649,341	$ 8.91	4.4 years
Granted	7,437,454	$ 1.87	
Exercised	(497,313)	$ 6.60	
Balance outstanding, December 31, 2019	10,589,482	$ 4.08	3.7 years
Granted	5,831,451	$ 1.70	
Exercised	(11,159,941)	$ 2.31	
Balance outstanding, December 31, 2020	5,260,992	$ 5.19	4.1 years

The above table excludes pre-funded warrants with a nominal exercise price of $.01 per share:

1. 605,072 pre-funded warrants outstanding as of December 31, 2019;
2. 386,967 pre-funded warrants which were issued during the twelve months ending December 31, 2020;
3. All 992,039 pre-funded warrants were exercised in full during the twelve months ending December 31, 2020.

Preferred Stock

A summary of our Company's classes of preferred stock is presented below:

Class	Par value	Shares designated	Liquidation preference	Shares outstanding As of December 31, 2020	Shares outstanding As of December 31, 2019
Series A Convertible Preferred Stock	$ 0.001	277,100	$ 606,000	60,600	60,600
Series B Convertible Preferred Stock	$ 0.001	8,860	None	—	—
Series C Convertible Preferred Stock	$ 0.001	200,000	None	—	—
Series D Convertible Preferred Stock	$ 0.0001	154,670	None	—	—
Series E Convertible Preferred Stock	$ 0.001	865,824	None	655,044	—

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, 2020 and 2019, the Company had $389,495 and $365,255, respectively in accrued cumulative unpaid preferred stock dividends, included in accrued liabilities in the Company's balance sheets, and $24,240 and $24,240 of accrued dividends were recorded during the years ended December 31, 2020 and 2019, 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 upon registration of the common stock underlying the Series A Convertible Preferred Stock. The relevant registration statement became effective on 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.

Series C Convertible Preferred Stock and Service Receivable

On January 25, 2019, the Company entered into a Master Services Agreement and a Stock and Warrant Subscription Agreement with PoC Capital, LLC ("PoC"), whereby PoC agreed to finance $1.675 million for the development costs associated with Phase 1b/2 study of onvansertib in combination with FOLFIRI and Avastin® in patients with metastatic Colorectal Cancer ("mCRC") harboring KRAS mutation in exchange for (i)183,334 shares of common stock, (ii) warrants to purchase an aggregate of 150,000 shares of common stock, with an exercise price of $3.762 per share, expiring on January 25, 2024, and (iii) 200,000 shares of Series C Convertible Preferred Stock, each share of which was convertible into 1.67 shares of common stock. In April of 2019, all 200,000 shares of Series C Convertible Preferred Stock were converted into 333,333 shares of the Company's common stock.

The Company evaluated the awards issued under this transaction and determined they should be classified as equity. These equity awards were fully vested and non-forfeitable. Since the equity awards were for clinical trial services yet to be provided, the Company recognized $1.675 million service receivables as contra equity. The Company releases the service receivables as clinical trial services are performed. The conversion feature of the Series C Convertible Preferred Stock at the time of issuance was determined to be beneficial on the commitment date. Because the Series C Convertible Preferred Stock was perpetual with no stated maturity date, and the conversions could occur any time from inception, the Company immediately recorded a non-cash deemed dividend of $0.3 million related to the beneficial conversion feature arising from the issuance of Series C Convertible Preferred Stock. This non-cash deemed dividend increased the Company's net loss attributable to common stockholders and net loss per share.

Series D Convertible Preferred Stock and Service Receivable

On May 8, 2020, the Company entered into a Stock and Warrant Subscription Agreement with PoC, whereby PoC agreed to finance an additional $2.3 million for a clinical trial in exchange for (i) 602,833 shares of its common stock (the "Common Stock"), (ii) 154,670 shares of its Series D Preferred Stock and (iii) a warrant exercisable for 859,813 shares of its Common Stock. In exchange, PoC is funding our clinical development of onvansertib in metastatic colorectal cancer pursuant to a Master Services Agreement dated as of January 25, 2019, as amended. The warrant will be exercisable six months following the date of issuance at an exercise price of $1.50 per share and will expire on November 7, 2025. In June of 2020, all 154,670 Series D Preferred Stock were converted to 1,546,700 shares of Common Stock.

The Company evaluated the awards issued under this transaction and determined they should be classified as equity. These equity awards were fully vested and non-forfeitable. Since the equity awards were for clinical trial services yet to be provided, the Company recognized $2.3 million service receivables as contra equity. The Company releases the service receivables as clinical trial services are performed. The conversion feature of the Series D Convertible Preferred Stock at the time of issuance was determined to be beneficial on the commitment date. Because the Series D Convertible Preferred Stock was perpetual with no stated maturity date, and the conversions could occur any time from inception, the Company immediately recorded a non-cash deemed dividend of $0.6 million related to the beneficial conversion feature arising from the issuance of Series D Convertible Preferred Stock. This non-cash deemed dividend increased the Company's net loss attributable to common stockholders and net loss per share.

Series E Convertible Preferred Stock

On June 15, 2020 the Company entered into a Securities Purchase Agreement with Acorn Bioventures LP ("Acorn"), CDK Associates, L.L.C. ("CDK") and Third Street Holdings LLC ("Third Street"), pursuant to which the Company agreed to offer, issue and sell to Acorn, CDK and Third Street, (i) in a registered direct offering, an aggregate of 1,984,328 shares of common stock and (ii) in a concurrent private placement, (a) an aggregate of 865,824 shares of Series E Preferred Stock ("Series E Preferred Stock") and (b) Series N warrants to purchase up to 2,213,115 shares of Common Stock. The Series E Preferred Stock is convertible at any time determined by dividing the $10 stated value per share of the Series E Preferred Stock by a conversion price of $2.44 per share, subject to adjustment in accordance with the Certificate of Designation. The Series N Warrants will be exercisable six months following the date of issuance at an exercise price of $2.39 per share and will expire on December 16, 2025. Certain investors converted 210,780 shares of Series E Convertible Preferred stock to 863,852 shares of Common Stock during December 2020.

