

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, 2019

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

**TROVAGENE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**11055 Flintkote Avenue, San Diego, California**

(Address of principal executive offices)

**27-2004382**

(I.R.S. Employer Identification No.)

**92121**

(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 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 \$2.50 per share, which was the last sale price of the common stock as of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was \$13,552,560.

As of February 20, 2020, 10,209,587 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.

## PART I

### ITEM 1. BUSINESS

We are a clinical-stage, oncology therapeutics company, taking a precision medicine approach to target cancers that are in need of new treatment options including KRAS-mutated metastatic colorectal cancer (“mCRC”), metastatic castrate-resistant prostate cancer (“mCRPC”) and acute myeloid leukemia (“AML”). 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 (formerly known as PCM-075), 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, a PLK1 inhibitor, from Nerviano Medical Sciences S.r.l. (“Nerviano”), the largest oncology research and development company in Italy 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. The Polo-like Kinase family consists of 5 members (PLK1-PLK5) and they are involved in multiple functions in cell division, including the regulation of centrosome maturation, checkpoint recovery, spindle assembly, cytokinesis, apoptosis and many others. PLK1 plays a crucial role in the regulation of mitotic checkpoints. The over-expression of PLK1 can lead to immature cell division with aneuploidy, a hallmark of cancer. PLK1 is over-expressed in a wide variety of hematologic and solid tumor malignancies including colorectal, prostate, lung, breast, as well as leukemias and lymphomas. In addition, several studies have shown that over-expression of PKL1 correlates with poor prognosis.

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

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. 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 three 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 (ClinicalTrials.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.

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 shown preclinical antitumor activity as a single agent and synergy (interaction of discrete drugs such that the total effect is greater than the sum of the individual effects) in combination with numerous different chemotherapeutics and targeted therapies, such as Zytiga® (abiraterone acetate), Avastin® (bevacizumab), Camptosa® (irinotecan), Gemzar® (gemcitabine), Beleodaq® (belinostat), Venclexta® (venetoclax), quizartinib (AC220), a development stage FLT3 inhibitor, Taxol® (paclitaxel), and Velcade® (bortezomib) in AML, mCRPC, mCRC and other hematologic and solid tumor cancers.

On October 18, 2017, we announced results of preclinical research indicating potential synergy of onvansertib with abiraterone acetate in C4-2 prostate cancer cells. This synergy assessment study was conducted by Dr. Michael Yaffe M.D., Ph.D. FACS, and David H. Koch Professor of Biology and Biological Engineering at Massachusetts Institute of Technology (“MIT”). The results appeared to indicate that the combination of onvansertib with Zytiga® (abiraterone) decreased cell

viability in mCRPC tumor cells and the apparent synergy observed was greater than the expected effect of combining the two drugs. Zytiga® is indicated for use in combination with prednisone for the treatment of patients with mCRPC who have received prior chemotherapy containing docetaxel. We believe there is an unmet medical need to improve on the resistance to hormone therapy and extend the benefit of response to abiraterone for mCRPC patients.

On April 23, 2019, we announced results of preclinical research demonstrating synergy of onvansertib in combination with Venclexta® (venetoclax) in a cell model of venetoclax-resistance AML. The data further supports our ongoing onvansertib clinical development program in patients with relapsed or refractory AML. We believe there is an opportunity to treat patients, who have relapsed following first-line treatment with venetoclax, with onvansertib in combination with a hypomethylating agent such as decitabine or azacytadine.

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. PLK1 uniquely phosphorylates translational control tumor protein (“TCTP”) to form pTCTP and inhibition of this enzymatic activity by onvansertib appears to be predictive of patient response to treatment.

### **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 mCRPC and mCRC.

### **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.

This ongoing Phase 1b/2 clinical study is being 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.

### **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.

Pharmacokinetics of onvansertib and correlative biomarker activity will be 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. Doses of onvansertib will be administered orally each day on Days 1-5, in a 21-28-day cycle in both Phase 1b and Phase 2.

In 2019, we completed the Phase 1b segment of this trial and began enrolling patients in Phase 2. 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, including CRC and AML. We are using our Precision Cancer Medicine™ (“PCM™”) technology to measure PLK1 enzymatic activity to potentially identify patients most likely to respond to onvansertib and to measure patient therapy response. The TCTP is phosphorylated by PLK1 at residue serine 46 (pTCTP) and has been shown to be a specific marker of PLK1 activity in-vivo in preclinical models. In our ongoing clinical trial in AML, we validated that pTCTP and TCTP are present and can be detected by capillary Western-Blot (“WB”) in peripheral blood mononuclear cells (“PBMC”) isolated from healthy donors and AML patients, 24-hours after blood collection. As an exploratory objective of the Phase 1b segment of the trial, we are assessing the extent of PLK1 inhibition by onvansertib in patients receiving treatment and plan to use this information and methodology going forward in the Phase 2 continuation trial, and beyond. 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 are highly predictive of radiographic response observed as tumor regression.

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 oncology therapeutics company developing targeted therapies to treat leukemias, lymphomas and solid tumor cancers, our objective is to optimize drug development by using our proprietary PCM™ expertise and biomarker strategy as part of our approach.

Our laboratory in San Diego, California, enables us to use our technology platform 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 oncology therapeutics 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 leukemias, lymphomas and solid tumor cancers.

There have been several drug candidates in this class of targeted oncology therapeutics to enter clinical trials; however, we believe onvansertib is the only 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<sub>50</sub>) 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.

We believe the efficacy of PLK1 inhibition in AML has already been shown in the proof-of-concept trial of volasertib. Therefore, onvansertib's highly-selective activity, oral dosing and short half-life could enable favorable efficacy and safety with potential survival benefits in AML patients with relapsed/refractory disease or newly-diagnosed disease and ineligible for intensive induction therapy.

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<sup>®</sup>. 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<sup>®</sup> in the second-line treatment setting. This study is on file at ClinicalTrials.gov with the Identifier NCT03829410. As such, we have three active IND applications in place with the FDA, one with the hematologic division and two with the solid tumor division. This enables us to quickly initiate additional clinical trials of our drug candidate, onvansertib, in leukemias, lymphomas and solid tumor cancers.

## **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 time lines. We believe that there is significant research potential for our PCM™ technology to be incorporated into these clinical trial protocols, and ultimately into post-approval patient identification protocols.

## **Our Business Strategy**

We are a clinical-stage, oncology therapeutics company, taking a precision medicine approach to target cancers with a need for new treatment options, including KRAS-mutated mCRC, mCRPC and AML. 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 drugs that target mitosis (cell division) to treat a variety of cancers and associated indications.

Our intellectual property and proprietary technology enables us to analyze ctDNA and clinically actionable markers for predicting response to cancer therapies.

## **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, 2019 and 2018 were approximately \$11.2 million and \$8.2 million, respectively.

## **Intellectual Property**

We consider the protection of our proprietary technologies and products, as well as our ability to maintain patent protection intended to cover the composition of matter of our product candidates, their methods of use, and other related technology and inventions, to be a critical element in the success of our business. As of December 31, 2019, our wholly-owned and licensed intellectual property included 62 issued patents and 13 pending patent applications in the U.S. and abroad. The pending applications include multiple international applications filed under the Patent Cooperation Treaty ("PCT applications") that may be used as the basis for multiple additional patent applications.

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 technology, 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 related to onvansertib grants us exclusive, worldwide licenses under a portfolio of patents covering three broad areas: (1) Directed to onvansertib, related compounds and processes for making compounds; pharmaceutical compositions and methods of treating diseases characterized by dysregulated protein kinase activity; (2) Directed to salts and pharmaceutical compositions of onvansertib; methods of treating mammals in need of PLK inhibition; and (3) Directed to synergistic combinations of onvansertib and one or more of a broad range of antineoplastic agents, and pharmaceutical compositions of those combinations. Members of this patent group expire between 2026 and 2029.

On October 11, 2017, we entered into a Patent Option Agreement with MIT for the exclusive rights to negotiate a royalty-bearing, limited-term exclusivity license to practice world-wide patent rights to US Patent 9,566,280, subject to the rights of MIT (research, testing, and educational purposes), Ortho McNeil Pharmaceuticals-Janssen Pharmaceuticals and its Affiliates (internal research and pre-clinical drug development purposes including some laboratory research) and the federal



government (government-funded inventions claimed in any patent rights and to exercise march in rights). This patent is generally directed to combination therapies including an antiandrogen or androgen antagonist and polo-like kinase inhibitor for the treatment of cancer.

On September 19, 2018, we entered into an Exclusive Patent License Agreement with MIT for combination therapy for anti-androgens and Polo-like kinase inhibitors in prostate cancer. The patent agreement covers the rights to develop combination therapies and identified predictive clinical biomarkers across cancer types, expanding potential indications for onvansertib. Under the agreement, Trovogene has exclusive rights to develop combination therapies that include 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.

On January 23, 2019, we announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer*, by the U.S. Patent and Trademark Office (“USPTO”). This patent broadens previously issued patent (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.

Another group of patents and patent applications are directed to various methods relating to detecting nucleic acid sequences in urine and nucleic acid modifications and alterations in urine; detecting and monitoring cancer through urine-based testing, nucleic acid screening, and monitoring in cases of transplantation and infectious diseases, detecting specific gene mutations and indicators of disease (including NPM1 mutations). Applications are also pending to protect proprietary methods of collecting, extracting, detecting and enriching small concentrations of short nucleic acid sequences, and detecting and monitoring mutations in diseases, such as cancer, over time. Members of this patent group expire between 2021 and 2036.

Wherever possible, we seek to protect our inventions by filing U.S. patents as well as foreign counterpart applications in select other 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 technology 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 supplier 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 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 manufacturers' 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. Since January 2017, President Trump has 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, which suggests that it could demonstrate survival benefits in relapsed or refractory AML patients without the adverse events that have prohibited the advancement of other PLK1 inhibitors. 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 hematologic and solid tumor cancers.

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 - with the first patient treated in August, 2019.

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 rogosertib - Oncova, a non-targeted broad-spectrum multi-kinase inhibitor (RAF, PI3K, PLK), evaluated for pancreatic cancer and Myelodysplastic Syndrome ("MDS"), which failed a Phase 3 trial in MDS. Currently, Oncova is testing an IV formulation of rogosertib in high-risk MDS patients. CY140 - Cyclacel, a PLK1, 2, 3 inhibitor, is currently in preclinical studies for the treatment of esophageal cancer.

## Employees

As of February 20, 2020, we had a total of 14 employees, 12 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 Trovogene, Inc. In May 2012, our common stock was listed on The Nasdaq Capital Market under the ticker symbol TROV. Our corporate website address is [www.trovogeneoncology.com](http://www.trovogeneoncology.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.trovogeneoncology.com](http://www.trovogeneoncology.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.

## 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 development stage company and may never earn a profit.***

We are a development stage company and have incurred losses since our formation. As of December 31, 2019, we have an accumulated total deficit of approximately \$208.9 million. For the fiscal years ended December 31, 2019 and 2018, we



had a net loss attributable to common stockholders of approximately \$16.7 million and \$19.3 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, 2019, our cash and cash equivalents balance was approximately \$10.2 million and our working capital was approximately \$6.6 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 financial statements include an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern, indicating the possibility that we may not be able to operate in the future.***

Primarily as a result of our losses incurred to date, our expected continued future losses, and limited cash balances, we have included an explanatory paragraph in our financial statements expressing substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing.

***Our product candidate, onvansertib, is in the early stages of 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 Thomas H. Adams, Ph.D., our Chairman and Chief Executive Officer (“CEO”). The loss of services of Dr. Adams 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 than 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, 2019. 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.

***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.

***We may become subject to federal and state tax assessments, penalties and interest with respect to past compensation paid to certain of our executives.***

During our internal review process, contingencies were identified regarding various federal and state tax exposures with respect to past compensation paid to certain of our executives. We have not recorded any accrued liabilities related to the potential federal and state tax exposure. If we become subject to any material tax assessment, penalties and interest by federal and state tax authorities in the future, our results of operations, financial performance and cash flows could be materially adversely affected.

***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. Since January 2017, President Trump has 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.

### **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**

***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.

***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, 2019, the closing price of our common stock ranged from a low of \$1.01 to a high of \$4.85. 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; 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.***

Our common stock is traded on The Nasdaq Capital Market and could be considered “thinly-traded,” meaning that the number of investors interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. 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.***

On September 7, 2018, we received a letter from Nasdaq indicating that, based upon our continued non-compliance with the Minimum Bid Price Rule, our common stock would be subject to delisting unless we requested a hearing before a Nasdaq Hearings Panel. We timely requested a hearing before the Panel which was held on November 8, 2018. On November 15, 2018, we announced that the Panel granted our request for continued listing on The Nasdaq Capital Market, subject to effecting a reverse stock split of our common stock and evidencing a closing bid price of over \$1.00 for at least 10

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consecutive trading days. On February 12, 2019, we announced 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 remain subject to a Nasdaq Panel Monitor until March 10, 2020.

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.

**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. The Company (as a sublessor) also subleases portions of its facility to third parties under two 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 "TROV" since May 30, 2012.

**Number of Stockholders**

As of February 20, 2020, we had approximately 57 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**

The following table summarizes information about our equity compensation plans as of December 31, 2019.

	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options, Warrants and Rights <sup>(1)</sup>	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity Compensation Plans Approved by Stockholders	1,014,665	\$ 12.60	167,888
Equity Compensation Plans Not Approved by Stockholders <sup>(2)</sup>	753	\$ 240.96	—
<b>Total</b>	<b>1,015,418</b>		<b>167,888</b>

(1) Total excludes 11,301 non-vested restricted stock units.

(2) Represents the following options to purchase common stock granted on November 17, 2010: (i) an option to purchase 463 shares with an exercise price of \$216.00 per share, (ii) an option to purchase 174 shares with an exercise price of \$324.00 per share, and (iii) an option to purchase 116 shares with an exercise price of \$216.00 per share. All the options were vested in full on the date of grant and will expire on November 17, 2020.

**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, oncology therapeutics company, taking a Precision Cancer Medicine™ ("PCM™") approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including prostate, colorectal and leukemia. By integrating a biomarker strategy into our development programs, we will be able to identify patients more likely to respond to treatment.

