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As filed with the Securities and Exchange Commission on May 21, 2019

Registration No. 333-224808

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 4
to
Post -Effective Amendment No. 1

To

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

TROVAGENE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2836**	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

11055 Flintkote Avenue
San Diego, CA 92121
(858) 952-7570
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Thomas H. Adams
Chief Executive Officer
Trovagene, Inc.
11055 Flintkote Avenue
San Diego, CA 92121
(858) 952-7570
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth 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 o	Accelerated filer o
Non-accelerated filer x	Smaller reporting company x
Emerging growth company o	

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 to Section 7(a)(2)(B) of the Securities Act. o

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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EXPLANATORY NOTE

Trovagene, Inc. (the "Company") previously filed a Registration Statement on Forms S-1 (File No. 333-224808 and File No. 333-225510) with the U.S. Securities and Exchange Commission (the "SEC") on May 10, 2018 and June 8, 2018, respectively, which was declared effective by the SEC on June 8, 2018 (the "Existing Registration Statement"). This Amendment No. 4 to Post-Effective Amendment No. 1 to the Existing Registration Statement is being filed to include the complete prospectus in Amendment No. 4 to Post-Effective No. 1 to Form S-1 ("Amendment No. 1").

Except as described above, no other changes have been made to Amendment No. 1.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement relating to these securities filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED MAY 21, 2019**

2,952,740 Shares of Common Stock Issuable upon Exercise of Outstanding Warrants

This prospectus relates to an aggregate 2,952,740 shares of our common stock, which, as of the date of this prospectus, are issuable upon exercise of warrants originally issued as part of our public offering, which closed on June 12, 2018 (the "Offering").

We will receive none of the proceeds from the sale of the shares. We will receive proceeds upon the exercise of outstanding warrants for shares of common stock covered by this prospectus if the warrants are exercised for cash.

Our common stock is listed on the Nasdaq Capital Market under the symbol "TROV." On May 20, 2019, the last reported sale price per share of our common stock on the Nasdaq Capital Market was $3.07.

There is no established trading market for the warrants, and we do not expect an active trading market to develop. We do not intend to list the warrants on any securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 10 of this prospectus, and under similar headings in any amendments or supplements to this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is May , 2019

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You may rely only on the information contained in this prospectus. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our securities. Neither the delivery of this prospectus nor any sale made in connection with this prospectus shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain, in addition to historical information, certain forward-looking statements. within the meaning of Section 27A of the Securities Act or 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended, that include information relating to future events, future financial performance, strategies, expectations, competitive environment, regulation and availability of resources. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should”, “could” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this prospectus or incorporated herein by reference.

You should read this prospectus and the documents we have incorporated by reference or filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual

future results may be materially different from what we expect. You should not assume that the information contained in this prospectus or any prospectus supplement or free writing prospectus is accurate as of any date other than the date on the front cover of those documents, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

Risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from those expressed or implied in our written or oral forward-looking statements may be found in this prospectus under the heading “Risk Factors” and in our Annual Report on Form 10-K for the year ended December 31, 2018 under the headings “Risk Factors” and “Business,” as updated in our Quarterly Report(s) on Form 10-Q.

Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and incorporated herein by reference, and particularly our forward-looking statements, by these cautionary statements.

PROSPECTUS SUMMARY

The following summary highlights certain of the information contained elsewhere in or incorporated by reference into this prospectus. Because this is only a summary, however, it does not contain all the information you should consider before investing in our securities and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information included elsewhere in or incorporated by reference into this prospectus. Before you make an investment decision, you should read this entire prospectus carefully, including the risks of investing in our securities discussed under the section of this prospectus entitled "Risk Factors" and similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part.

Unless the context otherwise requires, references to "we," "our," "us," "Trovagene" or the "Company" in this prospectus mean Trovagene, Inc.

Overview

We are a clinical-stage, oncology therapeutics company, taking a precision medicine approach to develop targeted therapies for the treatment of patients with leukemias, lymphomas and solid tumor cancers. 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 where there is a significant medical need to provide new therapeutic options.

Our drug candidate, onvansertib (formerly known as PCM-075), is a first-in-class, 3rd 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 highly expressed in most cancers, and its over-expression is associated with poor prognosis in patients. Data has shown that blocking the expression of PLK1 by kinase inhibitors can effectively inhibit the proliferation of and induce apoptosis (death) of tumor cells.

On March 15, 2017, we announced the licensing of onvansertib (PCM-075), 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).