The conversion feature of the Series E Convertible Preferred Stock at the time of issuance was determined to be beneficial on the commitment date. Because the Series E Convertible Preferred Stock was perpetual with no stated maturity date, and the conversions could occur any time from inception, the Company immediately recorded a non-cash deemed dividend of $2.7 million related to the beneficial conversion feature arising from the issuance of Series E Convertible Preferred Stock. This non-cash deemed dividend increased the Company's net loss attributable to common stockholders and net loss per share.

In conjunction with the June 15, 2020 offering, we issued 184,426 warrants as an advisory fee. These warrants are exercisable six months following the date of issuance at an exercise price of $3.05 per share and will expire 5.5 years following the date of issuance. These warrants are classified as equity and its estimated fair value of $370,666 was recognized as additional paid in capital on the issuance date. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

Securities Purchase Agreements with Lincoln Park Capital Fund, LLC

On March 30, 2020, the Company entered into a Securities Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company agreed to offer, issue and sell to LPC, (i) in a registered direct offering, an aggregate of (a) 800,000 shares of common stock and (b) Series I warrants to purchase up to 131,967 shares (the "Series I Warrant Shares") of common stock. In a concurrent private placement, the Company also sold to LPC Series J warrants (the "Series J Warrants") to purchase one share of common stock for each Share and for each Series I Warrant purchased for cash in the registered direct offering. The Series J Warrants are exercisable six months following the date of issuance at an exercise price of $0.948 per share and will expire 5.5 years following the date of issuance. The gross proceeds from this purchase were $1.0 million.

On April 9, 2020, the Company entered into a Securities Purchase Agreement with LPC, pursuant to which the Company agreed to offer, issue and sell to LPC, (i) in a registered direct offering, an aggregate of (a) 904,970 shares of common stock and (b) Series K warrants to purchase up to 255,000 shares (the "Series K Warrant Shares") of common stock. In a concurrent private placement, the Company also sold to LPC Series L warrants (the "Series L Warrants") to purchase one share of Common Stock for each Share and for each Series K Warrant purchased for cash in the registered direct offering. The Series L Warrants are exercisable six months following the date of issuance at an exercise price of $0.81 per share and will expire 5.5 years following the date of issuance. The gross proceeds from this purchase were $1.1 million.

Securities Purchase Agreement with Certain Directors and Executives

On May 11, 2020 and May 14, 2020, the Company entered into Securities Purchase Agreements with certain directors and executives of the Company pursuant to which the Company sold 447,761 shares of common stock at a purchase price of $1.34 per share and 146,854 shares of common stock at a purchase price of $1.43 per share. The gross proceeds from these purchases were $810,000.

Securities Purchase Agreement with Acorn Bioventures LP

On May 26, 2020, the Company entered into a Securities Purchase Agreement with Acorn, pursuant to which the Company agreed to offer, issue and sell to Acorn, (i) in a registered direct offering, an aggregate of 1,205,400 shares of common stock and (ii) in a concurrent private placement, Series M warrants to purchase up to 482,160 shares of common stock. The Series M Warrants are exercisable six months following the date of issuance at an exercise price of $2.024 per share and will expire 5.5 years following the date of issuance. The gross proceeds from this purchase were $2.5 million.

Underwritten Public Offering

On October 2, 2020 the Company completed an underwritten public offering of 6,500,000 shares of its common stock at a price to the public of $13.50 per share. In addition, the underwriters exercised in full an option to purchase an additional 975,000 shares of common stock at the public offering price, less the underwriting discounts and commissions. All of the shares in the offering were sold by the Company, with gross proceeds of approximately $100.9 million, and net proceeds of approximately $94.0 million, after deducting underwriting discounts, commissions and estimated offering expenses.

6. Stock-Based Compensation

The Cardiff Oncology, Inc. 2014 Equity Incentive Plan (the "2014 EIP"), authorizing up to 34,722 shares of common stock for issuance under the 2014 EIP, was approved by the Board in June 2014 and approved by the stockholders of the Company at the September 17, 2014 Annual Meeting of Stockholders. The total number of authorized shares was increased to 243,056 between the inception of the 2014 EIP through December 31, 2018. At the June 6, 2019 Annual Meeting of Stockholders, the stockholders approved the increase of number of authorized shares in the 2014 EIP to 1,243,056. At the April 6, 2020 Annual meeting of Stockholders, the stockholders approved the increase of number of authorized shares in the 2014 EIP to 2,243,056

As of December 31, 2020, there were 260,446 shares available for issuance under the 2014 EIP.

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

	Years ended December 31,	
	2020	2019
Research and development expenses	354,692	399,687
Selling, general and administrative expenses	1,410,112	485,256
Total stock-based compensation	$ 1,764,804	$ 884,943

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,	
	2020	2019
Risk-free interest rate	0.39% - 0.93%	1.66% - 2.33%
Dividend yield	0%	0%
Expected volatility (range)	102% - 106%	95% - 99%
Expected volatility (weighted-average)	105%	96%
Expected term (in years)	5.9 years	5.9 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 option term represents the period that stock-based awards are expected to be outstanding based on the simplified method, which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Options are considered to be "plain vanilla" if they have the following basic characteristics: (1) are granted "at-the-money"; (2) exercisability is conditioned upon service through the vesting date; (3) termination of service prior to vesting results in forfeiture; (4) limited exercise period following termination of service; and (5) are non-transferable and non-hedgeable.

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, 2020 and 2019, estimated as of the grant date using the Black-Scholes option valuation model, was $2.09 and $1.91 per share, respectively.