On March 15, 2017, we announced that we licensed onvansertib, a PLK1 inhibitor, from Nerviano, pursuant to a license agreement with Nerviano 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 was developed to have high selectivity to PLK1 (at low nanomolar IC<sub>50</sub> levels), 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 has been successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs*.

We currently have three active clinical trials: a Phase 2 open-label clinical trial of onvansertib in combination with abiraterone acetate (Zytiga<sup>®</sup>) and prednisone in patients with mCRPC, being conducted at Beth Israel Deaconess Medical Center ("BIDMC"), Dana-Farber Cancer Institute ("DFCI"), and Massachusetts General Hospital ("MGH"); a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI and Avastin<sup>®</sup> in patients with mCRC with a KRAS mutation, being conducted at USC Norris Comprehensive Cancer Center and The Mayo Clinic; and a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy in patients with AML, being conducted at eight sites across the U.S.

Onvansertib is a first-in-class, third-generation, oral and highly-selective PLK1 inhibitor with demonstrated antitumor activity in different preclinical models. Polo-like kinase family consists of 5 members (PLK1-PLK5) and they are involved in multiple functions in cell division, including the regulation of centrosome maturation, checkpoint recovery, spindle assembly, cytokinesis, apoptosis and many others. PLK1 is essential for the maintenance of genomic stability during cell division. The over-expression of PLK1 can lead to immature cell division followed by aneuploidy and cell death, a hallmark of cancer. PLK1 is over-expressed in a wide variety of leukemias/lymphomas and solid tumor cancers, including acute myeloid leukemia, non-Hodgkin lymphoma, prostate, lung, breast, ovarian, colorectal and adrenocortical carcinoma. In addition, several studies have shown that over-expression of PLK1 is associated with poor prognosis. Blocking the expression of PLK1 by kinase inhibitors, such as onvansertib, can effectively inhibit growth of, and induce, tumor cell death.

Studies have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in AML where response rates with a prior PLK inhibitor of up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine ("LDAC")) versus a 13.3% response rate with LDAC alone. We believe the more selective nature 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 useful in addressing clinical therapeutic needs across a variety of cancers.

Onvansertib has been tested in-vivo in different xenograft and transgenic models suggesting tumor growth inhibition or tumor regression when used in combination with other therapies. Onvansertib has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an IC<sub>50</sub> (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC<sub>50</sub> 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.

In in-vitro and in-vivo preclinical studies, synergy (interaction of discrete drugs such that the total effect is greater than the sum of the individual effects) has been demonstrated with onvansertib when used in combination with numerous different chemotherapies, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, as well as targeted therapeutics, such as abiraterone acetate (Zytiga<sup>®</sup>), histone deacetylase ("HDAC") inhibitors, such as belinostat (Beleodaq<sup>®</sup>), quizartinib (AC220), a development stage FLT3 inhibitor, and bortezomib (Velcade<sup>®</sup>). These therapies are used clinically for the treatment of leukemias, lymphomas and solid tumor cancers, including AML, Non-Hodgkin Lymphoma ("NHL"), mCRPC, mCRC, and Triple Negative Breast Cancer ("TNBC").

We achieved a number of key milestones throughout 2019 and anticipate achieving additional milestones through the end of 2020:

*Phase 2 Trial of Onvansertib in Combination with Abiraterone Acetate (Zytiga<sup>®</sup>) and Prednisone for the Treatment of Metastatic Castration-Resistant Prostate Cancer*

- Initiated enrollment and evaluation of 3 safety lead-in patients in the second arm (2-week dosing schedule) with onvansertib at 18 mg/m<sup>2</sup> in combination with abiraterone acetate (Zytiga) and prednisone.
- Provide safety and preliminary efficacy data of onvansertib in combination with abiraterone acetate (Zytiga<sup>®</sup>) and prednisone in patients treated through the end of 2019 and into 2020.



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- Presented data from the mCRPC trial at key oncology conferences throughout 2019, including the Asia-Pacific Prostate Cancer Conference ("APPC"), and first quarter of 2020 including ASCO-GU.

### *Phase 1b/2 Trial of Onvansertib in Combination with FOLFIRI and Bevacizumab (Avastin®) for Second-Line Treatment of Metastatic Colorectal Cancer with a KRAS Mutation*

- Completed enrollment and evaluation of the initial dose level cohort of onvansertib 12 mg/m<sup>2</sup> and fully enrolled the second dose level (onvansertib 15 mg/m<sup>2</sup>) cohort.
- Presented data from the mCRC trial at key oncology conferences throughout 2019, including the European Society for Medical Oncology ("ESMO"), and first quarter of 2020 including ASCO-GI.

### *Phase 1b/2 Trial of Onvansertib in Combination with Either Low-Dose Cytarabine or Decitabine for the Treatment of Acute Myeloid Leukemia*

- Completed Phase 1b dose escalation safety segment of trial, identified the recommended Phase 2 dose ("RP2D") of onvansertib at 60mg/m<sup>2</sup>.
- Initiated the Phase 2 segment of the AML trial, which will enroll approximately 32 patients, for continued evaluation of safety and efficacy of onvansertib in combination with decitabine.
- Presented data from the AML trial at key oncology conferences, including the European Society for Medical Oncology ("ESMO") and the American Society of Hematology ("ASH") annual meetings.

During 2019, we advanced our business with the following activities:

- Announced positive data presented in an oral session at the American Society of Hematology ("ASH") conference response to treatment in patients with acute myeloid leukemia.

On December 9, 2019, we announced the presentation of data demonstrating efficacy, durability of response and safety of onvansertib from the completed Phase 1b segment of the ongoing trial in acute myeloid leukemia, in an oral session at ASH. Efficacy was observed in patients treated at onvansertib doses ranging from 27 to 90 mg/m<sup>2</sup>, with a complete response (CR) and CR with incomplete count recovery (Cri) rate of 31% (5 out of 16 patients). Treatment was well tolerated; adverse events related to onvansertib were primarily on-target hematological (based on mechanism of action) and were easily managed and reversible. Biomarker positive patients showed a higher response to treatment; 67% (4 out of 6) patients had marked decreases in bone marrow blast cells vs only 18% (1 out of 11) biomarker negative patients.

- Announced data showing the ability of onvansertib to rescue patients previously treated with, and resistant to, venetoclax in acute myeloid leukemia.

On December 4, 2019, we announced data showing the ability of onvansertib to rescue venetoclax-resistant AML patients. Patients develop resistance to venetoclax in approximately 11 months following the start of treatment with no viable therapeutic options and a median survival of only 1.7 to 2.3 months and a poor prognosis. Onvansertib as a single agent inhibits tumor growth in both venetoclax-resistant in-vitro and in-vivo AML models. The combination of onvansertib and venetoclax is synergistic, which supports the addition of onvansertib to venetoclax in venetoclax-resistant AML patients.

- Announced positive response to treatment in Phase 2 trial of onvansertib in patients with metastatic castration-resistant prostate cancer.

On November 14, 2019, we announced data demonstrating positive response to treatment in patients enrolled in our Phase 2 trial of onvansertib in combination with Zytiga (abiraterone acetate) in patients with mCRPC. 72% of patients had decreases in PSA levels with the addition of onvansertib following 1 cycle of treatment. 60% of patients completing 3 months of treatment and evaluable for efficacy achieved the primary endpoint of disease control.

- Announced positive response to treatment in Phase 1b/2 trial of onvansertib in patients with KRAS-mutated metastatic colorectal cancer.

On October 22, 2019, we announced data demonstrating positive response to treatment in patients enrolled in our Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin (bevacizumab) for second-line treatment of KRAS-mutated mCRC. Decreases in tumor KRAS mutational burden in response to treatment with onvansertib was observed in all four patients who completed their first cycle of therapy, as measured by quantitative analysis of circulating tumor DNA (ctDNA).

- Announced data presented at ESMO providing rationale for a clinical trial of onvansertib in subset of patients with Highly-Aggressive Triple Negative Breast Cancer (TNBC).

On October 2, 2019, we announced the presentation of data in a poster at ESMO demonstrating significant tumor regression observed with onvansertib in combination with standard-of-care paclitaxel in models of p53-mutated TNBC. Onvansertib preclinical data provides rationale for conducting a clinical trial targeting the 80% of TNBC that harbors the p53 mutation. The combination has potential to address critical medical need to provide targeted treatment option to overcome resistance to paclitaxel as single agent therapy in TNBC.

- Announced presentation of a poster at ESMO of Phase 1b/2 trial of onvansertib in patients with KRAS-mutated mCRC.

On October 1, 2019, we announced the presentation of a poster at ESMO providing an overview of our Phase 1b/2 trial in metastatic Colorectal Cancer, to assess the safety and efficacy of onvansertib in combination with FOLFIRI and Avastin<sup>®</sup> (bevacizumab) in KRAS-mutated mCRC. Approximately 50% of patients harbor the KRAS mutation; current standard-of-care therapy has only a 5% response rate. Biomarker data demonstrates ability to assess patient response to therapy within one week of treatment with onvansertib.

- Announced oral presentation of positive data from Trovagen Phase 1b/2 AML Study of onvansertib at ESMO Conference.

On September 30, 2019, we announced positive data from our Phase 1b/2 trial in AML which was presented in an oral plenary session at the ESMO conference. The data showed that administration of onvansertib in combination with standard-of-care chemotherapy is safe and well-tolerated and resulted in anti-leukemic activity that appears to be sustainable over time. There is a strong correlation between biomarker positive patients and treatment response; observed in 6 of 9 biomarker positive patients versus 1 of 11 biomarker negative patients. Phase 2 is open to enrolling 32 patients for treatment with onvansertib at the recommended dose of 60 mg/m<sup>2</sup>, in combination with decitabine, to further assess safety and efficacy of the regimen.

- Announced Successful Completion of the AML Phase 1b Trial and Initiation of the Phase 2 Continuation Trial.

On September 19, 2019, we announced the successful completion of our Phase 1b trial in AML and the initiation of patient enrollment in Phase 2. The Phase 1b dose escalation clinical trial confirmed safety, preliminary efficacy and identified the recommended phase 2 dose of onvansertib. Complete response (CR + CRi) was achieved in 5 of 21 patients treated with onvansertib in combination with decitabine. Phase 2 will treat 32 patients with onvansertib + decitabine; eligible patients will have relapsed after receiving up to one prior therapy including patients who have developed resistance to first-line treatment with venetoclax.

- Announced the Presentation of Positive Clinical Data from Ongoing Phase 2 Study of Onvansertib in mCRPC at the Asia-Pacific Prostate Cancer Conference.

On August 26, 2019, we announced findings from our Phase 2 trial in mCRPC that leads to the discovery that onvansertib stops the rise in PSA in patients with treatment-resistant, highly-aggressive and difficult-to-treat androgen-receptor variant 7 ("AR-V7") tumors. Data demonstrates efficacy of onvansertib in patients showing early signs of resistance to androgen receptor signaling ("ARS") inhibitor, Zytiga<sup>®</sup>. The addition of onvansertib appears to extend the duration of response to ARS inhibitor therapy in this incurable and lethal cancer.

- Announced research collaboration with Nektar Therapeutics to evaluate the efficacy of the combination of onvansertib and ONZEALD<sup>™</sup> in models of colorectal cancer.

On May 23, 2019, we announced we entered into a research collaboration agreement with Nektar Therapeutics to explore the combination of our PLK1 inhibitor, onvansertib, and Nektar's topoisomerase I inhibitor, ONZEALD, for the treatment of mCRC. Under the collaboration, the two companies will evaluate the antitumor activity and tolerability of the combination of onvansertib and ONZEALD in two (HT29 - BRAF mutant and HCT-116 - KRAS mutant) preclinical tumor models of colorectal cancer.

- Announced Data Demonstrating Significant Synergy of Onvansertib in Combination with Venetoclax in Cell Model of Venetoclax-Resistant AML.

On April 23, 2019, we announced preclinical data that evaluated the effect of combining onvansertib with venetoclax in an AML cell model known to be resistant to venetoclax (Venclexta® - AbbVie). This combination demonstrated synergy (the combined effect of the two drugs is greater than the sum of their individual effects) with a significant decrease in tumor cell viability. This data provides support for clinical evaluation of onvansertib in combination with venetoclax in patients with difficult-to-treat relapsed/refractory AML, for which there are limited treatment options and the prognosis is poor.

- Announced New Patent Issued for Combination of Onvansertib with Anti-Androgen Drugs to Treat Non-Metastatic and Metastatic Prostate Cancer.

On January 23, 2019, we announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer*, by the U.S. Patent and Trademark Office ("USPTO"). This patent broadens previously issued patent (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 accumulated deficit through December 31, 2019 is \$208,897,883. 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

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. 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.

### *Royalty and License Revenues*

We license and sublicense our 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 we have no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is probable.

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- Minimum royalties are recognized as earned, and royalties are earned based on the licensee's use. We estimate and record 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*

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 Trovogene'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, 2019 and 2018, the fair value of such warrants was \$4,127 and \$32,315, 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, 2019, 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, 2019 and 2018**

##### **Revenues**

Our total revenues were \$244,632 and \$378,325 for the years ended December 31, 2019 and 2018, respectively. Total revenues consisted of the following:

	For the years ended December 31,		
	2019	2018	Increase/(Decrease)
Royalty income	\$ 243,137	\$ 250,453	\$ (7,316)
Service revenue	1,495	127,872	(126,377)
<b>Total revenues</b>	<b>\$ 244,632</b>	<b>\$ 378,325</b>	<b>\$ (133,693)</b>

The decrease in service revenue for the year ended December 31, 2019 as compared to the prior period is primarily from the disposition of our CLIA laboratory. We expect our royalties to fluctuate as the royalties are sales-based or usage-based royalties on our intellectual property license. Revenue recognition of royalty income depends on the timing and overall sales activities of the licensees.

### **Cost of Revenue**

Our total cost of revenue was \$0 in the year ended December 31, 2019, as compared to \$597,457 in the year ended December 31, 2018. Cost of revenues relates to the costs of our service revenues. The decrease in cost of revenues compared to the same period of last year is mainly due to the disposition of our CLIA laboratory. We do not expect any cost of revenue based on our current business model.