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 of 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 overexpression 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 acute myeloid leukemia, prostate, lung, breast, and colorectal cancer. In addition, several studies have shown that over-expression of PLK1 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. The antiproliferative activity of onvansertib was evaluated on a panel of 148 tumor cell lines and appeared highly active with an IC50 (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC50 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"), two ongoing clinical studies and a third study planned for initiation in mid-2019. 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-dosecytarabine ("LDAC") or

decitabine for patients with relapsed or refractory Acute Myeloid Leukemia (“AML”). The second study is TROV-053(ClinicalTrials.gov Identifier NCT03414034), a Phase 2 open-label clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, all administered orally, for patients with metastatic Castration-Resistant Prostate Cancer (“mCRPC”). The third study is TROV-054 (ClincalTrials.gov Identifier NCT03829410), a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI (folinic acid, fluorouracil and irinotecan) and Avastin® (bevacizumab) for patients with metastatic Colorectal Cancer (“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 August 16, 2017, we announced results of preclinical research indicating potential synergy of onvansertib with an investigational FLT3 Inhibitor, quizartinib by Daiichi Sankyo, in FLT3 mutant xenograft mouse models. This synergy assessment study was conducted for us by a third-party contract research group. Approximately one third of AML patients harbor FLT3-mutated blood cancer cells. In the fourth quarter of 2018, the FDA approved Xospata (gilteritinib) by Astellas, which joins Rydapt® (midostaurin) by Novartis for the treatment of adult patients with AML that are FLT3 mutation-positive. A third FLT3 inhibitor, quizartinib by Daiichi Sankyo, is currently under review by the FDA. We believe that a combination of onvansertib with a FLT3 inhibitor for AML patients with a FLT3 mutation could extend treatment response and possibly slow or reduce resistance to FLT3 activity.

On August 21, 2017, we announced results of preclinical research indicating potential synergy of onvansertib with a histone deacetylase (“HDAC”) inhibitor in Non-Hodgkin Lymphoma (“NHL”) cell lines. This synergy assessment study was conducted by Dr. Steven Grant, Associate Director for Translational Research and co-Leader, Developmental Therapeutics Program, Massey Cancer Center. Patients with relapsed or refractory NHL, such as cutaneous T cell lymphoma and peripheral T cell lymphoma, may be prescribed approved HDAC inhibitors and we believe this continues to be an area of unmet medical need. Dr. Grant’s data appeared to indicate that the combination of onvansertib with Beleodaq® (belinostat), an HDAC inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, reduced cancer cells by up to 80% in two different forms of NHL (aggressive double-hit B-cell lymphoma and mantle cell lymphoma) cell lines.

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, 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.

Our strategy includes integrating a predictive clinical biomarker approach into our onvansertib clinical development program, 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 gastrointestinal 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 metastatic Colorectal Cancer 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, "*A Phase 1b/2 Study of Onvansertib (PCM-075) in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation*" will enroll up to 44 patients. We plan to conduct this trial at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona, with initiation anticipated in mid-2019.

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 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-daycycle in both Phase 1b and Phase 2.

To date, we have completed the first four dose escalation treatment cohorts (12 mg/m2, 18 mg/m2, 27 mg/m2 and 40 mg/m2) in the Phase 1b segment of this trial. A total of nine sites are conducting this trial, which is being led by Hematologist Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and 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 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.

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 analysis 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 our 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, our geographic regions on any asset-based metrics. Therefore, geographic information is not presented for revenues or long-lived assets.

Company Information

We were incorporated in the State of Florida on April 26, 2002. On July 2, 2004, we acquired Xenomics, a California corporation, which was in business to develop and commercialize urine-based molecular diagnostics technology. In 2007, we changed our fiscal year end from January 31 to December 31 and in January 2010, we re-domesticated our state of incorporation from Florida to Delaware and our name was changed to Trovagene, Inc. We have trademarks for the name TROVAGENE, TROVAGENE PRECISION CANCER MEDICINE and TROVAGENE ONCOLOGY. Our principal executive offices are located at 11055 Flintkote Avenue, San Diego, CA 92121, and our telephone number is 858-952-7570. Our website address is *www.trovageneoncology.com*. The information on our website is not part of this prospectus supplement. We have included our website address as a factual reference and do not intend it to be an active link to our website.

THE OFFERING

Common stock offered by the Company	2,952,740 shares of common stock issuable upon exercise of warrants
Use of proceeds	If all of the warrants are exercised for cash in full, the proceeds would be approximately $19.5 million. We intend to use the net proceeds of any such warrant exercises, if any, for working capital purposes. We will receive proceeds upon the exercise of outstanding warrants for shares of common stock covered by this prospectus if the warrants are exercised for cash. See “Use of Proceeds.”
Risk factors	This investment involves a high degree of risk. You should read the description of risks set forth under “Risk Factors” beginning on page 10 of this prospectus for a discussion of factors to consider before deciding to purchase our securities.
Nasdaq Capital Market Trading Symbol of Common Stock	“TROV”

RISK FACTORS

Any investment in our securities involves a high degree of risk. Before deciding whether to purchase our securities, investors should carefully consider the risks described below together with the "Risk Factors" described in our Annual Report on Form 10-K for the year ended December 31, 2018 and any updates described in our Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, as may be amended, supplemented or superseded from time to time by other reports we file with the Securities Exchange Commission ("SEC"). Our business, financial condition, operating results and prospects are subject to the following material risks as well as those material risks incorporated by reference. Additional risks and uncertainties not presently foreseeable to us may also impair our business operations. Our business, financial condition or operating results could be materially adversely affected by any of these risks. In such case, the trading price of our common stock could decline, and our stockholders may lose all or part of their investment in our securities.