The unrecognized compensation cost related to non-vested stock options outstanding at December 31, 2020 was $1,519,004. The weighted-average remaining amortization period at December 31, 2020 for non-vested stock options was 1.9 years.

The total fair value of shares vested during the years ended December 31, 2020 and 2019 was $1,522,984 and $386,654, respectively.

The intrinsic value of stock options exercised during the year ended December 31, 2019 was $0.

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, 2019	1,015,418	$ 12.77	$ —	9.1 years
Granted	969,965	$ 2.53		
Exercised	(60,195)	$ 2.46	$ 970,145	
Forfeited	(48,537)	$ 22.91		
Expired	(16,144)	$ 21.29		
Balance outstanding, December 31, 2020	1,860,507	$ 7.43	$ 27,963,363	8.9 years
Vested and exercisable, December 31, 2020	753,206	$ 14.63	$ 10,837,211	8.5 years
Vested and expected to vest, December 31, 2020	1,777,407	$ 7.65	$ 26,682,849	8.9 years

Restricted Stock Units

RSU's are measured at the grant date based on the closing market price of the Company’s common stock at the grant date and recognized ratably over the service period through the vesting date. All RSU's were granted with no purchase price. Vesting of the RSU's is generally subject to service conditions.

A summary of the RSU's activity is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Intrinsic Value
Non-vested RSU's outstanding, December 31, 2018	30,132	$ 14.36	$ 95,005
Granted	9,167	$ 1.61	
Vested	(22,057)	$ 8.68	
Forfeited	(5,941)	$ 13.82	
Non-vested RSU's outstanding, December 31, 2019	11,301	$ 15.38	$ 14,013
Vested	(10,810)	$ 9.37	
Non-vested RSU's outstanding, December 31, 2020	491	$ 147.60	$ 7,641

The total fair values of RSU's vested during the year ended December 31, 2020 and 2019 were $101,290 and $191,436, respectively.

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. Changes in fair value are recorded within Company’s statements of operations.

The range of assumptions used to determine the fair value of the warrants valued using the Black-Scholes option pricing model during the periods indicated was:

	Year ended December 31,	
	2020	2019
Fair value of Cardiff Oncology common stock	$1.01 - $17.99	$1.24 - $3.75
Expected warrant term	2.1 - 3.1 years	3.1 - 4.1 years
Risk-free interest rate	0.13% - 1.62%	1.56% - 2.49%
Expected volatility	110% - 118%	102% - 111%
Dividend yield	—%	—%

	As of December 31, 2020
Weighted Average[(1)(2)]:	
Fair value of Cardiff Oncology common stock	$17.99
Expected warrant term	2.1 years
Risk-free interest rate	0.13 %
Expected volatility of Cardiff Oncology common stock	116 %
Dividend yield	0 %

(1) Weighted average is only disclosed for periods after January 1, 2020 under the adoption of ASU 2018-13.

(2) The weighted average was calculated using the relative fair value method.

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.

Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2018	Balance of derivative financial instruments—warrants liability	64,496	$ 32,315
	Change in fair value of derivative financial instruments—warrants during the year recognized as a gain in the statement of operations	—	(28,188)
December 31, 2019	Balance of derivative financial instruments—warrants liability	64,496	4,127
	Change in fair value of derivative financial instruments—warrants during the year recognized as a loss in the statement of operations	—	280,844
December 31, 2020	Balance of derivative financial instruments—warrants liability	64,496	$ 284,971

The remaining contractual term of the warrants outstanding at December 31, 2020 and 2019 was approximately 2.1 and 3.1 years, respectively.

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, 2020 and 2019:

	Fair Value Measurements at December 31, 2020			
	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 (1)	$ 129,987,804	$ —	$ —	$ 129,987,804
Total Assets	$ 129,987,804	$ —	$ —	$ 129,987,804
Liabilities:				
Derivative financial instruments—warrants	$ —	$ —	$ 284,971	$ 284,971
Total Liabilities	$ —	$ —	$ 284,971	$ 284,971

	Fair Value Measurements at December 31, 2019			
	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 (1)	$ 10,131,240	$ —	$ —	$ 10,131,240
Total Assets	$ 10,131,240	$ —	$ —	$ 10,131,240
Liabilities:				
Derivative financial instruments—warrants	$ —	$ —	$ 4,127	$ 4,127
Total Liabilities	$ —	$ —	$ 4,127	$ 4,127

(1) Included as a component of cash and cash equivalents on the accompanying balance sheet.

The change in the fair value of the "derivative financial instruments—warrants" is recorded as a gain or loss in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40 and ASC Topic 480-10. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments that trade infrequently and therefore have little or no price transparency are classified as Level 3.

9. Income Taxes

At December 31, 2020, Cardiff Oncology had federal net operating loss carryforwards ("NOLs") of approximately $128.9 million which, if not used, will continue to expire through 2037, and federal net operating loss carryforwards of approximately $48.4 million, which do not expire. Cardiff Oncology also has California NOLs of approximately $70.7 million which, if not used, will begin to expire in 2029. Cardiff Oncology has Federal and California capital loss carryforwards of $0.7 million which, if not used, will begin to expire in 2022. Cardiff Oncology also has research and development tax credits available for federal and California purposes of approximately $2.5 million and $1.8 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 not completed such an analysis pursuant to Sections 382 and 383 and therefore 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 (in thousands):

	Years ended December 31,	
	2020	2019
Current:		
State	$ 1	$ 1
Total current provision	1	1
Deferred:		
Federal	(4,043)	(2,634)
State	(92)	(148)
Total deferred (benefit) expense	(4,135)	(2,782)
Valuation allowance	4,134	2,781
Total income tax provision	$ —	$ —

Significant components of the Company's taxes and the rates as of December 31 are shown below (in thousands, except percentages):