### **Research and Development Expenses**

Research and development expenses consisted of the following:

	For the years ended December 31,		
	2019	2018	Increase/(Decrease)
Salaries and staff costs	\$ 1,585,381	\$ 1,652,071	\$ (66,690)
Stock-based compensation	399,687	752,127	(352,440)
Clinical trials, outside services, and lab supplies	8,250,313	4,744,448	3,505,865
Facilities and Other	926,855	1,015,365	(88,510)
<b>Total research and development expenses</b>	<b>\$ 11,162,236</b>	<b>\$ 8,164,011</b>	<b>\$ 2,998,225</b>

Research and development expenses increased by \$2,998,225 to \$11,162,236 for the year ended December 31, 2019 from \$8,164,011 for the year ended December 31, 2018. The overall increase in research and development expenses was primarily due to the increased clinical trials and outside service costs for three ongoing clinical trials related to the development of our drug candidate, onvansertib. We expect an increase in research and development costs as we advance the development of onvansertib.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses consisted of the following:

	For the years ended December 31,		
	2019	2018	Increase/(Decrease)
Salaries and staff costs	\$ 1,955,305	\$ 2,797,588	\$ (842,283)
Stock-based compensation	485,256	1,392,012	(906,756)
Outside services and professional fees	1,986,039	2,091,657	(105,618)
Facilities and other	1,334,290	1,724,326	(390,036)
<b>Total selling, general and administrative</b>	<b>\$ 5,760,890</b>	<b>\$ 8,005,583</b>	<b>\$ (2,244,693)</b>

Selling, general and administrative expenses decreased by \$2,244,693 to \$5,760,890 for the year ended December 31, 2019, from \$8,005,583 for the year ended December 31, 2018. The significant components of the decrease were primarily due to the decrease in salaries and staff costs, stock-based compensation, and facilities costs. The decreased salaries and staff costs for the year ended December 31, 2019 as compared to the same period of 2018, was due to decreased headcount in 2019, and a one-time executive severance expense occurring in the second quarter of 2018. The decreased stock-based compensation

related to one-time employee stock option grants in lieu of cash bonuses occurring in January 2018, these options were immediately expensed. Our selling, general and administrative costs may increase in future periods in order to support financing and general business activities as we continue to develop and introduce new product offerings.

### **Restructuring**

In May 2018, we closed our CLIA laboratory operations in order to streamline our business model. The loss recognized from disposition of the CLIA laboratory was reported as restructuring charges in the December 31, 2018 financial statements. For the year ended December 31, 2018, we recorded total restructuring charges of approximately \$664,000, the majority of which was related to loss on sublease of office and laboratory space.

### **Interest Income and Expense**

Interest income was \$234,169 and \$219,430 for the years ended December 31, 2019 and 2018, respectively. The increase of interest income is primarily due to a higher average money market fund balance and higher average interest rates during 2019 as compared to 2018. Interest expense was \$0 and \$25,409 for the years ended December 31, 2019 and 2018, respectively. The decrease of interest expense is resulting from pay-off of our Equipment Line of Credit.

### **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, 2019, the derivative financial instruments—warrants liabilities related to securities issued, and were revalued to \$4,127, resulting in a decrease in fair value of \$28,188 from December 31, 2018 based primarily upon the change in our stock price from \$3.15 at December 31, 2018 to \$1.24 at December 31, 2019, and the changes in the expected term, volatility and risk-free interest rates for the expected term. The decrease in value was recorded as non-operating gain for the year ended December 31, 2019.

### **Net Loss**

Net loss and per share amounts were as follows:

	For the years ended December 31,		
	2019	2018	Increase/(Decrease)
Net loss attributable to common stockholders	\$ (16,706,668)	\$ (19,254,951)	\$ (2,548,283)
Net loss per common share — basic and diluted	\$ (2.80)	\$ (8.26)	\$ (5.46)
Weighted-average shares outstanding — basic and diluted	5,973,906	2,330,180	3,643,726

The \$2,548,283 decrease in net loss attributable to common shareholders was primarily the result of a decrease in Series B deemed dividend expense of \$2,769,533, and a decrease in operating expenses of \$508,611 offset by a decrease in gain from change in fair value of derivative financial instruments—warrants of \$588,884 for the for the year ended December 31, 2019 as compared to the same period of 2018. The \$5.46 decrease in basic and diluted net loss per share was impacted by the decrease in net loss attributable to shareholders and the increase in basic weighted average shares outstanding resulting primarily from the sales of approximately 3.9 million shares of common stock and common stock equivalents through public and direct offerings, issuance of approximately 0.5 million shares of common stock upon exercise of warrants, and 0.3 million shares of common stock upon conversion of Series C Convertible Preferred Stock.

## Liquidity and Capital Resources

As of December 31, 2019, we had \$10,195,292 in cash and cash equivalents. Net cash used in operating activities for the year ended December 31, 2019 was \$13,267,500, compared to \$13,199,013 for the year ended December 31, 2018. Our use of cash was primarily a result of the net loss of \$16,414,159 for the year ended December 31, 2019, adjusted for items mainly related to stock-based compensation of \$884,943, release of clinical trial funding commitment of \$703,327, and depreciation and amortization of \$494,232. The changes in our operating assets and liabilities consisted primarily of higher accounts payable and accrued expenses. At our current and anticipated levels of operating losses, we expect to continue to incur an operating cash outflow for the next several years. As of December 31, 2019 and 2018, we had working capital of \$6,571,985 and \$9,841,947, respectively. The decrease in working capital is primarily due to the decrease in cash and cash equivalents and an increase in accrued liabilities.

Net cash (used)/provided by investing activities was \$(67,622) and \$22,842 for the years ended December 31, 2019 and 2018, respectively. Investing activities during the year ended December 31, 2019 consisted primarily of the purchase of capital equipment of \$67,622, while investing activities during the year ended December 31, 2018 consisted primarily of cash provided by disposal of capital equipment of \$27,942.

Net cash provided by financing activities was \$12,077,281 during the year ended December 31, 2019, compared to \$16,403,540 provided in financing activities during the year ended December 31, 2018. Financing activities during the year ended December 31, 2019 related primarily to sales of Common Stock, Warrants and proceeds from exercise of warrants. Financing activities during the year ended December 31, 2018 related primarily to sales of Common Stock and Series B Convertible Preferred Stock and proceeds from exercise of warrants, offset by the pay-off of our Equipment Line of Credit.

Based on our current business plan and assumptions, we expect to continue to incur significant losses and require significant additional capital to further advance our clinical trial programs and support our other operations. Considering our current cash resources, we believe our existing resources will be sufficient to fund our planned operations into third quarter of 2020. In addition, we have based our cash sufficiency estimates on our current business plan and assumptions that may prove to be wrong. We could utilize our available capital resources sooner than we currently expect, and we could need additional funding to sustain our operations even sooner than currently anticipated. These circumstances raise substantial doubt about our ability to continue as a going concern.

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 Offering and Public Offerings*

On May 27, 2016 we filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, debt securities, warrants, or units having an aggregate initial offering price not exceeding \$250,000,000. The preferred stock, debt securities, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other securities. This Registration Statement was declared effective on June 13, 2016. Gross proceeds of \$2.4 million from the sale of 5,859 shares of our common stock at a weighted-average price of \$403.92 under a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. as sales agent (the "Agent") have been raised since the date of effectiveness of the Form S-3 on June 13, 2016.

On March 15, 2017, we filed a supplement to our Form S-3 registration statement to offer and sell additional shares of our common stock having an aggregate offering price up to \$20,698,357 through the Agent. Gross proceeds of approximately \$0.1 million were raised in 2017 through the Controlled Equity Offering Agreement with the Agent.

On June 12, 2018, we closed an underwritten public offering (“June 2018 underwritten public offering”) consisting of (i) 1,523,333 shares of common stock, (ii) warrants to purchase an aggregate of 3,450,000 shares of common stock, including the over-allotment option for 450,000 option warrants, at an exercise price of \$6.60 per share, expiring on June 12, 2023, and (iii) 8,860 shares of Series B Convertible Preferred Stock with a stated value of \$1,000. The net proceeds to us were approximately \$16.2 million. In March 2019 we received approximately \$3.3 million in proceeds from the exercise of approximately 497,000 warrants under the June 2018 underwritten public offering.

On January 25, 2019, we entered into a Master Services Agreement and a Stock and Warrant Subscription Agreement with PoC Capital, LLC (“PoC”), whereby PoC has agreed to finance \$1.7 million in clinical studies, including the development costs associated with Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® in patients with mCRC harboring KRAS mutation in exchange for (i) 183,334 shares of common stock, (ii) 200,000 shares of Series C Convertible Preferred Stock, each share of which is convertible into 1.67 shares of common stock, and (iii) warrants to purchase 150,000 shares of common stock with an exercise price of \$3.762 per share, expiring on January 25, 2024. Any clinical costs in excess of the financed amount will be our responsibility. PoC will not make payments to us, but directly to the contract research organization based on their invoices.

On April 4, 2019, we entered into a Securities Purchase Agreement with Lincoln Park Capital Fund, LLC (“LPC”), gross proceeds were approximately \$1.5 million. The April 2019 Securities Purchase Agreement consisted of (i) 382,166 shares of common stock (including pre-funded warrants) at a purchase price of \$3.925 per share and (ii) 382,166 Series B Warrants with an exercise price of \$3.80 per share, expiring on October 5, 2024. None of the Series B Warrants have been exercised as of February 20, 2020.

On May 10, 2019, we entered into a Securities Purchase Agreement with LPC, gross proceeds were approximately \$1.5 million. The May 2019 Securities Purchase Agreement consisted of (i) 458,015 shares of common stock (including pre-funded warrants) at a purchase price of \$3.275 per share and (ii) 458,015 Series D Warrants with an exercise price of \$3.15 per share, expiring on November 12, 2024. None of the Series D Warrants have been exercised as of February 20, 2020.

On August 20, 2019, we entered into a Securities Purchase Agreement with LPC, gross proceeds were approximately \$1.5 million. The August 2019 Securities Purchase Agreement consisted of (i) 727,802 shares of common stock (including pre-funded warrants) at a purchase price of \$2.061 per share and (ii) 727,802 Series F Warrants with an exercise price of \$1.936 per share, expiring on February 24, 2025. None of the Series F Warrants have been exercised as of February 20, 2020.

On October 30, 2019, we closed a private placement with certain institutional investors for gross proceeds of approximately \$5.0 million. We sold an aggregate of (i) 2,756,340 shares of common stock (including pre-funded warrants) at a purchase price of \$1.814 per share, (ii) 2,756,340 Series G Warrants with an exercise price of \$1.56 per share, expiring on April 30, 2025, (iii) 2,756,340 Series H Warrants with an exercise price of \$1.56 per share, expiring on April 30, 2021, and (iv) 206,726 Placement Agent Warrants at an exercise price of \$2.2675 per share, expiring on April 30, 2025. None of the Series G or Placement Agent Warrants have been exercised as of February 20, 2020. We received net proceeds of approximately \$1.5 million from the exercise of 1,005,072 Series H Warrants on January 27, 2020.

#### *Nasdaq Notice*

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.

On March 6, 2018, Nasdaq informed us that we were eligible for an additional 180 calendar day period until September 4, 2018 to regain compliance with the minimum \$1.00 bid price per share requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for at least ten consecutive business days during this 180 calendar day period.

On September 7, 2018, we received a letter from Nasdaq indicating that, based upon our continued non-compliance with the Minimum Bid Price Rule, our common stock would be subject to delisting unless we requested a hearing before a Nasdaq Hearings Panel. We timely requested a hearing before the Panel which was held on November 8, 2018. On November 15, 2018, we announced that the Panel granted our request for continued listing on The Nasdaq Capital Market,



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subject to effecting a reverse stock split of our common stock and evidencing a closing bid price of over \$1.00 for at least 10 consecutive trading days. On February 12, 2019, we announced 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 remain subject to a Nasdaq Panel Monitor until March 10, 2020.

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.

### Contractual Obligations and Commitments

The following table is a summary of contractual obligations that existed as of December 31, 2019, and is based on information appearing in the notes to Financial Statements included elsewhere in this Annual Report on Form 10-K.

	Payments Due by period				
	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	\$ 1,842,835	\$ 865,379	\$ 974,033	\$ 3,423	\$ —
Total obligations	\$ 1,842,835	\$ 865,379	\$ 974,033	\$ 3,423	\$ —

### 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, 2019. 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, 2019 and 2018. 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 the 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, 2019 and 2018.

#### Effects of Inflation

We do not believe that inflation and changing prices during the years ended December 31, 2019 and 2018 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, 2019. 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, 2019, 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, 2019, 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, 2019 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****Executive Officers, Directors and Key Employees**

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each as of February 20, 2020.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Thomas H. Adams, Ph.D.	77	Chief Executive Officer and Chairman of the Board
Mark Erlander, Ph.D.	60	Chief Scientific Officer
John Brancaccio	71	Director
Gary S. Jacob, Ph.D.	72	Director
Dr. Rodney S. Markin, M.D., Ph.D.	63	Director

All directors hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers serve at the discretion of the board.

**Executive Biographies**

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows:

**Thomas H. Adams, Ph.D. - Chairman and Chief Executive Officer**

Dr. Adams has served as Chairman of the Board since April 2009 and as our Chief Executive Officer since June 2018. He is currently a Director at Hepion Pharmaceuticals, Inc. where he has served since 2014. Previously, Dr. Adams served as Chairman of Clearbridge BioPhotonics, Inc., an imaging solutions company, from 2013 to 2019, and as Director of Synergy Pharmaceuticals, Inc. from 2009 to 2019. He served in several leadership roles at IRIS International, including Director, Head of Personalized Medicine and Chief Technology Officer, from 2005 until the company's acquisition by Danaher Corporation in 2012. From 1998 to 2006, Dr. Adams was Chairman and Chief Executive Officer of Leucadia Technologies, a privately held biotechnology company which was acquired by IRIS International, Inc. in 2006. Dr. Adams founded Genta, Inc. in 1989 and served as its Chief Executive Officer until 1997. He also founded Gen-Probe, Inc. in 1984 and served as Chairman and Chief Executive Officer until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Dr. Adams holds a Ph.D. in Biochemistry from the University of California, Riverside. The Board believes that Dr. Adams' executive leadership and the extensive healthcare expertise he has developed qualifies Dr. Adams to serve as a director of our company.