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, 2018, we have an accumulated total deficit of approximately $192.2 million. For the fiscal years ended December 31, 2018 and 2017, we had a net loss attributable to common stockholders of approximately $19.3 million and $24.9 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, 2018, our cash and cash equivalents balance was approximately $11.5 million and our working capital was approximately $9.8 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, our financial statements note there is 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 new drug application, or NDA, or a biologic license application, or 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 demonstrates 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 the expertise and experience of 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 payers, 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 payers 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 payer, 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 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 Nerviano and its subsidiaries 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 payers 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 payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers 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 health care 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 health care 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 third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

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

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated current good marketing practices or cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

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

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

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

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

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

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our clinical trials in the aggregate amount of $5 million. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to 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 is 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, 2018. 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.

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. health care 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. 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.

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.

Health care 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 health care 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 Tax Cuts and Jobs Act of 2017 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 would transition 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 as of December 31, 2012, which was remedied in the year ended December 31, 2013. 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 carry-forwards 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, 2018, the closing price of our common stock ranged from a low of $3.08 to a high of $33.34. 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 consolidated 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 Capital Market LLC ("Nasdaq") or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

If we fail to comply with the continuing minimum closing bid requirement of Nasdaq 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.

USE OF PROCEEDS

If all of the warrants are exercised for cash in full, the proceeds would be approximately $19.5 million. We intend to use the net proceeds of any such warrant exercises, if any, for working capital purposes. We can make no assurances that any of the warrants will be exercised, or if exercised, that they will be exercised for cash, the quantity which will be exercised or in the period in which they will be exercised.

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock has traded on the Nasdaq Capital Market under the symbol “TROV” since May 30, 2012. There were 63 shareholders of record of our common stock as of May 9, 2019.

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.

BUSINESS

We are a clinical-stage, oncology therapeutics company, taking a precision medicine approach to develop targeted therapies for the treatment of patients with leukemias, lymphomas and solid tumor cancers. 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 where there is a significant medical need to provide new therapeutic options.

Our drug candidate, onvansertib (formerly known as PCM-075), is a first-in-class, 3rd 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 highly expressed in most cancers, and its over-expression is associated with poor prognosis in patients. Data has shown that blocking the expression of PLK1 by kinase inhibitors can effectively inhibit the proliferation of 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).

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 overexpression 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 acute myeloid leukemia, prostate, lung, breast, and colorectal cancer. 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_{50} (a measure concentration for 50% target inhibition) below 100 nM in 75 cell lines and IC_{50} values below 1 uM in 133 out of 148 cell lines.

Onvansertib 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"), two ongoing clinical studies and a third study planned for initiation in mid-2019. 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 Acute Myeloid Leukemia ("AML"). The second study is TROV-053 (ClinicalTrials.gov Identifier NCT03414034), a Phase 2 open-label clinical trial of onvansertib in combination with Zytiga® (abiraterone acetate)/prednisone, all administered orally, for patients with metastatic Castration-Resistant Prostate Cancer ("mCRPC"). The third study is TROV-054 (ClincalTrials.gov Identifier NCT03829410), a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI (folinic acid, fluorouracil and irinotecan) and Avastin® (bevacizumab) for patients with metastatic Colorectal Cancer ("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 August 16, 2017, we announced results of preclinical research indicating potential synergy of onvansertib with an investigational FLT3 Inhibitor, quizartinib by Daiichi Sankyo, in FLT3 mutant xenograft mouse models. This synergy assessment study was conducted for us by a third-party contract research group. Approximately one third of AML patients harbor FLT3-mutated blood cancer cells. In the fourth quarter of 2018, the FDA approved Xospata (gilteritinib) by Astellas, which joins Rydapt® (midostaurin) by Novartis for the treatment adult patients with AML that are FLT3 mutation-positive. A third FLT3 inhibitors, quizartinib by Daiichi Sankyo, is currently under review by the FDA. We believe that a combination of onvansertib with a FLT3 inhibitor for AML patients with a FLT3 mutation could extend treatment response and possibly slow or reduce resistance to FLT3 activity.

On August 21, 2017, we announced results of preclinical research indicating potential synergy of onvansertib with a histone deacetylase (“HDAC”) inhibitor in Non-Hodgkin Lymphoma (“NHL”) cell lines. This synergy assessment study was conducted by Dr. Steven Grant, Associate Director for Translational Research and co-Leader, Developmental Therapeutics Program, Massey Cancer Center. Patients with relapsed or refractory NHL, such as cutaneous T-cell lymphoma and peripheral T-cell lymphoma, may be prescribed approved HDAC inhibitors and we believe this continues to be an area of unmet medical need. Dr. Grant’s data appeared to indicate that the combination of onvansertib with Beleodaq® (belinostat), an HDAC inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, reduced cancer cells by up to 80% in two different forms of NHL (aggressive double-hit B-cell lymphoma and mantle cell lymphoma) cell lines.