	Years ended December 31,			
	2020		2019	
Tax computed at the federal statutory rate	$ (4,054)	21 %	$ (3,447)	21 %
State tax, net of federal tax benefit	(122)	1 %	(177)	1 %
Permanent Items	261	(1)%	353	(2)%
Stock options true-up	81	(1)%	875	(5)%
Tax credits	(300)	2 %	(384)	2 %
Valuation allowance increase (decrease)	4,134	(22)%	2,780	(17)%
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):

	Years ended December 31,	
	2020	2019
Deferred tax assets:		
Tax loss carryforwards	$ 42,331	$ 38,494
Research and development credits and other tax credits	3,904	3,710
Stock-based compensation	684	531
Other	1,116	1,252
Total deferred tax assets	48,035	43,987
Deferred tax liabilities:		
Operating lease right-of-use assets	(74)	(154)
Other	(6)	(12)
Total deferred tax liabilities	(80)	(166)
Net deferred tax assets before valuation allowance	47,955	43,821
Valuation allowance	(47,955)	(43,821)
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. Onvansertib is an oral, investigative drug and a highly-selective adenosine triphosphate competitive inhibitor of the serine/threonine PLK1. The Company plans to develop onvansertib in patients with leukemias/lymphomas and solid tumor cancers. Upon execution of the agreement, the Company paid $2.0 million in license fees which were expensed to research and development costs. The Company was committed to order $1.0 million of future services provided by Nerviano, such as the cost to manufacture drug product, no later than June 30, 2019, and these services have been purchased. Terms of the agreement also provide for the Company to pay development milestones and royalties based on sales volume.

The Company is a party to various agreements under which it licenses technology on an exclusive basis in the field of human diagnostics and oncology therapeutics. License fees are generally calculated as a percentage of product revenues, with rates that vary by agreement. To date, 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.

12. Related Party Transactions

Leucadia Life Sciences

In November 2018, the Company entered into a Material Transfer Agreement ("MTA") with Leucadia Life Sciences ("Leucadia") pursuant to which Leucadia will develop a PCR-based assay for onvansertib for Acute Myeloid Leukemia ("AML"). One of the Company's Directors, Dr. Thomas Adams, is a principal stockholder of Leucadia. In connection with the MTA, the Company entered into a consulting agreement with Tommy Adams, Co-Founder & Chief Operating Officer of Leucadia, who is the son of Dr. Adams. During the years ended December 31, 2020 and 2019, the Company incurred and recorded approximately $1,083,000 and $1,005,000, respectively, of research and development expenses for services performed by Leucadia and Tommy Adams. The assay was completed in December 2020.

Gary Pace Securities Purchase Agreement

In May 2020, the Company entered into a Securities Purchase Agreement with Gary W. Pace, one of the Company's directors. Dr. Pace purchased 447,761 shares of the Company's common stock at $1.34 per share for an aggregate purchase price of $600,000 (see Note 5).

13. COVID-19

The COVID-19 outbreak in the United States has caused significant business disruption. The extent of the impact of COVID-19 on the Company's future operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, and impact on the Company's clinical trials, employees and vendors, all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 may impact the Company's future financial condition or results of operations is uncertain. While there has not been a material impact on the Company's financial statements for the twelve months ended December 31, 2020, a prolonged outbreak could have a material adverse impact on financial results and business operations of the Company, including the timing and ability of the Company to complete certain clinical trials and other efforts required to advance the development of its drugs and raise additional capital.

In response to the pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act, among other things, includes tax provisions relating to refundable payroll tax credits, deferment of employer's social security payments, net operating loss utilization and carryback periods, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company is utilizing the deferment of employer social security payments. The CARES Act did not have a material impact on our income tax provision for the twelve months ended December 31, 2020. We continue to monitor changes and revisions of the CARES Act and its impact on our financial position, results of operations and cash flows.

Repayment of Small Business Administration Payroll Protection Program Loan

On April 15, 2020, the Company was granted a loan (the "Loan") from JPMorgan Chase Bank, N.A. in the aggregate amount of $305,000, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act with an interest rate of 0.98% per annum. On October 19, 2020 the Company repaid in full the outstanding principal and interest of the PPP Loan.

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement (the "Agreement") is made and entered into effective as of February 22, 2021 (the "Effective Date"), by and between Mark Erlander (the "Executive") and Cardiff Oncology, Inc., a Delaware corporation (the "Company").

R E C I T A L S

WHEREAS, Executive serves as the Chief Executive Officer of the Company;

WHEREAS, in order to provide Executive with financial security, the Board of Directors of the Company (the "Board") believes that it is in the best interests of the Company to provide Executive with certain engagement terms and severance benefits as set forth herein;

WHEREAS, the Company and the Executive entered into that certain Employment Agreement dated February 18, 2016.

AGREEMENT

In consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of a material act of fraud, embezzlement or misappropriation, which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) a material breach of Executive's proprietary information agreement that is materially injurious to the Company; or (iv) Executive's (1) material failure to perform his duties as set forth in this Agreement, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i)the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), obtains "beneficial ownership" (as defined in Rule 13d-3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("Voting Stock");

(ii)the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly more than fifty percent (50%) or more of the voting stock of the resulting entity or a parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii)there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "Disability" means totally and permanently disabled as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof.

(d) "Good Reason" shall mean without Executive's express written consent any of the following: (i) a material reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) the relocation of Executive to a facility or a location more than twenty-five (25) miles from the Company's then current principal location; (iv) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (v) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 12 below.