**Mark Erlander, Ph.D. - Chief Scientific Officer**

Dr. Erlander has served as our Chief Scientific Officer since March 2013. Prior to his current assignment, he was Chief Scientific Officer at bioTheragnostics, a subsidiary of bioMérieux, a molecular diagnostic testing company focused on clinical applications in oncology, where he served from 2008 to 2013. From 2000 to 2008, Dr. Erlander was Chief Scientific Officer at Arcturus, Inc. (later AviraDx), which was acquired by bioMérieux in 2008. Dr. Erlander entered therapeutics as a Group Leader and then Research Fellow in drug discovery at Johnson & Johnson from 1994 to 2000. From 1991 to 1994, Dr. Erlander was a Postdoctoral Fellow and then Assistant Professor at Scripps Research. He has 44 issued patents, over 50 pending applications, and has co-authored over 90 scientific publications. Dr. Erlander holds a B.S. in Biochemistry from the University of California, Davis, an M.S. degree in Biochemistry from Iowa State University, and a Ph.D. in Neuroscience from the University of California, Los Angeles.

**John Brancaccio - Independent Director**

Mr. Brancaccio, a retired CPA, has been a Director since December 2005. Mr. Brancaccio currently serves on the boards of Rasna Therapeutics, Inc. since 2016, Hepion Pharmaceuticals, Inc. since 2013, and Tamir Biotechnology, Inc. (formerly Alfacell Corporation) since 2004. Previously, Mr. Brancaccio served as Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies from 2004 until his retirement in 2017. The Board believes Mr. Brancaccio's experience as a chief financial officer provides valuable financial and accounting expertise that qualifies him to serve as a director of our company.

**Gary S. Jacob, Ph.D. - Independent Director**

Dr. Jacob has been a Director since February 2009. He is Chief Executive Officer of Immuron Limited, an Australian public biotechnology company, where he has served since November 2018 and has been Chairman of Hepion Pharmaceuticals, Inc. since 2013. From 2008 to 2017, Dr. Jacob served as President and Chief Executive Officer of Synergy Pharmaceuticals, Inc. and as Chairman from 2013 to 2018. In December of 2018, Synergy Pharmaceuticals, Inc. filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code. Dr. Jacob served as Chief Executive Officer of Callisto Pharmaceuticals, Inc. from 2003 to 2013 and as Director from 2004 until its merger with Synergy Pharmaceuticals, Inc. in 2013. The Board believes Dr. Jacob's broad management expertise in the pharmaceutical and biotechnology industry provides relevant experience in a number of strategic and operational areas that qualifies him to serve as a director of our company.

**Dr. Rodney S. Markin, M.D., Ph.D. - Independent Director**

Dr. Markin has been a Director since February 2014. He is currently Vice President for Network Development, Nebraska Medicine and Associate Vice Chancellor for Business and Executive Director of the UNeTech Institute at the University of Nebraska Medical Center, a public center of health sciences research, patient care, and education, where he has served since July 1985. Dr. Markin also serves concurrently as Courtesy Professor of Psychiatry and Courtesy Professor of Surgery at the University of Nebraska and David T. Purtilo Distinguished Professor of Pathology and Microbiology since 2005 and Professor of Pathology and Microbiology. He serves on the boards of Perceptimed Inc. since 2014, MikroScan Technologies Inc. since 2015, Afaxys Inc. since 2017, and Paradigm Diagnostics Inc. since 2018. In the non-profit sector, Dr. Markin serves as a Director of Children's Hospital and Medical Center Foundation and as Trustee for Keck Graduate Institute, and the Make-A-Wish Foundation, since 2015. Previously, Dr. Markin served as Chief Technology Officer and Associate Vice Chancellor for Business Development at the University of Nebraska from 2011 to 2017, and as Director of Transgenomic, Inc. from 2007 to 2014. The Board believes Dr. Markin's medical insight, board experience and executive experience in institutional healthcare qualifies him to serve as a director of our company.

**Family Relationships and Other Arrangements**

There are no family relationships among our directors and executive officers. There are no arrangements or understandings between or among our executive officers and directors pursuant to which any director or executive officer was or is to be selected as a director or executive officer.

**Board Leadership Structure and Role in Risk Oversight**

From April 2009 to June 2018, we separated the roles of Chairman of the Board ("Chairman") and Chief Executive Officer. Although the separation of roles has been appropriate for us during this time period, in the view of the Board, the advisability of the separation of these roles depends upon the specific circumstances and dynamics of our leadership.

The Board, as a unified body and through committee participation, organizes the execution of its monitoring and oversight roles and does not expect its Chairman to organize those functions.

The Board has three standing committees-Audit, Compensation and Corporate Governance/Nominating. The membership of each of the committees of the Board is comprised of independent directors, with each of the committees having a chairman, each of whom is an independent director. Our non-management members of the Board meet in executive session at each regular Board meeting.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of the risks we face, while the Board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the Board is responsible for satisfying itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The Board believes that establishing the right “tone at the top” and that full and open communication between executive management and the Board are essential for effective risk management and oversight. Our CEO communicates frequently with members of the Board to discuss strategy and challenges facing our company. Senior management usually attends our regular quarterly Board meetings and is available to address any questions or concerns raised by the Board on risk management-related and any other matters. Each quarter, the Board receives presentations from senior management on matters involving our key areas of operations.

### **Audit Committee**

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The Audit Committee’s responsibilities include, among other things: (i) selecting and retaining an independent registered public accounting firm to act as our independent auditors, setting the compensation for our independent auditors, overseeing the work done by our independent auditors and terminating our independent auditors, if necessary, (ii) periodically evaluating the qualifications, performance and independence of our independent auditors, (iii) pre-approving all auditing and permitted non-audit services to be provided by our independent auditors, (iv) reviewing with management and our independent auditors our annual audited financial statements and our quarterly reports prior to filing such reports with the SEC, including the results of our independent auditors’ review of our quarterly financial statements, and (v) reviewing with management and our independent auditors significant financial reporting issues and judgments made in connection with the preparation of our financial statements. The Audit Committee also prepares the Audit Committee report that is required to be included in our annual proxy statement pursuant to the rules of the SEC.

As of December 31, 2019, the Audit Committee consisted of John P. Brancaccio, chairman of the Audit Committee, Dr. Rodney S. Markin and Dr. Athena Countouriotis, who resigned from the Board on January 24, 2020. Dr. Jacob replaced Dr. Countouriotis as a member of the Audit Committee in 2020. Under the applicable rules and regulations of Nasdaq, each member of a company’s audit committee must be considered independent in accordance with Nasdaq Listing Rule 5605(c)(2)(A)(i) and (ii) and Rule 10A-3(b)(1) under the Exchange Act. The Board has determined that each of Mr. Brancaccio, Dr. Markin, Dr. Jacob and Dr. Countouriotis is “independent” as that term is defined under applicable Nasdaq and SEC rules. Mr. Brancaccio is our audit committee financial expert. The Board has adopted a written charter setting forth the authority and responsibilities of the Audit Committee, which is available on our website at <http://trovageneoncology.investorroom.com/> under “Corporate Governance”.

### **Compensation Committee**

The purpose of the Compensation Committee is to discharge the Board’s responsibilities relating to compensation of our directors and executive officers. The Compensation Committee has responsibility for, among other things, (i) recommending to the Board for approval the overall compensation philosophy for our company and periodically reviewing the overall compensation philosophy for all employees to ensure it is appropriate and does not incentivize unnecessary and excessive risk taking, (ii) reviewing annually and making recommendations to the Board for approval, as necessary or appropriate, with respect to our compensation plans, (iii) based on an annual review, determining and approving, or at the discretion of the Compensation Committee, recommending to the Board for determination and approval, the compensation and other terms of employment of each of our officers, (iv) reviewing and making recommendations to the Board with respect to the compensation of directors, (v) overseeing our regulatory compliance with respect to compensation matters, (vi) reviewing and discussing with management, prior to the filing of our annual proxy statement or annual report on Form 10-K, our disclosure relating to executive compensation, including our Compensation Discussion and Analysis and executive and director compensation tables as required by SEC rules, and (vii) preparing an annual report regarding executive compensation for inclusion in our annual proxy statement or our annual report on Form 10-K. The Compensation Committee has the power to form one or more subcommittees, each of which may take such actions as may be delegated by the Compensation Committee.

The charter of the Compensation Committee grants the Compensation Committee authority to select, retain, compensate, oversee and terminate any compensation consultant to be used to assist in the evaluation of director, chief executive officer, officer and our other compensation and benefit plans and to approve the compensation consultant’s fees and other retention terms. The Compensation Committee is directly responsible for the appointment, compensation and oversight of the work of any internal or external legal, accounting or other advisors and consultants retained by the Compensation

Committee. The Compensation Committee may also select or retain advice and assistance from an internal or external legal, accounting or other advisor as the Compensation Committee determines to be necessary or advisable in connection with the discharge of its duties and responsibilities and will have the direct responsibility to appoint, compensate and oversee any such advisor. During the past year, the Compensation Committee engaged Marsh & McLennan Agency LLC (“Marsh & McLennan”) as a compensation consultant.

As of December 31, 2019, the Compensation Committee consisted of Dr. Rodney S. Markin, chairman of the Compensation Committee, Dr. Gary S. Jacob and John Brancaccio. The Board has determined that all of the members are “independent” under Nasdaq Listing Rule 5605(a)(2). The Board has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee, which is available on our website at <http://trovagineoncology.investorroom.com/> under “Corporate Governance”.

### **Corporate Governance/Nominating Committee**

The Corporate Governance/Nominating Committee has responsibility for assisting the Board in, among other things, (i) effecting Board organization, membership and function, including identifying qualified board nominees, (ii) effecting the organization, membership and function of the committees of the Board, including the composition of the committees of the Board and recommending qualified candidates for the committees of the Board, (iii) evaluating and providing successor planning for the chief executive officer and our other executive officers, (iv) identifying and evaluating candidates for director in accordance with certain general and specific criteria, (v) developing and recommending to the Board Corporate Governance Guidelines and any changes thereto, setting forth the corporate governance principles applicable to us, and overseeing compliance with the Corporate Governance Guidelines, and (vi) reviewing potential conflicts of interest involving directors and determining whether such directors may vote on issues as to which there may be a conflict. The Corporate Governance/Nominating Committee is responsible for identifying and evaluating candidates for director. Potential nominees are identified by the Board based on the criteria, skills and qualifications that are deemed appropriate by the Corporate Governance/Nominating Committee. The Corporate Governance/Nominating Committee believes that candidates for director should have certain minimum qualifications, including high character and integrity, an inquiring mind and vision, willingness to ask hard questions, ability to work well with others, freedom from conflicts of interest, willingness to devote sufficient time to the Company’s affairs, diligence in fulfilling his or her responsibilities and the capacity and desire to represent the best interests of the Company and our stockholders as a whole and not primarily a special interest group or constituency. While our nominating criteria does not prescribe specific diversity standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, difference in viewpoints and skills, and personal qualities that will result in a well-rounded Board.

As of December 31, 2019, the Corporate Governance/Nominating Committee consisted of Dr. Rodney S. Markin, chairman of the Corporate Governance/Nominating Committee, Mr. John Brancaccio, and Dr. Athena Countouriotis, who resigned from the Board on January 24, 2020. The Board has determined that all of the members are “independent” under Nasdaq Listing Rule 5605(a)(2). The Board has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee, which is available on our website at <http://trovagineoncology.investorroom.com/> under “Corporate Governance”.

### **Code of Business Conduct and Ethics**

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, officers and employees. Our Code of Business Conduct and Ethics can be found on our website ([www.trovagineoncology.com](http://www.trovagineoncology.com)). A copy of our Code of Business Conduct and Ethics may be obtained without charge upon written request to Secretary, Trovagine, Inc., 11055 Flintkote Avenue, San Diego, California 92121. If we make any substantive amendments to our Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website ([www.trovagineoncology.com](http://www.trovagineoncology.com)) and/or in our public filings with the SEC.

### **Corporate Governance Guidelines**

The Board has adopted Corporate Governance Guidelines, which are designed to help us achieve our goals, govern us with high standards of integrity and increase stockholder value. These Corporate Governance Guidelines provide a framework for the conduct of the Board’s business.

The Corporate Governance Guidelines also set forth the practices our Board will follow with respect to Board composition and selection, Board meetings and Board committees and Chief Executive Officer performance evaluation and compensation. Our Corporate Governance Guidelines can be found on our website ([www.trovageneoncology.com](http://www.trovageneoncology.com)).

### Hedging and Pledging Policies

As part of our Insider Trading Policy, all of our officers, all of our directors, certain of our employees and consultants and family members or others sharing a household with any of the foregoing are prohibited from engaging in short sales of our securities, any hedging or monetization transactions involving our securities and in transactions involving puts, calls or other derivative securities based on our securities. Our Insider Trading Policy further prohibits such persons from purchasing our securities on margin, borrowing against any account in which our securities are held or pledging our securities as collateral for a loan unless pre-cleared by our Insider Trading Compliance Officer. As of February 20, 2020, none of our directors or executive officers had pledged any shares of our common stock.

## ITEM 11. EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Principal Executive Officer and our other highest paid executive officer whose total annual salary and bonus exceeded \$100,000 (collectively, the “named executive officers”) for fiscal year 2019.

Name and Principal Position	Year	Salary (\$)	Non-Equity Incentive Plan Compensation (\$) <sup>(1)</sup>	Option Awards (\$) <sup>(2)</sup>	Stock Awards (\$) <sup>(3)</sup>	Total (\$)
Thomas H. Adams, CEO	2019	491,132	244,625	568,877	—	1,304,634
	2018	286,346 <sup>(4)</sup>	79,167	11,679 <sup>(5)</sup>	—	377,192
Mark Erlander, CSO	2019	398,729	198,600	255,622	—	852,951
	2018	387,155	342,576	144,008	34,785	908,524

(1) The amounts in this column relate to bonuses earned by the Named Executive Officers in 2019 and 2018.

(2) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts represent the aggregate grant date fair value of stock option awards determined in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 718. The valuation assumptions used in determining 2019 and 2018 amounts are described in Note 6 to our financial statements included in our Annual Reports on Form 10-K for the fiscal years ended December 31, 2019 and 2018. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options on the date the options are exercised.

(3) This reflects the grant date fair value of awards granted during fiscal years ended December 31, 2019 and 2018.

(4) Of this amount, \$60,000 was the compensation paid for non-employee director service in 2018.

(5) Stock option awards were granted for non-employee director service in 2018.

### Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options and RSU's as well as the exercise prices and expiration dates thereof, as of December 31, 2019. Except for the options and RSU's set forth in the table below, no other equity awards were held by any our named executive officers as of December 31, 2019.

Name	Option Awards <sup>(1)</sup>				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (\$)
Thomas H. Adams	4,219	—	216.00	8/5/2021		
	98	—	237.60	1/26/2022		
	175	—	499.68	2/14/2023		
	272	—	447.84	2/25/2024		
	223	—	516.96	3/17/2025		
	223	—	372.96	1/4/2026		
	530	—	51.84	10/4/2027		
	755	—	21.60	1/23/2028		
	—	298,230	2.48	6/20/2029		
Mark Erlander	70	—	204.48	9/13/2022	521	646
	139	—	350.64	12/10/2022	1,250	1,550
	2,778	—	506.88	1/28/2023		
	1,389	—	398.16	12/11/2023		
	2,778	—	236.88	7/16/2024		
	834	—	316.08	12/11/2024		
	2,040	44	372.96	1/4/2026		
	5,348	—	61.20	8/22/2027		
	7,948	1,388	21.60	1/23/2028		
—	134,203	2.48	6/20/2029			

(1) For each executive officer, the shares listed in this table are subject to a single stock option award carrying the varying exercise prices as set forth herein. The option awards remain exercisable until they expire ten years from the date of grant, subject to earlier expiration following termination of employment.

### Director Compensation

Under our non-employee director compensation policy, a new non-employee director receives an initial grant of options to purchase a number of shares of common stock equal to 0.1% of our shares of common stock issued and outstanding as of the date of grant (subject to adjustment for recapitalizations, stock split, stock dividends and the like). In addition, each non-employee director receives the following annual compensation for his or her service: (i) an annual retainer fee of \$50,000, payable quarterly, and an equity grant of options to purchase a number of shares of common stock equal to 0.1% of shares of our common stock issued and outstanding as of the date of grant (subject to adjustment for recapitalizations, stock split, stock dividends and the like), all of which vest on the one year anniversary of the date of grant, (ii) an additional annual retainer fee of \$40,000, payable quarterly, if such non-employee director serves as the Chairman of the Board of Directors, (iii) an additional annual retainer fee of \$16,000, \$10,000 and \$8,000 payable quarterly, if such non-employee director serves as the chair of the Audit Committee, Compensation Committee or Nominating/Corporate Governance Committee, respectively, and (iv) an additional annual retainer fee of \$8,000, \$6,000 and \$4,000 to such non-employee director if he or she serves as a non-chair member of the Audit Committee, Compensation Committee and Nominating/Corporate Governance Committee, respectively, per committee. We also reimburse all of our directors for out-of-pocket expenses incurred in connection with the rendering of services as a director.

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2019 for services to our company.



Name	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(1)</sup>	Total (\$)
John Brancaccio <sup>(2)</sup>	76,000	83,963	159,963
Gary S. Jacob <sup>(3)</sup>	56,000	83,963	139,963
Rodney S. Markin <sup>(4)</sup>	76,000	83,963	159,963
Athena Countouriotis <sup>(5)</sup>	62,000	83,963	145,963

(1) Amounts shown in this column do not reflect dollar amounts actually received by our non-employee directors. Instead, these amounts represent the aggregate grant date fair value of stock option awards determined in accordance with FASB ASC Topic 718. The valuation assumptions used in determining 2019 amounts are described in Note 6 to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Our non-employee directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options on the date the options are exercised.

(2) As of December 31, 2019, 47,806 stock options were outstanding, of which 3,072 were exercisable.

(3) As of December 31, 2019, 47,376 stock options were outstanding, of which 2,642 were exercisable.

(4) As of December 31, 2019, 46,969 stock options were outstanding, of which 2,235 were exercisable.

(5) As of December 31, 2019, 46,019 stock options were outstanding, of which 1,109 were exercisable. Dr. Countouriotis resigned from the Board on January 24, 2020.

## Employment Agreements

### *Mark Erlander Employment Agreement*

On February 18, 2016, we entered into an employment agreement with Dr. Erlander (the “Erlander Employment Agreement”). The term of the Erlander Employment Agreement commenced on February 18, 2016 and will continue until January 1, 2020, following which time the Erlander Employment Agreement will be automatically renewed for successive one year periods at the end of each term, unless either party delivers written notice to the other party of their intent to not renew the agreement. Pursuant to the Erlander Employment Agreement, Dr. Erlander’s base compensation, as of December 31, 2019, was \$397,201 per year. Dr. Erlander is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria.

If Dr. Erlander’s employment is terminated by us for cause or as a result of Dr. Erlander’s death or permanent disability, or if Dr. Erlander terminates his employment agreement voluntarily, Dr. Erlander will be entitled to receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus earned but not yet paid through the date of his termination, and (iii) all business expenses reasonably and necessarily incurred by Dr. Erlander prior to the date of termination. If Dr. Erlander’s employment is terminated by us without cause or by Dr. Erlander for good reason, Dr. Erlander will be entitled to receive the amounts due upon termination of his employment by us for cause or as a result of his death or permanent disability, or upon termination by Dr. Erlander of his employment voluntarily, in addition to (provided that Dr. Erlander executes a written release with respect to certain matters) a severance payment equal to his base compensation for 12 months from the date of termination and the bonus and any benefits that Dr. Erlander would be eligible for during such 12 month period. In addition, if Dr. Erlander’s employment is terminated: (a) by us without cause within 12 months prior to a change of control (as defined in the Erlander Employment Agreement) that was pending during such 12 month period, (b) by Dr. Erlander for good reason within 12 months after a change of control, or (c) by us without cause at any time upon or within 12 months after a change of control, Dr. Erlander will be entitled to receive the amounts due upon termination of his employment by us for cause or as a result of his death or permanent disability, or upon termination by Dr. Erlander of his employment voluntarily, in addition to the severance payments due if Dr. Erlander’s employment is terminated by us without cause or by Dr. Erlander for good reason, and all of Dr. Erlander’s unvested stock options and other equity awards would immediately vest and become fully exercisable (x) in the event a change of control transaction is pending, for a period of six months following the date of termination, and (y) in the event a change of control transaction is not then pending, for the period of time set forth in the applicable agreement evidencing the award.

**Potential Payments Upon Termination Or Change In Control**

Other than the provisions of the executive severance benefits to which our named executive officers would be entitled to at December 31, 2019 as set forth above, we have no liabilities under termination or change in control conditions. We do not have a formal policy to determine executive severance benefits. Each executive severance arrangement is negotiated on an individual basis.

The table below estimates the current value of amounts payable to our named executive officer in the event that a termination of employment occurred on December 31, 2019. The closing price of our common stock, as reported on The Nasdaq Capital Market, was \$1.24 on December 31, 2019. The following table excludes certain benefits, such as accrued vacation, that are available to all employees generally. The actual amount of payments and benefits that would be provided can only be determined at the time of a change in control and/or the named executive officer's qualifying separation from our Company.

**Mark Erlander**

	Termination	
	By Trovogene Without Cause Outside a Change In Control	By Trovogene Without Cause or by Dr. Erlander for Good Reason in Connection with a Change In Control <sup>(1)</sup>
Value of Equity Securities Accelerated	\$ —	\$ 118,764
Cash Payments	397,201	397,201
<b>Total Cash Benefits and Payments</b>	<b>\$ 397,201</b>	<b>\$ 515,965</b>

(1) Relates to the termination of the Erlander Employment Agreement: (a) by us without cause within 12 months prior to a change of control that was pending during such 12 month period, (b) by Dr. Erlander for good reason within 12 months after a change of control, or (c) by us without cause at any time upon or within 12 months after a change of control.

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

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of February 20, 2020 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers, and (iv) all of our directors and executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Name of Beneficial Owner (1)	Shares of Common Stock Beneficially Owned	Percentage (2)
<b>Executive officers and directors:</b>		
Thomas H. Adams	11,384 <sup>(3)</sup>	*
John Brancaccio	5,339 <sup>(4)</sup>	*
Gary S. Jacob	4,711 <sup>(5)</sup>	*
Rodney S. Markin	9,416 <sup>(6)</sup>	*
Athena Countouriotis	1,109 <sup>(7)</sup>	*
Mark Erlander	30,438 <sup>(8)</sup>	*
All Officers and Directors as a Group (6 persons)	62,397 <sup>(9)</sup>	*

\*less than 1%

(1) The address of each person is c/o Trovogene, Inc., 11055 Flintkote Avenue, San Diego, CA 92121 unless otherwise indicated herein.

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- (2) The calculation in this column is based upon 10,209,587 shares of common stock outstanding on February 20, 2020. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or exercisable within 60 days of February 20, 2020 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.
- (3) Includes 6,495 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.
- (4) Includes 3,072 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.
- (5) Includes 2,642 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.
- (6) Includes 2,235 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.
- (7) Includes 1,109 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020. Dr. Countouriotis resigned from the Board on January 24, 2020.
- (8) Includes 24,062 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.
- (9) Includes 39,615 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after February 20, 2020.

### **Section 16(A) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2019, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

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

The following is a description of transactions or series of transactions since January 1, 2019, or any currently proposed transaction, to which we were or are to be a participant and in which the amount involved in the transaction or series of transactions exceeds \$120,000, and in which any of our directors, executive officers or persons who we know hold more than five percent of any class of our capital stock, including their immediate family members, had or will have a direct or indirect material interest, other than compensation arrangements with our directors and executive officers.

In November 2018, we 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 AML. Our CEO, Dr. Thomas Adams, is a principal stockholder of Leucadia. In connection with the MTA, we entered into a consulting agreement with Tommy Adams, VP of Operations of Leucadia, who is the son of Dr. Adams. During the years ended December 31, 2019 and 2018, we incurred and recorded approximately \$1,005,000 and \$183,000, respectively, of research and development expenses for services performed by Leucadia and Tommy Adams.

We have entered into indemnification agreements with our directors and executive officers under which we agreed to indemnify those individuals under the circumstances and to the extent provided for in the agreements, for expenses, damages, judgments, fines, settlements and any other amounts they may be required to pay in actions, suits or proceedings which they are or may be made a party or threatened to be made a party by reason of their position as a director, officer or other agent of ours, and otherwise to the fullest extent permitted under Delaware law and our By-Laws. We also have an insurance policy covering

our directors and executive officers with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or otherwise.

Our board has adopted a written related party transaction policy to set forth the policies and procedures for the review, approval and ratification of related party transactions. This policy covers any financial transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships (including any indebtedness or guarantee of indebtedness) in which we are or are to be a participant, the amount involved will or may be expected to exceed \$50,000 since the beginning of our last completed fiscal year, and a related party has or will have a direct or indirect material interest. A related party is any individual who is, or who has been since the beginning of our last fiscal year, an executive officer, director or nominee for election as a director, or any person known to be the record or beneficial owner of more than 5% of any class of our voting securities, any immediate family member of any of the foregoing persons or any entity which is owned or controlled by any of the foregoing persons, or any entity in which one of the foregoing persons has a substantial ownership interest in or control over such entity. Transactions involving the employment or compensation of our executive officers or compensation to our directors, transactions with another company at which a related party's only relationship is as a director and/or beneficial owner of less than 10% of such company's equity interests, transactions in which all of our stockholders receive proportional benefits, certain regulated transactions and certain banking-related services are not considered related-person transactions under this policy. Under our Audit Committee Charter and our related party transaction policy, our Audit Committee is responsible for reviewing and approving in advance any related party transaction. In connection with its review of a related party transaction, the Audit Committee will take into account, among other factors it deems appropriate, whether the related party transaction is on terms no less favorable than terms generally available to an unaffiliated third-party under the same or similar circumstances and the extent of the related party's interest in the related party transaction.

### Director Independence

Our Board has determined that a majority of the Board consists of members who are currently "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). The Board considers Drs. Jacob, Markin, and Mr. Brancaccio to be "independent".

## ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

### Audit and Non-Audit Fees

The aggregate fees billed to us by BDO, our independent registered public accounting firm, for the indicated services for each of the last two fiscal years were as follows:

	2019	2018
Audit fees (1)	\$ 339,507	\$ 226,646
Tax fees (2)	17,925	14,263
	<u>\$ 357,432</u>	<u>\$ 240,909</u>

(1) Audit fees consist of fees for professional services performed by BDO for the audit and review of our financial statements, preparation and filing of our registration statements, including issuance of comfort letters.

(2) Tax fees consist of fees for professional services performed by BDO with respect to tax compliance.

### Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our independent registered public accounting firm on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our independent registered public accounting firm.

**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Exhibit Number	Description of Exhibit
<b>(a)(1) Financial Statements</b>	
	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
<a href="#">3.1</a>	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).
<a href="#">3.2</a>	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).
<a href="#">3.3</a>	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Form 10-12G filed on November 25, 2011).
<a href="#">3.4</a>	Certificate of Amendment of 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 June 1, 2018).
<a href="#">3.5</a>	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).
<a href="#">3.6</a>	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).
<a href="#">3.7</a>	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).
<a href="#">3.8</a>	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).
<a href="#">4.1</a>	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).
<a href="#">4.2+</a>	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)
<a href="#">4.3</a>	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 28, 2012).
<a href="#">4.4</a>	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).
<a href="#">4.5+</a>	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).
<a href="#">4.6</a>	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on July 26, 2016).
<a href="#">4.7</a>	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on June 12, 2018).
<a href="#">4.8</a>	Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 29, 2019).
<a href="#">4.9</a>	Form of Series A Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on April 5, 2019).
<a href="#">4.10</a>	Form of Series B Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on April 5, 2019).
<a href="#">4.11</a>	Form of Series C Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on May 13, 2019).
<a href="#">4.12</a>	Form of Series D Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on May 13, 2019).
<a href="#">4.13</a>	Form of Series E Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 21, 2019).
<a href="#">4.14</a>	Form of Series F Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on August 21, 2019).
<a href="#">4.15</a>	Form of Series G, H and Pre-Funded Warrant and Placement Agent Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on October 28, 2019).