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.

Our strategy includes integrating a predictive clinical biomarker approach into our onvansertib clinical development program, 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 metastatic Colorectal Cancer 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 Captital, 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, *A Phase 1b/2 Study of Onvansertib in Combination with FOLFIRI and Bevacizumab for Second-Line Treatment of Metastatic Colorectal Cancer in Patients with a KRAS Mutation*, will enroll up to 44 patients. We plan to conduct this trial at two prestigious cancer centers: USC Norris Comprehensive Cancer Center and The Mayo Clinic Arizona, with initiation anticipated in mid-2019.

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 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 2018, we completed the first three dose escalation treatment cohorts (12mg/m^2, 18mg/m^2 and 27mg/m^2) in the Phase 1b segment of this trial. A total of nine sites are conducting this trial, which is being led by Hematologist Jorge Cortes, M.D., Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center and 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 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.

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 Precision Cancer Medicine 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 analysis 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 our 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, our 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, 3rd 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, onvansertib is the lead candidate and is differentiated from other ATP competitive inhibitors in that:

- its inhibition of PLK1 is highly-selective and the half maximal inhibitory concentration (IC_{50}) for PLK2 and PLK3 is over 5,000-fold of that for PLK1;
- it has a relatively short half-life of approximately 24 hours;
- it is available in an oral gelcap formulation;
- it allows for flexible dosing and scheduling;
- it has demonstrated safety and tolerability;
- 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 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®. The mCRPC Phase 2 trial is on file at ClinicalTrials.gov with the Identifier NCT03414034. In 2019 we plan to initiate a Phase 1b/2 open-label clinical trial in mCRC in patients with a KRAS mutation in combination with FOLFIRI and Avastin® in the second-line treatment setting. This study is on file at ClinicalTrials.gov with the Identifier NCT03829410. As 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 activate to conduct 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 protocol.

Our Business Strategy

We are a clinical-stage, oncology therapeutics company, taking a precision medicine approach to develop targeted therapies for the treatment of patients with leukemias, lymphomas and solid tumor cancers. 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 indications for which there is a significant medical need to introduce new treatment options for patients.

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, 2018 and 2017 were approximately $8.2 million and $7.9 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, 2018, our wholly-owned and licensed intellectual property included 61 issued patents and 10 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, Trovagene 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 2018 and 2034.

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 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 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. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses.

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

HIPAA, as amended by the Health Information Technology and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, which impose certain requirements relating to the privacy, security, transmission and breach reporting of individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and healthcare providers and their respective business associates that perform services for them that involve individually identifiable health

information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

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

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

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

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

Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer's ability to operate its business and the results of its operations.

Healthcare Reform in the United States

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. Most recently, 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 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, 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 nine 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. An IND and protocol for a Phase 1b/2 trial in mCRC was submitted to the FDA in December, 2018 and we received notification that the trial may proceed in January, 2019. The trial will be conducted at two sites - USC Norris Comprehensive Cancer Center and The Mayo Clinic - with anticipated activation in mid-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. 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 formualtion 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 April 22, 2019, we had a total of 13 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.

MANAGEMENT

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 April 22, 2019.

Name	Age	Position
Thomas H. Adams, Ph.D.	76	Chief Executive Officer and Chairman of the Board
Mark Erlander, Ph.D.	59	Chief Scientific Officer
John Brancaccio	71	Director
Gary S. Jacob, Ph.D.	72	Director
Dr. Rodney S. Markin	62	Director
Dr. Athena Countouriotis	47	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. Dr. Adams has been our Chairman of the Board since April 2009 and Chief Executive Officer since June 2018. Dr. Adams served as the Chairman of Clearbridge BioPhotonics, Inc., an imaging solutions company from April 2013 to June 2017. From June 2005 through 2011, Dr. Adams served as a director of IRIS International, Inc., a diagnostics company, and has served as Chief Technology Officer of IRIS since April 2006. Dr. Adams was the Head of Iris Molecular Diagnostics from 2006 until November 2012 and has served as the President of IRIS Personalized Medicine since 2011. In November 2012, IRIS was acquired by Danaher Corporation. Dr. Adams served as Chairman and Chief Executive Officer of Leucadia Technologies, a privately held medical-device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly held biotechnology company in the field of antisense technology, and served as its Chief Executive Officer until 1997.

Dr. Adams was Chairman of Genta-Jago, a controlled release-based drug delivery company, from 1992 until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its Chief Executive Officer and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Dr. Adams was Chief Technology Officer of Hybratech, Inc., which focused on monoclonal antibody-based diagnostics and therapeutics, from 1980 to 1984. Dr. Adams has served as a Director of ContraVir Pharmaceuticals, Inc. and Synergy Pharmaceuticals Inc. since September 2016. Dr. Adams served as a Director of Advanced Molecular Evolution, an antibody therapeutics company from 1991 until 2000. Dr. Adams served as a Director of Biosite, Inc., an antibody-based diagnostic company, from 1990 until 2000. Dr. Adams holds a Ph.D. in Biochemistry from the University of California, at Riverside. The Board believes that Dr. Adam's executive leadership in therapeutic and diagnostic fields, as well as the extensive healthcare expertise he has developed qualifies Dr. Adams to serve as a Director of our Company.