2. Duties and Scope of Position. During the Term (as defined below), Executive will serve as Chief Executive Officer of the Company, reporting to the Board of Directors, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing his investments, other business affairs and other matters or serving on civic or charitable boards or committees, provided that no such activities unduly interfere with the performance of his obligations under this Agreement, provided that Executive shall honor the non-competition and non-solicitation terms as per Section 15 below. During the

Term, Executive agrees to disclose to the Company those other companies of which he is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of February 22, 2021 (the "Effective Date") and shall continue until February 21, 2024, unless earlier terminated in accordance with Section 9 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the other party a written notice of their intent not to renew such employment, such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Term as that term is defined below. The period commencing as of the Effective Date and ending on Executive's last date of employment with the Company under this Agreement is the "Term" and the end of the Term is referred to herein as the "Expiration Date."

4. Base Compensation. The Company shall pay to Executive a base compensation (the "Base Compensation") of $533,000 per year (prorated for any partial year), payable at such times as the Company customarily pays its other senior executives (but in any event no less often than monthly). In addition, each year during the Term, Executive shall be reviewed for purposes of determining the appropriateness of his Base Compensation hereunder. The Base Compensation shall be subject to all federal, state and local payroll tax withholding and any other withholdings required by law. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4.

5. Benefits; Expense Reimbursement.

(a) Benefits. During the Term, Executive shall be entitled to participate in all company employee benefit plans. In the event Executive elects to pay to a self-funded health insurance program, Executive shall be reimbursed by the Company for such costs up to the maximum amount the Company would be obligated to pay for similar benefits pursuant to its health insurance plans.

(b) Expenses. During the Term, the Company shall promptly reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company.

6. Target Bonus. In addition to his Base Compensation, during the Term Executive shall be given the opportunity to earn an annual bonus (the "Bonus") of up to 50% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "Target Year") to be mutually agreed upon by the Executive and the Board or its compensation committee. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 6, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365. The determinations of the Board or its compensation committee with respect to Bonuses will be final and binding.

7. Intentionally omitted.

8. Intentionally omitted.

9. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in Section 10 below, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Term upon sixty (60) days' prior written notice for any reason or no reason.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in Section 10 below, Executive's employment shall terminate automatically upon his death. Subject to the obligations of the Company set forth in Section 10 below, in the event Executive is unable to perform his duties as a result of Disability during the Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

10. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability or Termination by Executive. In the event that Executive's employment hereunder is terminated during the Term by the Company for Cause, as a result of Executive's death or Disability, or voluntarily by Executive without Good Reason, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: on the date of termination, the Company shall pay Executive a lump sum amount equal to (i) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (ii) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (iii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination.

(b) Termination by Company Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, the Company shall compensate Executive as follows:

(i)on the date of termination, the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the

effective date of termination; (B) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and, provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, the Company shall pay Executive the Base Compensation for twelve (12) months from the date of termination, the potential Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period following the termination and any benefits (or benefits reimbursement payments) pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period. Without limiting the foregoing, Executive also shall be entitled to the severance benefits set forth under Section 10(c) below.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 10(a) or 10(b) herein to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause at any time within twelve (12) months prior to the consummation of a Change of Control if, prior to, or as of such termination, a Change of Control transaction was Pending (as defined in Section 10(d) below) at any time during such twelve (12)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time upon or within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i)on the date of termination (except as specified in clause (C)), the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination;

(ii)on the date of termination, the Company shall pay to Executive a lump sum amount equal to twelve (12) months of Executive's Base Compensation then in effect as of the day of termination, the maximum Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period;

(iii)notwithstanding any provision of any stock incentive plan, stock option agreement, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares and equity awards held by Executive that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change

of Control transaction Pending (as defined in Section 10(d) below) or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv)Severance benefits under this Section 10(c) and Section 10(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

In order to effectuate the provisions of Section 10(c)(iii) hereof, in the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, no equity award held by Executive shall expire or terminate prior to the earlier to occur of (a) ten (10) years after the date of the award and (b) fifteen (15) months after Executive's termination of employment with the Company.

(d) Definition of "Pending." For purposes of Section 10(c) herein, a Change of Control transaction shall be deemed to be "Pending" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction; or (C) a third party has publicly announced, through a filing with the Securities and Exchange Commission, its intent to commence a tender offer or similar transaction to acquire 50% or more of the outstanding voting interests of the Company.

11. Code Section 409A.

(i)The parties agree that this Agreement shall be interpreted to comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder to the extent applicable (collectively "Code Section 409A"), and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Code Section 409A. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Code Section 409A or any damages for failing to comply with Code Section 409A.

(ii)A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits considered "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered nonqualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (i) the expiration of the six (6)-month period measured from the date of such "separation from

service" of Executive, and (ii) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 13.7(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed on the first business day following the expiration of the Delay Period to Executive in a lump sum, and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(iii)With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits, to be provided in any other taxable year, provided, that, this clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense occurred.

(iv)For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within thirty (30) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

12. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing delivered to Executive, at or prior to such Change of Control, to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a Change of Control. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by contract, operation of law or otherwise.

13. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given (a) when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or (b) three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

14. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit B, and incorporated herein by this reference.

15. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered

Area. For the purpose of this Section 15 (a), (i) "Competing Business" means the current business of the Company and (ii) "Covered Area" means all geographical areas of the United States and other foreign jurisdictions where Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly traded, so long as ownership of such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

(b) Non-Solicitation. Executive further agrees that during the Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by Executive of his covenants and agreements set forth herein. Accordingly, Executive agrees and acknowledges that any such violation of this Section 15 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to seek injunctive relief against the breach of this Section 15 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

16. Employment Relationship. Executive's employment with the Company will be "at will," meaning that either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time-to-time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

17. Miscellaneous Provisions.

(a) Survival. Sections 1, 5, 6, 10, 11, 13, 14, 15 and 17 herein, including this Section 17(a), shall survive the termination of Executive's employment with the Company, the expiration of this Agreement and the termination of this Agreement for any reason.