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<a href="#">4.16</a>	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
<a href="#">10.1</a>	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).
<a href="#">10.2</a>	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).
<a href="#">10.3</a>	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).
<a href="#">10.4</a>	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).
<a href="#">10.5</a>	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).
<a href="#">10.6</a>	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).
<a href="#">10.7</a>	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).
<a href="#">10.8+</a>	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).
<a href="#">10.9+</a>	Employment Agreement, dated February 18, 2016, by and between the Company and Mark Erlander (incorporated by reference to Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2016).
<a href="#">10.10</a>	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).
<a href="#">10.11*</a>	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).
<a href="#">10.12</a>	Stock and Warrant Subscription Agreement entered into as of January 25, 2019 by and between Trovagene, Inc. and PoC Capital, LLC (incorporated by reference to Exhibit 10.1 to Form 8-K filed on January 29, 2019).
<a href="#">10.13</a>	Securities Purchase Agreement dated April 4, 2019 by and between Trovagene, Inc. and the Purchaser (incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 5, 2019).
<a href="#">10.14</a>	Securities Purchase Agreement dated May 10, 2019 by and between Trovagene, Inc. and the Purchaser (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 13, 2019).
<a href="#">10.15</a>	Securities Purchase Agreement dated August 20, 2019 by and between Trovagene, Inc. and the Purchaser (incorporated by reference to Exhibit 10.1 to Form 8-K filed on August 21, 2019).
<a href="#">10.16</a>	Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 28, 2019).
<a href="#">10.17</a>	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to Form 8-K filed on October 28, 2019).
<a href="#">23.1</a>	Consent of BDO USA, LLP.
<a href="#">24</a>	Power of Attorney (included on signature page hereto).
<a href="#">31.1</a>	Certification of Principal Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
<a href="#">31.2</a>	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
<a href="#">32.1</a>	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.
<a href="#">32.2</a>	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.

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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.

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+ 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.

TROVAGENE, INC.

/s/ Thomas H. Adams

2/27/2020

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 Thomas H. Adams 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.

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Thomas H. Adams</u> Thomas H. Adams	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	2/27/2020
<u>/s/ Brigitte Lindsay</u> Brigitte Lindsay	VP, Finance (Principal Financial and Accounting Officer)	2/27/2020
<u>/s/ John Brancaccio</u> John Brancaccio	Director	2/27/2020
<u>/s/ Gary S. Jacob</u> Gary S. Jacob	Director	2/27/2020
<u>/s/ Rodney S. Markin</u> Rodney S. Markin	Director	2/27/2020



**TROVAGENE, INC.**  
**Index to Financial Statements**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-2</a>
<a href="#">Balance Sheets</a>	<a href="#">F-3</a>
<a href="#">Statements of Operations</a>	<a href="#">F-4</a>
<a href="#">Statements of Stockholders' Equity</a>	<a href="#">F-5</a>
<a href="#">Statements of Cash Flows</a>	<a href="#">F-6</a>
<a href="#">Notes to Financial Statements</a>	<a href="#">F-8</a>

## Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders  
Trovagene, Inc.  
San Diego, California

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Trovagene, Inc. (the “Company”) as of December 31, 2019 and 2018, 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, 2019 and 2018, 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.

### Change in Accounting Principle

As discussed in Note 2 of the financial statements, the Company has changed its method of accounting for leases during the year ended December 31, 2019 due to the adoption of Accounting Standards Codification Topic 842, *Leases*.

### Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### 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.

/s/ BDO USA, LLP

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

San Diego, California  
February 27, 2020

**Trovagene, Inc.**  
**Balance Sheets**

Assets	December 31, 2019	December 31, 2018
<b>Current assets:</b>		
Cash and cash equivalents	\$ 10,195,292	\$ 11,453,133
Accounts receivable and unbilled receivable	203,480	167,755
Prepaid expenses	954,957	1,144,377
Total current assets	11,353,729	12,765,265
Property and equipment, net	877,823	1,304,433
Operating lease right-of-use assets	697,418	—
Other assets	157,576	102,798
Total Assets	<u>\$ 13,086,546</u>	<u>\$ 14,172,496</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 656,304	\$ 664,840
Accrued liabilities	3,260,061	1,771,842
Deferred rent	—	486,636
Operating lease liabilities	865,379	—
Total current liabilities	4,781,744	2,923,318
Derivative financial instruments—warrants	4,127	32,315
Operating lease liabilities, net of current portion	860,963	—
Deferred rent, net of current portion	—	1,090,671
Other liabilities	128,368	42,000
Total liabilities	5,775,202	4,088,304
Commitments and contingencies (Note 11)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 20,000,000 shares authorized; 277,100 designated as Series A Convertible Preferred Stock; 60,600 shares outstanding at December 31, 2019 and December 31, 2018 with liquidation preference of \$606,000 at December 31, 2019 and December 31, 2018; 8,860 designated as Series B Convertible Preferred Stock; 0 shares outstanding at December 31, 2019 and 2018, respectively; 200,000 designated as Series C Convertible Preferred Stock; 0 shares outstanding at December 31, 2019 and December 31, 2018	60	60
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 8,593,633 and 3,831,879 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	8,312	7,742
Additional paid-in capital	217,172,528	202,267,605
Service receivables	(971,673)	—
Accumulated deficit	(208,897,883)	(192,191,215)
Total stockholders' equity	7,311,344	10,084,192
Total Liabilities and Stockholders' Equity	<u>\$ 13,086,546</u>	<u>\$ 14,172,496</u>

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

**Trovagene, Inc.**  
**Statements of Operations**

	Year Ended December 31,	
	2019	2018
Revenues:		
Royalties	\$ 243,137	\$ 250,453
Services	1,495	127,872
Total revenues	<u>244,632</u>	<u>378,325</u>
Costs and expenses:		
Cost of revenue	—	597,457
Research and development	11,162,236	8,164,011
Selling, general and administrative	5,760,890	8,005,583
Restructuring charges	—	664,686
Total operating expenses	<u>16,923,126</u>	<u>17,431,737</u>
Loss from operations	<u>(16,678,494)</u>	<u>(17,053,412)</u>
Interest income	234,169	219,430
Interest expense	—	(25,409)
Other gain (loss), net	1,978	(236,833)
Gain on extinguishment of debt	—	17,974
Gain from changes in fair value of derivative financial instruments—warrants	28,188	617,072
Net loss	<u>(16,414,159)</u>	<u>(16,461,178)</u>
Preferred stock dividend payable on Series A Convertible Preferred Stock	(24,240)	(24,240)
Deemed dividend recognized on beneficial conversion features of Series B Convertible Preferred Stock issuance	—	(2,769,533)
Deemed dividend recognized on beneficial conversion features of Series C Convertible Preferred Stock issuance	(268,269)	—
Net loss attributable to common stockholders	<u>\$ (16,706,668)</u>	<u>\$ (19,254,951)</u>
Net loss per common share — basic and diluted	<u>\$ (2.80)</u>	<u>\$ (8.26)</u>
Weighted-average shares outstanding — basic and diluted	<u>5,973,906</u>	<u>2,330,180</u>

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

**Trovagene, 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, January 1, 2018	60,600	\$ 60	733,217	\$ 5,279	\$ 179,546,954	\$ —	\$ (173,046,186)	\$ 6,506,107
Sale of common stock and warrants, net of expenses	—	—	1,523,333	914	11,778,611	—	—	11,779,525
Sale of Series B Convertible Preferred Stock, net of expenses	8,860	9	—	—	4,386,753	—	—	4,386,762
Stock-based compensation	—	—	—	—	2,174,627	—	—	2,174,627
Issuance of common stock upon exercise of warrants	—	—	78,917	569	1,612,098	—	—	1,612,667
Issuance of common stock upon vesting of restricted stock units	—	—	18,609	94	(94)	—	—	—
Deemed dividend recognized on beneficial conversion features of Series B Convertible Preferred Stock issuance	—	—	—	—	2,769,533	—	(2,769,533)	—
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(8,860)	(9)	1,476,667	886	(877)	—	—	—
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	—	—	1,136	—	—	—	—	—
Cumulative effect of change in accounting principle related to revenue recognition	—	—	—	—	—	—	109,922	109,922
Net loss	—	—	—	—	—	—	(16,461,178)	(16,461,178)
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

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

**Trovagene, Inc.**  
**Statements of Cash Flows**

	Year ended December 31,	
	2019	2018
<b>Operating activities</b>		
Net loss	\$ (16,414,159)	\$ (16,461,178)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of assets	—	362,949
Impairment loss	—	187,500
Depreciation and amortization	494,232	859,487
Stock-based compensation expense	884,943	2,174,627
Gain on extinguishment of debt	—	(17,974)
Deferred rent	—	59,206
Change in fair value of derivative financial instruments—warrants	(28,188)	(617,072)
Release of clinical trial funding commitment	703,327	—
Changes in operating assets and liabilities:		
Other assets	(54,778)	(23,755)
Accounts receivable and unbilled receivable	(35,725)	19,262
Prepaid expenses	115,459	21,451
Operating lease right-of-use assets	302,491	—
Accounts payable and accrued expenses	1,455,336	214,484
Operating lease liabilities	(776,806)	—
Other liabilities	86,368	22,000
Net cash used in operating activities	(13,267,500)	(13,199,013)
<b>Investing activities</b>		
Capital expenditures	(67,622)	(5,100)
Proceeds from disposals of capital equipment	—	27,942
Purchases of short-term investments	—	(31,500)
Sales of short-term investments	—	31,500
Net cash provided (used) by investing activities	(67,622)	22,842
<b>Financing activities</b>		
Proceeds from sale of common stock and warrants, net of expenses of \$158,678 and \$1,336,123 respectively	8,817,772	11,779,525
Proceeds from sales of Series B Convertible Preferred Stock, net of expenses of \$0 and \$497,617 respectively	—	4,386,762
Costs related to the clinical trial funding commitment	(40,000)	—
Proceeds from exercise of warrants	3,299,509	1,612,667
Repayments under equipment line of credit	—	(1,200,033)
Payment upon debt extinguishment	—	(175,381)
Net cash provided by financing activities	12,077,281	16,403,540
Net change in cash and cash equivalents	(1,257,841)	3,227,369
Cash and cash equivalents—Beginning of period	11,453,133	8,225,764
Cash and cash equivalents—End of period	\$ 10,195,292	\$ 11,453,133
Supplementary disclosure of cash flow activity:		
Cash paid for taxes	\$ 800	\$ 800
Cash paid for interest	\$ —	\$ 22,482
Supplemental disclosure of non-cash investing and financing activities:		
Preferred stock dividend payable on Series A Convertible Preferred Stock	\$ 24,240	\$ 24,240

	Year ended December 31,	
	2019	2018
Deemed dividend recognized for beneficial conversion features of Series B Convertible Preferred Stock issuance	\$ —	\$ 2,769,533
Deemed dividend recognized for beneficial conversion features of Series C Convertible Preferred Stock issuance	\$ 268,269	\$ —
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	\$ —
Common stock issued upon conversion of Series B Convertible Preferred Stock	\$ —	\$ 886
Common stock issued upon conversion of Series C Convertible Preferred Stock	\$ 33	\$ —

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

**Trovagene, Inc.**  
**Notes to Financial Statements**

**1. Business Overview and Going Concerns**

*Business Organization and Overview*

Trovagene, Inc. (“Trovagene” or the “Company”) headquartered in San Diego, California, is a clinical-stage, oncology therapeutics company, taking a Precision Cancer Medicine™ (“PCM™”) approach to develop drugs that target mitosis (cell division) to treat various types of cancer, including leukemias, lymphomas and solid tumors.

Trovagene’s intellectual property and proprietary technology enables the Company to analyze circulating tumor DNA (“ctDNA”) and clinically actionable markers. Unique to the Company’s clinical development plan, and a key component of its PCM™ approach, is the integration of predictive clinical biomarkers to identify patients most likely to respond to treatment.

*Going Concern Uncertainty*

Trovagene’s financial statements as of December 31, 2019 have been prepared under the assumption that Trovagene will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company’s ability to continue as a going concern.

The Company has incurred net losses since its inception and has negative operating cash flows. Management estimates that the Company’s current cash resources will be sufficient to fund the Company’s planned operations into third quarter of 2020. Based on its current business plan and assumptions, the Company expects to continue to incur significant losses and require significant additional capital to further advance its clinical trial programs and support its other operations. The Company has based its cash sufficiency estimates on its current business plan and its assumptions that may prove to be wrong. The Company could utilize its available capital resources sooner than it currently expects, and it could need additional funding to sustain its operations even sooner than currently anticipated. These circumstances raise substantial doubt about the Company’s ability to continue as a going concern. For the foreseeable future, the Company’s ability to continue its operations is dependent upon its ability to obtain additional capital.

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 significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company’s ability to conduct its business.

If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of its product candidates, all of which would have a material adverse impact on the Company’s operations. The Company may also be required to:

- 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; and
- Relinquish licenses or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize themselves, on unfavorable terms.

The Company is evaluating the following options to both raise additional capital as well as reduce costs, in an effort to strengthen its liquidity position:

- Raising capital through public and private equity offerings;
- Introducing operation and business development initiatives to bring in new revenue streams;
- Reducing operating costs by identifying internal synergies; and
- Engaging in strategic partnerships.



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Between January 1, 2020 and February 27, 2020 the Company received approximately \$1.5 million of net proceeds through the exercise of 1,005,072 Series H warrants.

## **2. Basis of Presentation and Summary of Significant Accounting Policies**

The accompanying financial statements of Trovogene 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 12, effective June 1, 2018. On February 19, 2019 the Company made an additional reverse split of its common stock, \$0.0001 par value, at a ratio of 1 for 6. All share and per share information in the financial statements and the accompanying notes have been retroactively adjusted to reflect the reverse stock splits 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 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.

### *Cash and Cash Equivalents*

Cash and cash equivalents consist of operating and money market accounts as of December 31, 2019 and 2018 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 fixed income instruments 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 is 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 Trovogene'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 historical volatility as an input to derive the fair value, classifies such warrants as Level 3 (See "*Fair Value of Financial Instruments*" below). At December 31, 2019 and 2018, the fair value of these warrants was \$4,127 and \$32,315, 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 and cash equivalents, short-term investments, accounts receivable, accounts payable, debt and derivative liabilities. The Company has adopted 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 and finite-lived intangible assets. 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. Amortization of leasehold improvements is computed based on the shorter of the life of the asset or the term of the lease. Amortization of intangible assets is calculated using the straight-line method over the estimated useful life of the assets, based on when the Company expects to receive cash inflows generated by the intangible assets.