Mark Erlander, Ph.D. Mark Erlander, Ph.D., has been our Chief Scientific Officer since March 2013. Dr. Erlander has more than 20 years of experience directing drug discovery efforts and developing precision cancer diagnostics and his expertise is focused on leveraging the intersection of targeted therapies with molecular diagnostic biomarkers. Prior to joining Trovagene, Dr. Erlander was Chief Scientific Officer at bioTheranostics (a bioMerieux company), which was previously AviaraDx and acquired by bioMerieux, from September 2008 to February 2013. As CSO, he led R&D, Medical & Scientific Affairs and clinical laboratory operations or the development of proprietary predictive tests in oncology to inform therapy decisions. Dr. Erlander entered therapeutics as a Group Leader and then Research Fellow in drug discovery at Johnson & Johnson. At J&J, Dr. Erlander led both efforts in drug discovery and the use of genomic technologies to identify new drug targets. Previous to this, he was an Assistant Professor at The Scripps Research Institute where he also received his post-doctoral training. Dr. Erlander is an accomplished researcher in oncology therapeutics, diagnostics and genomic technologies with 44 issued U.S. patents and over 50 pending applications. He has co-authored over 90 scientific publications. Dr. Erlander holds a BS degree in Biochemistry from the University of California, Davis; an MS degree in Biochemistry from Iowa State University; and a Ph.D. in Neuroscience from the University of California, Los Angeles.

John Brancaccio. John Brancaccio, a retired CPA, has served as a director of our company since December 2005. From April 2004 until his retirement in May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio served as a director of Callisto Pharmaceuticals, Inc. from April 2004 until its merger with Synergy Pharmaceuticals, Inc. in January 2013 and has been a director of Tamir Biotechnology, Inc. (formerly Alfacell Corporation) since April 2004, as well as a director of Synergy Pharmaceuticals Inc. since July 2008 and ContraVir Pharmaceuticals, Inc. since December 2013 and Rasna Therapeutics, Inc. since August 2016. The Board believes that Mr. Brancaccio's experience as a chief financial officer provides him with valuable financial and accounting expertise that qualifies him to serve as a director of our company.

Gary S. Jacob. Gary S. Jacob, Ph.D., has served as a director of our company since February 2009. Since November 2018, Dr. Jacob has been the Chief Executive Officer of Immuron Limited, an Australian microbiome biopharmaceutical company. From July 2008 until December 2017, Dr. Jacob was President and Chief Executive Officer of Synergy Pharmaceuticals Inc., and he served as its Chairman from September 2013 to November 2018. On December 12, 2018, Synergy Pharmaceuticals Inc. filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code. Dr. Jacob has been Chairman of ContraVir Pharmaceuticals, Inc. since May 2013. Dr. Jacob also served as a director of Callisto Pharmaceuticals, Inc. from October 2004 until its merger with Synergy Pharmaceuticals, Inc. in January 2013. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998, he was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob earned a B.S. in Chemistry from the University of Missouri, and holds a Ph.D. in Biochemistry from the University of Wisconsin-Madison. The Board believes that Dr. Jacob's broad management expertise in the pharmaceutical and biotechnology industries provides relevant experience in a number of strategic and operational areas and qualifies him to serve as a director of our company.

Dr. Rodney S. Markin. Rodney S. Markin, M.D., Ph.D., has been a director of our company since February 2014. Dr. Markin has served as Chief Operating Officer of University of Nebraska since August 2017. Dr. Markin has served as Chief Technology Officer and Associate Vice Chancellor for Business Development at the University of Nebraska Medical Center from 2011 to July 2017; as a Professor of Pathology and

Microbiology since 1985; as David T. Purtilo Distinguished Professor Pathology and Microbiology since 2005; as Courtesy Professor of Surgery since 1990 and as Courtesy Professor of Psychiatry since 2013. Dr. Markin is also a director on the Board of Children's Hospital and Medical Center Foundation, on the Board of Trustees for Keck Graduate Institute, on the Board of the Make-A-Wish Foundation and on the Board of PerceptiMed since July 2015. Dr. Markin served on the Board of Directors of Transgenomic, Inc. from March 2007 to December 2014. The Board believes that Dr. Markin's valuable executive experience in the healthcare business qualifies him to serve as a director of our company.