(b) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in

writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Entire Agreement. This Agreement supersedes, amends and restates all prior agreements and understandings between the parties, oral or written, including, without limitation, the Executive Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(g) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(h) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

Cardiff Oncology, Inc.

By: /s/ Rodney Markin

Name: Rodney Markin

Title: Chairman of the Board

EXECUTIVE:

/s/ Mark Erlander
Mark Erlander

Exhibit A

Form of Release Agreement

Exhibit B

Confidentiality and Inventions Agreement

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made and entered into effective as of February 22, 2021 (the "Effective Date"), by and between Vicki Kelemen (the "Executive") and Cardiff Oncology, Inc., a Delaware corporation (the "Company").

R E C I T A L S

WHEREAS, Executive serves as the Executive Vice President and Chief Operating Officer of the Company; and

WHEREAS, in order to provide Executive with financial security, the Board of Directors of the Company (the "Board") believes that it is in the best interests of the Company to provide Executive with certain engagement terms and severance benefits as set forth herein.

AGREEMENT

In consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of a material act of fraud, embezzlement or misappropriation, which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) a material breach of Executive's proprietary information agreement that is materially injurious to the Company; or (iv) Executive's (1) material failure to perform his duties as set forth in this Agreement, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i)the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), obtains "beneficial ownership" (as defined in Rule 13d-3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("Voting Stock");

(ii)the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly more than fifty percent (50%) or more of the voting stock of the resulting entity or a

parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii)there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "Disability" means totally and permanently disabled as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof.

(d) "Good Reason" shall mean without Executive's express written consent any of the following: (i) a material reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) the relocation of Executive to a facility or a location more than twenty-five (25) miles from the Company's then current principal location; (iv) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (v) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 12 below.

2. Duties and Scope of Position. During the Term (as defined below), Executive will serve as Executive Vice President, Chief Operating Officer of the Company, reporting to the Chief Executive Officer, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing her investments, other business affairs and other matters or serving on civic or charitable boards or committees, provided that no such activities unduly interfere with the performance of her obligations under this Agreement, provided that Executive shall honor the non-competition and non-solicitation terms as per Section 15 below. During the Term, Executive agrees to disclose to the Company those other companies of which she is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of February 22, 2021 (the "Effective Date") and shall continue until February 21,

2024, unless earlier terminated in accordance with Section 9 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the other party a written notice of their intent not to renew such employment, such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Term as that term is defined below. The period commencing as of the Effective Date and ending on Executive's last date of employment with the Company under this Agreement is the "Term" and the end of the Term is referred to herein as the "Expiration Date."

4. Base Compensation. The Company shall pay to Executive a base compensation (the "Base Compensation") of $360,000 per year (prorated for any partial year), payable at such times as the Company customarily pays its other senior executives (but in any event no less often than monthly). In addition, each year during the Term, Executive shall be reviewed for purposes of determining the appropriateness of his Base Compensation hereunder. The Base Compensation shall be subject to all federal, state and local payroll tax withholding and any other withholdings required by law. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4.

5. Benefits; Expense Reimbursement.

(a) Benefits. During the Term, Executive shall be entitled to participate in all company employee benefit plans. In the event Executive elects to pay to a self-funded health insurance program, Executive shall be reimbursed by the Company for such costs up to the maximum amount the Company would be obligated to pay for similar benefits pursuant to its health insurance plans.

(b) Expenses. During the Term, the Company shall promptly reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company.

6. Target Bonus. In addition to her Base Compensation, during the Term Executive shall be given the opportunity to earn an annual bonus (the "Bonus") of up to 45% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "Target Year") to be mutually agreed upon by the Executive and the Board or its compensation committee. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 6, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365. The determinations of the Board or its compensation committee with respect to Bonuses will be final and binding.

7. Intentionally omitted.

8. Intentionally omitted.

9. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in Section 10 below, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Term upon sixty (60) days' prior written notice for any reason or no reason.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in Section 10 below, Executive's employment shall terminate automatically upon his death. Subject to the obligations of the Company set forth in Section 10 below, in the event Executive is unable to perform his duties as a result of Disability during the Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

10. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability or Termination by Executive. In the event that Executive's employment hereunder is terminated during the Term by the Company for Cause, as a result of Executive's death or Disability, or voluntarily by Executive without Good Reason, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: on the date of termination, the Company shall pay Executive a lump sum amount equal to (i) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (ii) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (iii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination.

(b) Termination by Company Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, the Company shall compensate Executive as follows:

(i)on the date of termination, the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and,

provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, the Company shall pay Executive the Base Compensation for twelve (12) months from the date of termination, the potential Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period following the termination and any benefits (or benefits reimbursement payments) pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period. Without limiting the foregoing, Executive also shall be entitled to the severance benefits set forth under Section 10(c) below.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 10(a) or 10(b) herein to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause at any time within twelve (12) months prior to the consummation of a Change of Control if, prior to, or as of such termination, a Change of Control transaction was Pending (as defined in Section 10(d) below) at any time during such twelve (12)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time upon or within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i)on the date of termination (except as specified in clause (C)), the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination;

(ii)on the date of termination, the Company shall pay to Executive a lump sum amount equal to twelve (12) months of Executive's Base Compensation then in effect as of the day of termination, the maximum Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period;

(iii)notwithstanding any provision of any stock incentive plan, stock option agreement, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares and equity awards held by Executive that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending (as defined in Section 10(d) below) or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv)Severance benefits under this Section 10(c) and Section 10(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

In order to effectuate the provisions of Section 10(c)(iii) hereof, in the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, no equity award held by Executive shall expire or terminate prior to the earlier to occur of (a) ten (10) years after the date of the award and (b) fifteen (15) months after Executive's termination of employment with the Company.