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. During the year ended December 31, 2019 and 2018, the Company recorded \$0 and \$187,500 of impairment losses on long-lived intangible assets, respectively.

#### *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.

#### *Restructuring*

Restructuring costs are included in loss from operations in the statements of operations. One-time termination benefits are recorded at the time they are communicated to the affected employees. In May 2018, the Company closed its CLIA laboratory operations. Costs associated with winding down the CLIA laboratory were recorded in the restructuring charges in the December 31, 2018 financial statements. See Note 13 to the financial statements for further information.

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### *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 Trovogene'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, Trovogene 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, *Accounting for Contingencies*, Trovogene records such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. Trovogene, in accordance with this guidance, does not recognize gain contingencies until realized.

### *Cost of Revenue*

Cost of revenue represents the cost of materials, personnel costs, costs associated with processing specimens including pathological review, quality control analyses, and delivery charges necessary to render an individualized test result. Costs associated with performing tests are recorded as the tests are processed.

### *Research and Development*

Research and development expenses, which 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.

While certain of the Company's research and development costs may have future benefits, the Company's policy of expensing all research and development expenditures is predicated on the fact that Trovogene has no history of successful commercialization of molecular diagnostic products to base any estimate of the number of future periods that would be benefited.

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 share is presented for all periods presented. In accordance with this guidance, 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 are included in net loss attributable to common stockholders in the computation of basic and diluted earnings per share. Shares used in calculating diluted net loss per common share exclude as anti-dilutive the following share equivalents:

	December 31,	
	2019	2018
Options to purchase Common Stock	1,015,418	83,345
Warrants to purchase Common Stock	10,589,482	3,649,341
Restricted Stock Units	11,301	30,132
Series A Convertible Preferred Stock	877	877
	<u>11,617,078</u>	<u>3,763,695</u>

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The following table summarizes the Company's diluted net loss per share:

	December 31,	
	2019	2018
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (16,706,668)	\$ (19,254,951)
Net loss used for basic and diluted loss per share	<u>\$ (16,706,668)</u>	<u>\$ (19,254,951)</u>
<b>Denominator:</b>		
Weighted-average shares used to compute basic and diluted net loss per share	5,973,906	2,330,180
<b>Net loss per share attributable to common stockholders:</b>		
Basic and diluted	<u>\$ (2.80)</u>	<u>\$ (8.26)</u>

*Revision of Previously Issued Financial Statements for Correction of Immaterial Errors*

During the fourth quarter of 2019, the Company identified an immaterial error related to pre-funded warrants. The correction of the error resulted in higher weighted-average shares used to compute basic and diluted net loss per share for the three months ended June 30, 2019 and September 30, 2019, the six months ended June 30, 2019 and the nine months ended September 30, 2019. The following table summarizes the immaterial adjustments and corrected amounts:

	Three Months Ended		Six Months Ended June 30, 2019	Nine Months Ended September 30, 2019
	June 30, 2019	September 30, 2019		
<i>Unaudited</i>				
<b>Weighted-average shares used to compute basic and diluted net loss per share:</b>				
Previously Reported	5,241,924	5,822,818	4,667,434	5,056,794
Adjustment	166,200	201,862	83,559	123,427
Revised	<u>5,408,124</u>	<u>6,024,680</u>	<u>4,750,993</u>	<u>5,180,221</u>
<b>Basic and diluted loss per share:</b>				
Previously reported	\$ (0.79)	\$ (0.71)	\$ (1.78)	\$ (2.46)
Adjustment	0.03	0.02	0.03	0.06
Revised	<u>\$ (0.76)</u>	<u>\$ (0.69)</u>	<u>\$ (1.75)</u>	<u>\$ (2.40)</u>

*Recently Adopted Accounting Pronouncement*

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 changes accounting for leases and requires lessees to recognize the assets and liabilities arising from most leases, including those classified as operating leases under previous accounting guidance, on the balance sheet and requires disclosure of key information about leasing arrangements to increase transparency and comparability among organizations. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, which provides narrow amendments to clarify how to apply certain aspects of the new lease standard. In July 2018, ASU 2018-11, *Leases: Targeted Improvements*, was issued to provide relief to companies from restating comparative periods. Pursuant to this ASU, in the period of adoption the Company will not restate comparative periods presented in its financial statements.

The Company adopted ASU 2016-02 as of January 1, 2019 utilizing the modified retrospective transition method through a cumulative-effect adjustment and did not restate comparative periods. The Company has elected the package of practical expedients, which allows the Company not to reassess (1) whether any expired or existing contracts as of the adoption date are or contain a lease, (2) lease classification for any expired or existing leases as of the adoption date, and (3) initial direct costs for any existing leases as of the adoption date. The Company did not elect to apply the hindsight practical expedient when determining lease term and assessing impairment of right-of-use assets. The adoption of ASU 2016-02 on January 1, 2019

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resulted in the recognition of right-of-use assets of approximately \$1,000,000 and lease liabilities for operating leases of approximately \$2,503,000. There was no cumulative effect adjustment to accumulated deficit as a result of the adoption and there was not a material impact to the Company's statement of operations. Refer to Note 4 to the financial statements for further details.

*Recent Accounting Pronouncement Not Yet Adopted*

In August 2018, the FASB issued ASU No. 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. Early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

**3. Supplementary Balance Sheet Information***Property and Equipment*

Fixed assets consists of furniture and office equipment, leasehold improvements and laboratory equipment. Depreciation and amortization expense for property and equipment for the years ended December 31, 2019 and 2018 was \$494,232 and \$736,088, respectively. Property and equipment consisted of the following:

	As of December 31,	
	2019	2018
Furniture and office equipment	\$ 775,030	\$ 775,030
Leasehold improvements	1,962,230	1,962,230
Laboratory equipment	744,856	677,234
	3,482,116	3,414,494
Less—accumulated depreciation and amortization	(2,604,293)	(2,110,061)
Property and equipment, net	<u>\$ 877,823</u>	<u>\$ 1,304,433</u>

*Accrued Liabilities*

Accrued liabilities consisted of the following:

	As of December 31,	
	2019	2018
Accrued compensation	\$ 1,003,383	\$ 780,848
Preferred stock dividend	365,255	341,015
Research agreements and clinical trials	1,686,068	319,898
Director fees	67,500	80,008
Professional fees and outside services	21,000	107,006
Patent, license and other fees	69,950	58,398
Other accrued liabilities	46,905	84,669
Total accrued liabilities	<u>\$ 3,260,061</u>	<u>\$ 1,771,842</u>

**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 two 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*

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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 \$76,000, with 3% annual escalation. The lease also contains one five-year renewal option with minimum monthly rent equal to the then-current fair market value, subject to a 3% annual increase. As the Company is not reasonably certain to exercise this option, it has not been included in the calculation of the lease liability or right-of-use asset related to this lease.

#### 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 two separate sublease agreements, which both expire December 31, 2021. An additional sublease expired on October 31, 2019 and was not renewed. The Company recorded a cease-use loss liability and expense in 2018 pursuant to ASC 420, *Exit or Disposal Cost Obligations*, representing the total expected shortfall in sublease income for two of the subleases as compared to its required payments for those spaces under the remainder of the master lease term. This liability was being amortized over the remaining lease term until the adoption of ASC 842, whereupon the remaining cease-use loss liability of approximately \$487,000 was eliminated and treated as a reduction to the beginning ROU asset value for the master lease as of January 1, 2019. Income will continue to be recognized on a straight-line basis over the term of the sublease.

The components of lease expense were as follows:

	<b>Twelve Months Ended December 31, 2019</b>
Operating lease cost	\$ 444,878
Operating sublease income	(381,653)
Net operating lease cost	\$ 63,225

Supplemental balance sheet information related to leases was as follows:

	<b>December 31, 2019</b>
Operating lease ROU assets	\$ 697,418
Current operating lease liabilities	\$ 865,379
Non-current operating lease liabilities	860,963
Total operating lease liabilities	\$ 1,726,342

Weighted-average remaining lease term—operating leases	2.0 years
Weighted-average discount rate—operating leases	6.5%

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

	<b>Twelve Months Ended December 31, 2019</b>
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 916,762

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

<b>Year Ending December 31,</b>	<b>Operating Leases</b>	<b>Sublease Income</b>	<b>Net Operating Leases</b>
2020	\$ 865,379	\$ (291,173)	\$ 574,206
2021	968,165	(291,173)	676,992
2022	5,868	—	5,868
2023	3,423	—	3,423
Total future minimum lease payments	1,842,835	\$ (582,346)	\$ 1,260,489
Less imputed interest	(116,493)		
<b>Total</b>	<b>\$ 1,726,342</b>		

Total annual commitments under non-cancelable lease agreements as of December 31, 2018 under the previous lease accounting guidance are as follows:

<b>Year Ending December 31,</b>	<b>Operating Leases</b>	<b>Sublease Income</b>	<b>Net Operating Leases</b>
2019	\$ 914,540	\$ (333,124)	\$ 581,416
2020	941,670	—	941,670
2021	968,165	—	968,165
2022	5,868	—	5,868
2023	3,423	—	3,423
<b>Total</b>	<b>\$ 2,833,666</b>	<b>\$ (333,124)</b>	<b>\$ 2,500,542</b>

## 5. Stockholders' Equity

### Common Stock

During the year ended December 31, 2019, the Company issued a total of 4,761,754 shares of Common Stock, the issuances were a result of the following:

- 2,221,635 shares of common stock were issued upon exercise of pre-funded warrants and warrants, 1,724,322 and 497,313, respectively;
- 1,994,929 shares of common stock were issued through private placements with certain accredited investors;
- 333,333 shares were issued upon conversion of Series C Convertible Preferred Stock;
- 183,334 shares of common stock in connection with a clinical trial funding commitment;
- 22,057 shares were issued upon vesting of RSU's; and
- 6,466 shares were issued for share rounding as a result of the reverse stock split.

During the year ended December 31, 2018, the Company issued a total of 3,098,662 shares of common stock, the issuances were a result of the following:

- 1,523,333 shares of common stock were sold through an underwritten public offering;
- 1,476,667 shares were issued upon conversion of Series B Convertible Preferred Stock;
- 78,917 shares were issued upon exercise of warrants;
- 18,609 shares were issued upon vesting of RSU's; and
- 1,136 shares were issued for share rounding as a result of the reverse stock split.



*Warrants*

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

	Number of Warrants (1)	Weighted-Average Exercise Price Per Share (1)	Weighted-Average Remaining Contractual Term (1)
Balance outstanding, December 31, 2017	322,774	\$ 68.07	4.4 years
Granted	3,450,000	\$ 6.60	
Exercised	(74,518)	\$ 21.60	
Expired	(48,915)	\$ 217.17	
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	<u>10,589,482</u>	\$ 4.08	3.7 years

(1) Balance outstanding, December 31, 2019 excludes 605,072 pre-funded warrants to purchase shares of common stock at a nominal exercise price of \$0.01 per share. The pre-funded warrants expire when exercised in full. As of February 20, 2020 all of the pre-funded warrants have been exercised.

In connection with an underwritten public offering occurred in June 2018, the Company issued warrants to purchase an aggregate of 3,450,000 shares of common stock at an exercise price of \$6.60 per share which expire on the 5 year anniversary of the original issuance date. Approximately 497,000 of these warrants were exercised during 2019.

In connection with registered direct offerings during the twelve months ending December 31, 2019 the Company issued the following warrants:

- On April 5, 2019 the Company issued Series B Warrants to purchase an aggregate of 382,166 shares of common stock at an exercise price of \$3.80 per share, which vested 6 months after issuance and expire 5.5 years from the issuance date;
- On May 13, 2019 the Company issued Series D Warrants to purchase an aggregate of 458,015 shares of common stock at an exercise price of \$3.15 per share, which vested 6 months after issuance and expire 5.5 years from the issuance date;
- On August 22, 2019 the Company issued Series F Warrants to purchase an aggregate of 727,802 shares of common stock at an exercise price of \$1.936 per share, which vested 6 months after issuance and expire 5.5 years from the issuance date;
- On October 30, 2019 the Company issued Series G Warrants to purchase an aggregate of 2,756,340 shares of common stock at an exercise price of \$1.56 per share, which vested immediately and expire 5.5 years from the issuance date;
- On October 30, 2019 the Company issued Series H Warrants to purchase an aggregate of 2,756,340 shares of common stock at an exercise price of \$1.56 per share, which vested immediately and expire 1.5 years from the issuance date; and
- On October 30, 2019 the Company issued Placement Agent Warrants to purchase an aggregate of 206,726 shares of common stock at an exercise price of \$2.2675 per share, which vested immediately and expire 5.5 years from the issuance date.

*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, 2019 and 2018, the Company had \$365,255 and \$341,015, 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 was recorded during the years ended December 31, 2019 and 2018, 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.

As of each of December 31, 2019 and 2018, there were 60,600 shares of Series A Convertible Preferred Stock outstanding.

#### *Series B Convertible Preferred Stock*

On June 12, 2018, the Company closed an underwritten public offering for total gross proceeds of \$18.0 million. The total related offering costs were approximately \$1.8 million. The securities offered by the Company consisted of (i) 1,523,333 shares of common stock, at an offering price of \$6.00 per share, (ii) warrants to purchase an aggregate of 3,450,000 shares of common stock, including the over-allotment option for 450,000 option warrants, at an exercise price of \$6.60 per share, and (iii) 8,860 shares of Series B Convertible Preferred Stock, with a stated value of \$1,000, and convertible into an aggregate of 1,476,667 shares of common stock. The conversion feature of the Series B Convertible Preferred Stock at the time of issuance was determined to be beneficial on commitment date. Because the Series B Convertible Preferred Stock is perpetual with no stated maturity date, and the conversions may occur any time from inception, the Company immediately recorded a one-time, non-cash deemed dividend of \$2.8 million related to the beneficial conversion feature arising from the issuance of Series B Convertible Preferred Stock. This one-time, non-cash deemed dividend increased the Company's net loss attributable to common stockholders and net loss per share. As of December 31, 2019 and 2018, there were no shares of Series B Convertible Preferred Stock outstanding, all of which has been converted to common stock.