Dr. Athena Countouriotis. Dr. Athena Countouriotis has been a director of our company since September 2017. Dr. Countouriotis has served as Chief Executive Officer of Turning Point Therapeutics, Inc. since September 2018 and previously was Executive Vice President and Chief Medical Officer beginning in May 2018. Dr. Countouriotis brings significant experience leading clinical development programs, from preclinical through clinical stages, and approval. Over the course of her career, she has been involved in multiple clinical programs, with a focus within oncology, both hematologic and solid tumor indications, that have supported regulatory approvals in the U.S. and Europe. From June 2017 to May 2018, Dr. Countouriotis served as Senior Vice President, Chief Medical Officer at Adverum Biotechnologies. Prior to joining Adverum, she served as Senior Vice President and Chief Medical Officer at Halozyme Therapeutics from January 2015 to May 2017. From February 2012 to January 2015, Dr. Countouriotis was Chief Medical Officer at Ambit Biosciences through the initial development of quizartinib, a small molecule FLT3 inhibitor for the treatment of Acute Myeloid Leukemia, and ultimate acquisition of the company by Daiichi Sankyo. Dr. Countouriotis also worked at both Pfizer and Bristol-Meyers Squibb in various roles leading clinical development of oncology focused therapeutics. She holds a M.D. from Tufts University School of Medicine, completed her pediatric residency at the University of California, Los Angeles, and did additional training at Fred Hutchinson Cancer Research Center in the pediatric hematology-oncology program. The Board believes that Dr. Countouriotis's medical and clinical research expertise in oncology provides relevant experience to the Board and management and qualifies her 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 separate 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 Securities and Exchange Commission, or 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, 2018, the Audit Committee consisted of John P. Brancaccio, chairman of the Audit Committee, Dr. Rodney S. Markin and Dr. Athena Countouriotis. 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 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, 2018, 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 5602(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://trovageneoncology.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 the Corporate Governance Guidelines and any changes thereto, setting forth the corporate governance principles applicable to us, and overseeing compliance with the our 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, 2018, 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. 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://trovageneoncology.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.trovagene.com). A copy of our Code of Business Conduct and Ethics may be obtained without charge upon written request to Secretary, Trovagene, 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.trovageneoncology.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).

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 Principal Financial 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 2018.

Name and Principal Position	Year	Salary ($)	Non-Equity Incentive Plan Compensation ($)(1)	Option Awards ($) (2)	Stock Awards ($) (3)	Total ($)
Thomas H. Adams, CEO	2018	286,346(4)	79,167	11,679(5)	—	377,192
William Welch, former CEO(6)	2018	630,152(7)	—	139,412	—	769,564
	2017	475,000	811,388(8)(9)	—	1,123,314	2,409,702
Dr. Mark Erlander, CSO	2018	387,155	342,576	144,008	34,785	908,524
	2017	374,400	125,229(2)(10)	225,866	296,252	1,021,747

(1) The amounts in this column relate to amounts earned by the Named Executive Officers in 2018 and 2017, as applicable, pursuant to our variable pay program described under "Elements of our Compensation Program-Variable Pay".

(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 2018 and 2017 amounts are described in Note 5 to our financial statements included in our Annual Reports on Form 10-K for the fiscal years ended December 31, 2018 and 2017. 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, 2018 and 2017.

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

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

(6) Mr. Welch resigned as CEO in June 2018.

(7) Of this amount, $350,000 was the severance payment to Mr. Welch upon termination of service pursuant to the Severance Agreement and Mutual Release with Mr. Welch.

(8) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officer. Instead, these amounts represent (1) a total of $652,511 income taxes we paid for our named executive officer related to the restricted stock awards granted and vested during the fiscal year ended December 31, 2017; and (2) 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 2017 amounts were described in Note 5 to our financial statements included in

our Annual Reports on Form 10-K for the fiscal years ended December 31, 2017. Our named executive officer 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.

(9) Received stock options to purchase 9,202 shares of common stock in lieu of cash bonus.

(10) Received stock options to purchase 7,253 shares of common stock in lieu of cash bonus.

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, as well as the exercise prices and expiration dates thereof, as of December 31, 2017. Except for the options set forth in the table below, no other equity awards were held by any our named executive officers as of December 31, 2017.

	Option Awards(1)				Stock Awards	
Name	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		
	28	—	237.60	1/26/2022		
	70	—	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		
Mark Erlander	70	—	204.48	9/13/2022	781	2,464
	139	—	350.64	12/10/2022	6,250	19,706
	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		
	1,522	562	372.96	1/4/2026		
	4,013	1,335	61.20	8/22/2027		
	7,253	2,083	21.60	1/23/2028		

(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 $30,000, 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 2018 for services to our company.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
John Brancaccio(2)	70,000	11,679	81,679
Gary S. Jacob(3)	54,000	11,679	65,679
Stanley Tennant(4)	64,000	1,083	65,083
Paul Billings(5)	24,167	11,679	35,846
Rodney S. Markin(6)	75,333	11,679	87,012
Athena Countouriotis(7)	55,000	11,679	66,679

(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 2018 amounts are described in Note 5 to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. 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, 2018, 3,072 stock options were outstanding, of which 2,317 were exercisable.

(3) As of December 31, 2018, 3,337 stock options were outstanding, of which 2,582 were exercisable.

(4) Dr. Tennant left the Board in December 2018. As of December 31, 2018, 2,584 stock options were outstanding, all of which were exercisable.