(d) Definition of "Pending." For purposes of Section 10(c) herein, a Change of Control transaction shall be deemed to be "Pending" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction; or (C) a third party has publicly announced, through a filing with the Securities and Exchange Commission, its intent to commence a tender offer or similar transaction to acquire 50% or more of the outstanding voting interests of the Company.

11. Code Section 409A.

(i)The parties agree that this Agreement shall be interpreted to comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder to the extent applicable (collectively "Code Section 409A"), and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Code Section 409A. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Code Section 409A or any damages for failing to comply with Code Section 409A.

(ii)A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits considered "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered nonqualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (i) the expiration of the six (6)-month period measured from the date of such "separation from service" of Executive, and (ii) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 13.7(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed on the first business day following the expiration of the Delay Period to Executive in a lump sum, and any remaining payments and

benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(iii)With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits, to be provided in any other taxable year, provided, that, this clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense occurred.

(iv)For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within thirty (30) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

12. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing delivered to Executive, at or prior to such Change of Control, to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a Change of Control. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by contract, operation of law or otherwise.

13. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given (a) when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or (b) three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

14. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales

techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit B, and incorporated herein by this reference.

15. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered Area. For the purpose of this Section 15 (a), (i) "Competing Business" means the current business of the Company and (ii) "Covered Area" means all geographical areas of the United States and other foreign jurisdictions where Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly traded, so

long as ownership of such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

(b) Non-Solicitation. Executive further agrees that during the Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by Executive of his covenants and agreements set forth herein. Accordingly, Executive agrees and acknowledges that any such violation of this Section 15 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to seek injunctive relief against the breach of this Section 15 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

16. Employment Relationship. Executive's employment with the Company will be "at will," meaning that either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time-to-time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

17. Miscellaneous Provisions.

(a) Survival. Sections 1, 5, 6, 10, 11, 13, 14, 15 and 17 herein, including this Section 17(a), shall survive the termination of Executive's employment with the Company, the expiration of this Agreement and the termination of this Agreement for any reason.

(b) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Entire Agreement. This Agreement supersedes, amends and restates all prior agreements and understandings between the parties, oral or written, including, without limitation, the Executive Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(g) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(h) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

Cardiff Oncology, Inc.

By: /s/ Mark Erlander

Name: Mark Erlander

Title: Chief Executive Officer

EXECUTIVE:

/s/ Vicki Kelemen
Vicki Kelemen

Exhibit A

Form of Release Agreement

Exhibit B

Confidentiality and Inventions Agreement

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made and entered into effective as of February 22, 2021 (the "Effective Date"), by and between Brigitte Lindsay (the "Executive") and Cardiff Oncology, Inc., a Delaware corporation (the "Company").

R E C I T A L S

WHEREAS, Executive serves as the Vice President, Finance of the Company; and

WHEREAS, in order to provide Executive with financial security, the Board of Directors of the Company (the "Board") believes that it is in the best interests of the Company to provide Executive with certain engagement terms and severance benefits as set forth herein.

AGREEMENT

In consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of a material act of fraud, embezzlement or misappropriation, which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) a material breach of Executive's proprietary information agreement that is materially injurious to the Company; or (iv) Executive's (1) material failure to perform his duties as set forth in this Agreement, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i)the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), obtains "beneficial ownership" (as defined in Rule 13d-3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("Voting Stock");

(ii)the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly more than fifty percent (50%) or more of the voting stock of the resulting entity or a

parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii)there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "Disability" means totally and permanently disabled as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof.

(d) "Good Reason" shall mean without Executive's express written consent any of the following: (i) a material reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) the relocation of Executive to a facility or a location more than twenty-five (25) miles from the Company's then current principal location; (iv) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (v) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 12 below.

2. Duties and Scope of Position. During the Term (as defined below), Executive will serve as Vice President, Finance of the Company, reporting to the Chief Executive Officer and Chief Operating Officer, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing her investments, other business affairs and other matters or serving on civic or charitable boards or committees, provided that no such activities unduly interfere with the performance of her obligations under this Agreement, provided that Executive shall honor the non-competition and non-solicitation terms as per Section 15 below. During the Term, Executive agrees to disclose to the Company those other companies of which she is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of _February 22, 2021 (the "Effective Date") and shall continue until February 21,

2024, unless earlier terminated in accordance with Section 9 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the other party a written notice of their intent not to renew such employment, such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Term as that term is defined below. The period commencing as of the Effective Date and ending on Executive's last date of employment with the Company under this Agreement is the "Term" and the end of the Term is referred to herein as the "Expiration Date."

4. Base Compensation. The Company shall pay to Executive a base compensation (the "Base Compensation") of $246,600 per year (prorated for any partial year), payable at such times as the Company customarily pays its other senior executives (but in any event no less often than monthly). In addition, each year during the Term, Executive shall be reviewed for purposes of determining the appropriateness of his Base Compensation hereunder. The Base Compensation shall be subject to all federal, state and local payroll tax withholding and any other withholdings required by law. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4.

5. Benefits; Expense Reimbursement.

(a) Benefits. During the Term, Executive shall be entitled to participate in all company employee benefit plans. In the event Executive elects to pay to a self-funded health insurance program, Executive shall be reimbursed by the Company for such costs up to the maximum amount the Company would be obligated to pay for similar benefits pursuant to its health insurance plans.

(b) Expenses. During the Term, the Company shall promptly reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company.

6. Target Bonus. In addition to her Base Compensation, during the Term Executive shall be given the opportunity to earn an annual bonus (the "Bonus") of up to 40% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "Target Year") to be mutually agreed upon by the Executive and the Board or its compensation committee. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 6, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365. The determinations of the Board or its compensation committee with respect to Bonuses will be final and binding.