The holders of Series B Convertible Preferred Stock are entitled to receive dividends on an as-if-converted-to-Common-Stock basis when, as and if such dividends are paid on shares of the Common Stock. Each share of Series B Convertible Preferred Stock shall entitle the holder to vote on an as-if-converted-to-Common-Stock basis (not exceeding the Beneficial Ownership Limitation). Upon any liquidation, dissolution or winding-up of the Company, the holders of Series B

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Convertible Preferred Stock are entitled to participate on an as-if-converted-to-Common Stock basis (without giving effect to the Beneficial Ownership Limitation) with holders of the Common Stock in any distribution of assets of the Company. Each share of Series B 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 of \$1,000 per share, by the conversion price. The conversion price was \$6.00 per share.

### Series C Convertible Preferred Stock

On January 25, 2019, the Company entered into a Master Services Agreement and a Stock and Warrant Subscription Agreement with PoC, whereby PoC agreed to finance \$1.675 million in clinical studies, including the development costs associated with Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® in patients with mCRC harboring KRAS mutations 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. As of December 31, 2019, there were no shares of Series C Convertible Preferred Stock outstanding.

The Company evaluated the awards issued under this transaction and determined they should be classified as equity. These equity awards were fully vested and nonforfeitable. 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.

The holders of Series C Convertible Preferred Stock were granted the right to vote, on an as-converted to common stock basis (limited to 93.41% of the then as-if converted common stock) on all matters submitted to a vote of holders of the Company's common stockholders. In the event of liquidation, dissolution or winding-up, holders of Series C Convertible Preferred Stock were entitled to receive the same amount that a holder of the Company's common stock would receive if the Series C Convertible Preferred Stock were fully converted into shares of the Company's common stock at the conversion price which amounts shall be paid *pari passu* with all holders of common stock.

## 6. Stock-Based Compensation

The Trovogene, 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 131,944 between the inception of the 2014 EIP through December 31, 2017. At the May 30, 2018 Annual Meeting of Stockholders, the stockholders approved the increase of number of authorized shares in the 2014 EIP to 243,056. 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.

As of December 31, 2019, there were 167,888 shares available for issuance under the 2014 EIP.

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

	Years ended December 31,	
	2019	2018
Cost of revenue	\$ —	\$ 30,488
Research and development expenses	399,687	752,127
Selling, general and administrative expenses	485,256	1,392,012
Total stock-based compensation	\$ 884,943	\$ 2,174,627

## 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,	
	2019	2018
Risk-free interest rate	1.66% - 2.33%	2.42% - 2.93%
Dividend yield	0%	0%
Expected volatility (range)	95% - 99%	89% - 98%
Expected volatility (weighted-average)	96%	91%
Expected term (in years)	5.9 years	5.2 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* — Trovogene 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 Trovogene'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, 2019 and 2018, estimated as of the grant date using the Black-Scholes option valuation model, was \$1.91 and \$13.08 per share, respectively.

The unrecognized compensation cost related to non-vested stock options outstanding at December 31, 2019 and 2018 was \$1,256,924 and \$375,548, respectively. The weighted-average remaining amortization period at December 31, 2019 and 2018 for non-vested stock options was 2.2 years and 1.2 years, respectively.

The total fair value of shares vested during the years ended December 31, 2019 and 2018 was \$386,654 and \$1,864,537, respectively.

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

	Number of Options	Weighted-Average Exercise Price Per Share	Intrinsic Value	Weighted-Average Remaining Contractual Life
Balance outstanding, December 31, 2017	62,376	\$ 291.10	\$ —	7.1 years
Granted	52,791	\$ 18.69		
Forfeited	(31,590)	\$ 219.03		
Expired	(232)	\$ 216.00		
Balance outstanding, December 31, 2018	83,345	\$ 146.09	\$ —	7.3 years
Granted	971,313	\$ 2.49		
Forfeited	(36,148)	\$ 26.55		
Expired	(3,092)	\$ 220.27		
Balance outstanding, December 31, 2019	1,015,418	\$ 12.77	\$ —	9.1 years
Vested and exercisable, December 31, 2019	71,518	\$ 147.46	\$ —	4.8 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, 2017	17,700	\$ 103.32	\$ 391,878
Granted	34,125	\$ 4.64	
Vested	(18,609)	\$ 59.06	
Forfeited	(3,084)	\$ 147.60	
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

The total fair values of RSU's vested during the year ended December 31, 2019 and 2018 were \$191,436 and \$1,099,058, 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,	
	2019	2018
Fair value of Trovogene common stock	\$1.24 - \$3.75	\$3.15 - \$25.14
Expected warrant term	3.1 - 4.1 years	0 - 5.1 years
Risk-free interest rate	1.56% - 2.49%	1.76% - 2.92%
Expected volatility	102% - 111%	47% - 131%
Dividend yield	—%	—%

Expected volatility is based on the historical volatility of Trovogene’s common stock. The warrants have a transferability provision and based on guidance for instruments issued with such a provision, Trovogene 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, 2017	Balance of derivative financial instruments—warrants liability	77,942	\$ 649,387
	Expiration of derivative financial instruments	(13,446)	—
	Change in fair value of derivative financial instruments—warrants during the year recognized as a gain in the statement of operations	—	(617,072)
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

The remaining contractual term of the warrants outstanding at December 31, 2019 and 2018 was approximately 3.1 and 4.1 years, respectively.

At December 31, 2019 and 2018, the total fair value of the above warrants accounted for as derivative financial instruments—warrants, valued using the Black-Scholes option pricing model, was \$4,127 and \$32,315, respectively, and is classified as derivative financial instruments—warrants liability on the balance sheet.

## 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, 2019 and 2018:

	Fair Value Measurements at December 31, 2019			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Money market fund (1)	\$ 10,131,240	\$ —	\$ —	\$ 10,131,240
<b>Total Assets</b>	<b>\$ 10,131,240</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 10,131,240</b>
<b>Liabilities:</b>				
Derivative financial instruments—warrants	\$ —	\$ —	\$ 4,127	\$ 4,127
<b>Total Liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 4,127</b>	<b>\$ 4,127</b>

	Fair Value Measurements at December 31, 2018			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
<b>Assets:</b>				
Money market fund (1)	\$ 11,392,093	\$ —	\$ —	\$ 11,392,093
<b>Total Assets</b>	<b>\$ 11,392,093</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 11,392,093</b>
<b>Liabilities:</b>				
Derivative financial instruments—warrants	\$ —	\$ —	\$ 32,315	\$ 32,315
<b>Total Liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 32,315</b>	<b>\$ 32,315</b>

(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. Debt

### *Equipment Line of Credit*

In November 2015, the Company entered into a Loan and Security Agreement with Silicon Valley Bank that provided for cash borrowings for equipment (“Equipment Advances”) of up to \$2.0 million, secured by the equipment financed. The Company repaid the outstanding Equipment Line of Credit in Full during 2018. Under the terms of the agreement, interest is equal to 1.25% above the Prime Rate. Interest only payments are due on borrowings through November 30, 2016, with both interest and principal payments commencing in December 2016. All unpaid principal and interest on each Equipment Advance will be due on November 1, 2019. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date. The Company is also subject to certain affirmative and negative covenants under the Equipment Line of Credit.

On June 20, 2017, the Company received a Notice of Event of Default (“Default Letter”) from SVB which stated that Events of Default had occurred and SVB will decide in its sole discretion whether or not to exercise rights and remedies. On April 6, 2018, the Company paid approximately \$1.1 million to SVB. This payment repaid the outstanding Equipment Line of Credit loan in full. The Company recorded \$25,161 in interest expense related to the Equipment Line of Credit during the year ended December 31, 2018.

## 10. Income Taxes

At December 31, 2019, Trovogene had federal net operating loss carryforwards (“NOLs”) of approximately \$129.0 million, if not used, will begin to expire in 2020, and federal net operating loss carryforwards of approximately \$30.3 million, which do not expire. Trovogene also has California NOLs of approximately \$70.1 million, if not used, will begin to expire in 2029. Trovogene also has research and development tax credits available for federal and California purposes of approximately \$2.4 million and \$1.7 million, respectively. The federal research and development tax credits will begin to expire on January 31, 2025. The California research and development tax credits are not set to expire.

The utilization of these NOLs and research and development tax credits is subject to limitations based on past and future changes in ownership of Trovogene pursuant to Section 382 (“Section 382”) of the Internal Revenue Code of 1986, as amended (the “Code”). The Company has determined that ownership changes have occurred for purposes of Section 382 and, therefore, the ability of the Company to utilize its NOLs is limited.

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

	Years ended December 31,	
	2019	2018
<b>Current:</b>		
State	\$ 1	\$ 1
<b>Total current provision</b>	<b>1</b>	<b>1</b>
<b>Deferred:</b>		
Federal	(2,634)	(1,307)
State	(148)	(2,428)
<b>Total deferred (benefit) expense</b>	<b>(2,782)</b>	<b>(3,735)</b>
Valuation allowance	2,781	3,734
<b>Total income tax provision</b>	<b>\$ —</b>	<b>\$ —</b>

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,			
	2019		2018	
Tax computed at the federal statutory rate	\$ (3,447)	21 %	\$ (3,457)	21 %
State tax, net of federal tax benefit	(177)	1 %	(184)	1 %
Permanent Items	353	(2)%	481	(3)%
Stock options true-up	875	(5)%	—	— %
Tax credits	(384)	2 %	(574)	3 %
Valuation allowance increase (decrease)	2,780	(17)%	3,734	(22)%
<b>Provision for income taxes</b>	<b>\$ —</b>	<b>— %</b>	<b>\$ —</b>	<b>— %</b>

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,	
	2019	2018
<b>Deferred tax assets:</b>		
Tax loss carryforwards	\$ 38,494	\$ 35,019
Research and development credits and other tax credits	3,710	3,595
Stock-based compensation	531	1,301
Other	1,252	1,126
<b>Total deferred tax assets</b>	<b>43,987</b>	<b>41,041</b>
<b>Deferred tax liabilities:</b>		
Operating lease right-of-use assets	(154)	—
Other	(12)	—
<b>Total deferred tax liabilities</b>	<b>(166)</b>	<b>—</b>
<b>Net deferred tax assets before valuation allowance</b>	<b>43,821</b>	<b>41,041</b>
Valuation allowance	(43,821)	(41,041)
<b>Net deferred tax asset</b>	<b>\$ —</b>	<b>\$ —</b>

Trovagene records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all, of the deferred tax assets will not be realized. Due to the substantial doubt related to Trovagene's ability to utilize its deferred tax assets, the Company recorded a valuation allowance against the deferred tax assets.

Trovagene does not have any unrecognized tax benefits. Trovagene'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.



## **11. 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 Trovogene 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 pay \$1.0 million for future services provided by Nerviano, such as the cost to manufacture drug product, no later than June 30, 2019, and these services have been ordered in full. Terms of the agreement also provide for the Company to pay royalties based on certain development and sales milestones.

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*

Trovogene 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.

## **12. 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.

## **13. Restructuring Charges**

In May 2018, the Company closed its CLIA laboratory operations in order to streamline the Company's business model. The loss recognized from disposition of CLIA laboratory was reported as restructuring charges, a component of operating loss in the financial statements. During the year ended December 31, 2018, the Company recorded total restructuring charges of approximately \$664,000 for CLIA laboratory disposal transactions, of which, approximately \$187,000 was related to impairment loss on CLIA laboratory license, approximately \$52,000 was related to loss on disposal of property and equipment and other non-capital assets, and approximately \$425,000 was related to loss on sublease of office and laboratory space.

## **14. Related Party Transactions**

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"). In December 2019, the MTA was amended and increased to \$1,470,000 to account for additional deliverables in development of the PCR-based assay. The Company's CEO, Dr. Thomas Adams, is a principal stockholder of Leucadia. In connection with the MTA, the Company entered into a consulting agreement with Tommy Adams, VP of Operations of Leucadia, who is the son of Dr. Adams. During the years ended December 31, 2019 and 2018, the Company incurred and recorded approximately \$1,005,000 and \$183,000, respectively, of research and development expenses for services performed by Leucadia and Tommy Adams.

## **15. Subsequent Events**

*Exercise of Warrants*

In January 2020 we received net proceeds of approximately \$1.5 million from the exercise of 1,005,072 Series H Warrants at \$1.56 per share.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

As of December 31, 2019, Trovogene, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, \$0.0001 par value per share ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Trovogene" in this Exhibit 4.1 refer to Trovogene, Inc.

**DESCRIPTION OF CAPITAL STOCK**

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and bylaws, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.16 is a part.

**Authorized Capitalization**

Our authorized capital stock consists of 150,000,000 shares of Common Stock and 20,000,000 shares of preferred stock, \$0.001 par value per share ("Preferred Stock") in one or more series. As of December 31, 2019, we had outstanding 8,593,633 shares of our Common Stock and 60,600 shares of our Series A Convertible Preferred Stock.

*Transfer Agent and Registrar.* The transfer agent for our Common Stock is Philadelphia Stock Transfer.

*Listing.* Our Common Stock is traded on the Nasdaq Capital Market under the symbol "TROV."

**Common Stock**

The holders of our common stock are entitled to one vote per share. Our amended and restated certificate of incorporation, as amended, does not provide for cumulative voting. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. Except for certain stockholders who have the right to participate, until August 22, 2020, in any issuance by us of common stock in a subsequent financing up to 50% of the subsequent financing, the holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

Consent of Independent Registered Public Accounting Firm

Trovagene, Inc.  
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-234442, 333-233568 and 333-224808), Form S-3 (Nos. 333-232321, 333-229693, 333-211705 and 333-208010) and Form S-8 (Nos. 333-232363, 333-226172, 333-220060, 333-211846, 333-205424 and 333-190415) of Trovagene, Inc. (the "Company") of our report dated February 27, 2020, relating to the financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California  
February 27, 2020

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER**

I, Thomas H. Adams, certify that:

1. I have reviewed this annual report on Form 10-K of Trovogene, 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.

2/27/2020

/s/ Thomas H. Adams

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Thomas H. Adams  
*Chief Executive Officer (Principal Executive Officer)*

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER**

I, Brigitte Lindsay, certify that:

1. I have reviewed this annual report on Form 10-K of Trovogene, 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.

2/27/2020

/s/ Brigitte Lindsay

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

**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 Trovogene, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas H. Adams, 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.

2/27/2020

/s/ Thomas H. Adams

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Thomas H. Adams  
*Chief Executive Officer (Principal Executive Officer)*

**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 Trovogene, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas H. Adams, 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.

2/27/2020

/s/ Brigitte Lindsay

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