(5) Dr. Billings left the Board in May 2018. As of December 31, 2018, 1,159 stock options were outstanding, all of which were exercisable.

(6) As of December 31, 2018, 2,235 stock options were outstanding, of which 1,480 were exercisable.

(7) As of December 31, 2018, 1,285 stock options were outstanding, of which 177 were exercisable.

Employment Agreements

William Welch Employment Agreement

On May 6, 2016, we entered into an employment agreement with Mr. Welch (the "Welch Employment Agreement"). The term of the Welch Employment Agreement commenced on May 6, 2016 and would continue until May 6, 2020, following which time the Welch Employment Agreement would 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 Welch Employment Agreement, Mr. Welch's base compensation was $475,000 per year. Mr. Welch was 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. In addition, upon entering into the Welch Employment Agreement, Mr. Welch was granted 10,417 stock options, which had an exercise price of $340.56 per share, 2,605 of which vested on April 25, 2017 and 217 vested monthly subsequent thereto. All of Mr. Welch's stock options have expired.

On July 30, 2018, we entered into a Severance Agreement and Mutual Release (the "Welch Severance Agreement") with Mr. Welch specifying the terms of Mr. Welch's termination of service with the Company. Pursuant to the Agreement, Mr. Welch was paid a lump sum of $350,000 less applicable federal, state and local tax withholdings on the eighth day after execution of the Agreement. The Welch Severance Agreement contains mutual releases on behalf of Mr. Welch and the Company.

William Welch Stock Award Agreement

On August 15, 2017, we entered into a stock award agreement (the "Welch Stock Award Agreement") with Mr. Welch, pursuant to which an initial grant of 10,352 shares of common stock was issued to Mr. Welch under our 2014 Equity Incentive Plan, all of which shares vested upon grant. In addition, we agreed to make additional grants of common stock to Mr. Welch over a two year time period. The Welch Stock Award Agreement was terminated and any obligations to Mr. Welch were terminated pursuant to the Welch Severance Agreement.

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 current base compensation is $397,200 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, 2018 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, 2018. The closing price of our common stock, as reported on The Nasdaq Capital Market, was $3.153 on December 31, 2018. 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, Ph.D.

	Termination	
	By Trovagene Without Cause Outside a Change In Control	By Trovagene Without Cause or by Mr. Erlander for Good Reason in Connection with a Change In Control(1)
Value of Equity Securities Accelerated	$ —	$ 26,147
Cash Payments	386,468	386,468
Total Cash Benefits and Payments	$ 386,468	$ 412,615

(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.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a description of transactions or series of transactions since January 1, 2018, 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 addition, 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 year ended December 31, 2018, we incurred and recorded approximately $183,000 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, Billings, Tennant, Countouriotis, and Markin and Mr. Brancaccio to be independent."

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of April 22, 2019 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)
Executive officers and directors:		
Thomas Adams	11,384(3)	*
William Welch	—	*
John Brancaccio	5,339(4)	*
Gary Jacob	5,406(5)	*
Rodney S. Markin	9,416(6)	*
Athena Countouriotis	932(7)	*
Mark Erlander	27,024(8)	*
All Officers and Directors as a Group (6 persons)	59,501(9)	1.2

*less than 1%

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

(2) The calculation in this column is based upon 4,922,201 shares of common stock outstanding on April 22, 2019. 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 April 22, 2019 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 April 22, 2019

(4) Includes 3,072 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

(5) Includes 3,337 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

(6) Includes 2,235 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

(7) Consists of shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

(8) Includes 23,064 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

(9) Includes 39,135 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after April 22, 2019.

DESCRIPTION OF SECURITIES

General

We are authorized to issue up to 150,000,000 shares of common stock, $0.0001 par value per share, and 20,000,000 shares of preferred stock, $0.001 par value per share.

As of April 22, 2019, a total of 4,922,201 shares of our common stock were issued and outstanding, 60,600 and 99,998 shares of our Series A Convertible Preferred Stock and Series C Convertible Preferred Stock were issued and outstanding, respectively.

Common Stock

The holders of our common stock are entitled to one vote per share. Our certificate of incorporation 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 a stockholder who has the right to participate, until April 5, 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.

Preferred Stock

The following is a summary of the material terms of our Series A Convertible Preferred Stock and Series C Convertible Preferred. This summary is not complete. The following summary is qualified in its entirety by reference to the Certificate of Designation of the Series A Convertible Preferred Stock, incorporated by reference herein, and the form of Certificate of Designation of Series C Convertible Preferred Stock, which has been filed as an exhibit to the registration statement of which this prospectus is a part.

Series A Convertible Preferred Stock

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

Dividends. Holders of our 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 our sole election, in cash or shares of Common Stock. As of December 31, 2018 and 2017, we had $341,015 and $316,775, respectively in accrued cumulative unpaid preferred stock dividends, included in accrued liabilities in our consolidated balance sheets, and $24,240 and $24,240 of accrued dividends was recorded during the years ended December 31, 2018 and 2017, respectively.