7. Intentionally omitted.

8. Intentionally omitted.

9. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in Section 10 below, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Term upon sixty (60) days' prior written notice for any reason or no reason.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in Section 10 below, Executive's employment shall terminate automatically upon his death. Subject to the obligations of the Company set forth in Section 10 below, in the event Executive is unable to perform his duties as a result of Disability during the Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

10. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability or Termination by Executive. In the event that Executive's employment hereunder is terminated during the Term by the Company for Cause, as a result of Executive's death or Disability, or voluntarily by Executive without Good Reason, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: on the date of termination, the Company shall pay Executive a lump sum amount equal to (i) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (ii) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (iii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination.

(b) Termination by Company Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, the Company shall compensate Executive as follows:

(i)on the date of termination, the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and,

provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, the Company shall pay Executive the Base Compensation for nine (9) months from the date of termination, the potential Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such nine (9) month period following the termination and any benefits (or benefits reimbursement payments) pursuant to Section 5 herein that the Executive is or would be eligible for during such nine (9) month period. Without limiting the foregoing, Executive also shall be entitled to the severance benefits set forth under Section 10(c) below.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 10(a) or 10(b) herein to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause at any time within twelve (12) months prior to the consummation of a Change of Control if, prior to, or as of such termination, a Change of Control transaction was Pending (as defined in Section 10(d) below) at any time during such twelve (12)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time upon or within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i)on the date of termination (except as specified in clause (C)), the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination;

(ii)on the date of termination, the Company shall pay to Executive a lump sum amount equal to nine (9) months of Executive's Base Compensation then in effect as of the day of termination, the maximum Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period;

(iii)notwithstanding any provision of any stock incentive plan, stock option agreement, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares and equity awards held by Executive that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending (as defined in Section 10(d) below) or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv)Severance benefits under this Section 10(c) and Section 10(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

In order to effectuate the provisions of Section 10(c)(iii) hereof, in the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, no equity award held by Executive shall expire or terminate prior to the earlier to occur of (a) ten (10) years after the date of the award and (b) fifteen (15) months after Executive's termination of employment with the Company.

(d) Definition of "Pending." For purposes of Section 10(c) herein, a Change of Control transaction shall be deemed to be "Pending" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction; or (C) a third party has publicly announced, through a filing with the Securities and Exchange Commission, its intent to commence a tender offer or similar transaction to acquire 50% or more of the outstanding voting interests of the Company.

11. Code Section 409A.

(i)The parties agree that this Agreement shall be interpreted to comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder to the extent applicable (collectively "Code Section 409A"), and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Code Section 409A. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Code Section 409A or any damages for failing to comply with Code Section 409A.

(ii)A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits considered "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered nonqualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (i) the expiration of the six (6)-month period measured from the date of such "separation from service" of Executive, and (ii) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 13.7(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed on the first business day following the expiration of the Delay Period to Executive in a lump sum, and any remaining payments and

benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(iii)With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits, to be provided in any other taxable year, provided, that, this clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense occurred.

(iv)For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within thirty (30) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

12. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing delivered to Executive, at or prior to such Change of Control, to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a Change of Control. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by contract, operation of law or otherwise.

13. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given (a) when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or (b) three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

14. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales

techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit B, and incorporated herein by this reference.

15. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered Area. For the purpose of this Section 15 (a), (i) "Competing Business" means the current business of the Company and (ii) "Covered Area" means all geographical areas of the United States and other foreign jurisdictions where Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly traded, so

long as ownership of such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

(b) Non-Solicitation. Executive further agrees that during the Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by Executive of his covenants and agreements set forth herein. Accordingly, Executive agrees and acknowledges that any such violation of this Section 15 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to seek injunctive relief against the breach of this Section 15 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

16. Employment Relationship. Executive's employment with the Company will be "at will," meaning that either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time-to-time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

17. Miscellaneous Provisions.

(a) Survival. Sections 1, 5, 6, 10, 11, 13, 14, 15 and 17 herein, including this Section 17(a), shall survive the termination of Executive's employment with the Company, the expiration of this Agreement and the termination of this Agreement for any reason.

(b) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Entire Agreement. This Agreement supersedes, amends and restates all prior agreements and understandings between the parties, oral or written, including, without limitation, the Executive Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(g) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(h) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

Cardiff Oncology, Inc.

By: /s/ Mark Erlander

Name: Mark Erlander

Title: Chief Executive Officer

EXECUTIVE:

/s/ Brigitte Lindsay
Brigitte Lindsay

Exhibit A

Form of Release Agreement

Exhibit B

Confidentiality and Inventions Agreement

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Cardiff Oncology, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-239464, 333-238623, 333-234442, and 333-233568), Form S-3 (Nos. 333-232321, 333-229693) and Form S-8 (Nos. 333-239725 and 333-232363) of Cardiff Oncology, Inc. (the “Company”) of our report dated February 25, 2021, relating to the financial statements which appears in this Annual Report form 10-K.

/s/ BDO USA, LLP

San Diego, California
February 25, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Mark Erlander, certify that:

1. I have reviewed this annual report on Form 10-K of Cardiff Oncology, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

2/25/2021

/s/ Mark Erlander

Mark Erlander
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Brigitte Lindsay, certify that:

1. I have reviewed this annual report on Form 10-K of Cardiff Oncology, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

2/25/2021

/s/ Brigitte Lindsay

Brigitte Lindsay
VP, Finance (Principal Financial and Accounting Officer)

Exhibit 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

In connection with the Annual Report of Cardiff Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark Erlander, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

2/25/2021

/s/ Mark Erlander

Mark Erlander
Chief Executive Officer (Principal Executive Officer)

Exhibit 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

In connection with the Annual Report of Cardiff Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brigitte Lindsay, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

2/25/2021

/s/ Brigitte Lindsay

Brigitte Lindsay
VP, Finance (Principal Financial and Accounting Officer)