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, we 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.

Liquidation. Upon any liquidation, dissolution or winding-up of our 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.

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.

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.

Automatic Conversion. If the price of our 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, we 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.

Series C Convertible Preferred Stock

General. Our board of directors has designated up to 200,000 shares of the 20,000,000 authorized shares of preferred stock as Series C Convertible Preferred Stock ("Series C Preferred"). When issued, the shares of Series C Preferred will be validly issued, fully paid and non-assessable.

Conversion. Each share of Series C Preferred will be convertible at the option of the holder into 1.67 shares of Common Stock (subject to adjustment as provided in the certificate of designation). Holders of Series C Preferred will be prohibited from converting Series C Preferred into shares of our Common Stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 4.99% (or upon the election by a holder, 9.99%) of the total number of shares of our Common Stock then issued and outstanding.

Liquidation Preference. In the event of our liquidation, dissolution or winding-up, holders of Series C Preferred will be entitled to receive the same amount that a holder of our Common Stock would receive if the Series C Preferred were fully converted into shares of our Common Stock at the conversion price which amounts shall be paid *pari passu* with all holders of Common Stock.

Voting Rights. The holders of Series C Preferred shall have the right to vote as-if-converted to Common Stock (limited to 93.41% of the then as if converted Common Stock) all matters submitted to a vote of holders of the Company's Common Stock. The holders of Series C Preferred shall vote together with all other classes and series of Common Stock of the Company as a single class on all actions to be taken by the Common Stock holders of the Company except to the extent that voting as a separate class or series is required by law.

Dividends. Shares of Series C Preferred will not be entitled to receive any dividends, unless and until specifically declared by our board of directors.

Warrants

The following summary is not complete and is qualified in its entirety by reference to the warrants, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

Exercisability. The warrants are exercisable at any time after June 12, 2018 until June 12, 2023. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will, at our sole discretion, either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up such fractional amount to the next whole share.

Exercise Limitation. A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Exercise Price. The exercise price per share of common stock purchasable upon exercise of the warrants is $6.60. The warrants may also be exercised via cashless exercise, whereby the holder will receive upon exercise of the warrant (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder’s ownership of shares of our common stock, the holder of a warrant will not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

PLAN OF DISTRIBUTION

We will issue shares of common stock offered hereby upon exercise of the warrants. As of the date of this prospectus, the warrants are exercisable for a total of up to 2,952,740 shares of our common stock, which can be adjusted pursuant to the terms of the warrants. We will not issue fractional shares upon exercise of the warrants. Each of the warrants contains instructions for exercise.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon for us by Sheppard Mullin Richter & Hampton LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018 included in this prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC to register resale of shares of our Common Stock being offered by this prospectus. For further information with respect to us and our Common Stock, please see the registration statement on Form S-1 and the exhibits thereto. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website, *http://www.sec.gov* that contains reports, proxy statements and information statements and other information regarding registrants that file electronically with the SEC, including us. Our SEC filings are also available to the public from commercial document retrieval services. Information contained on our website should not be considered part of this prospectus.

You may also request a copy of these filings, at no cost, by writing or telephoning us at: 11055 Flintkote Avenue, San Diego, California, 92121, (858) 952-7570.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus. We are incorporating by reference the documents listed below (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary), which we have already filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 6, 2019;
- Our Quarterly Report on Form 10-Q filed on May 7, 2019;
- Our Current Reports on Form 8-K filed January 15, 2019, January 23, 2019, January 29, 2019, January 31, 2019, February 12, 2019, February 14, 2019, February 20, 2019, February 28, 2019, March 4, 2019, March 12, 2019, March 13, 2019, April 1, 2019, April 5, 2019, April 23, 2019 and May 13, 2019; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on May 23, 2012.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

Documents incorporated by reference are available from us, without charge. You may obtain documents incorporated by reference in this prospectus by requesting them in writing or by telephone at the following address:

Trovagene, Inc.
11055 Flintkote Avenue
San Diego, CA 92121
Telephone: (858) 952-7570

You also may access these filings on our Internet site at *www.trovageneoncology.com*. Our web site and the information contained on that site, or connected to that site, are not incorporated into this prospectus or the registration statement of which this prospectus is a part.

2,952,740 Shares of Common Stock Issuable upon Exercise of Outstanding Warrants

PROSPECTUS

, 2019

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 21st day of May 2019.

TROVAGENE, INC.

By: /s/ Thomas H. Adams
Thomas H. Adams
Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated

Signature	Title	Date
/s/ Thomas H. Adams Thomas H. Adams	Chief Executive Officer and Chairman (Principal Executive Officer and Principal Financial and Accounting Officer)	May 21, 2019
* John P. Brancaccio	Director	May 21, 2019
* Gary S. Jacob	Director	May 21, 2019
* Rodney S. Markin	Director	May 21, 2019
* Athena Countouriotis	Director	May 21, 2019

* By: /s/ Thomas H. Adams
Attorney-In-Fact