

Trovogene, Inc.  
Form S-3  
February 14, 2019  
**Table of Contents**

As filed with the Securities and Exchange Commission on February 14, 2019

Registration No. 333-

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

**FORM S-3**  
**REGISTRATION STATEMENT**  
***UNDER***  
***THE SECURITIES ACT OF 1933***

**TROVAGENE, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary Standard Industrial  
Classification Code Number)

**27-2004382**  
(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 Adams**

**Chief Executive Officer**

**Trovogene, 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:*

**Jeffrey J. Fessler, Esq.**

**Nazia J. Khan, Esq.**

**Sheppard, Mullin, Richter & Hampton LLP**

**30 Rockefeller Plaza, 39<sup>th</sup> Floor**

**New York, New York 10112**

**Tel: (212) 653-8700**

**Fax: (212) 653-8701**

## Edgar Filing: Trovagene, Inc. - Form S-3

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

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

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.

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.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered(1)	Amount to be	Proposed Maximum	Proposed Maximum	Amount of
---	--------------	------------------	------------------	-----------

	Registered	Offering Price Per Share(2)	Aggregate Offering Price(2)	Registration Fee
Common Stock, par value \$0.0001 per share	1,100,000	\$0.57	\$627,000	\$75.99
Common Stock, par value \$0.0001 per share(3)	900,000	\$0.57	\$513,000	\$62.18
Common Stock, par value \$0.0001 per share(4)	2,000,000	\$0.57	\$1,140,000	\$138.17
Total	4,000,000		\$2,280,000	\$276.34

- (1) The shares of our common stock being registered hereunder are being registered for sale by the selling security holders named in the prospectus. Under Rule 416 of the Securities Act of 1933, as amended, the shares being registered include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered in this registration statement as a result of any stock splits, stock dividends or other similar event.
- (2) The proposed maximum offering price per share and the proposed maximum aggregate offering price have been estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(c) under the Securities Act of 1933, as amended, using the average of the high and low prices for the Registrant's common stock as reported on the Nasdaq Capital Market on February 13, 2019, a date within five business days prior to the filing of this Registration Statement.
- (3) Represents shares of common stock issuable upon exercise of outstanding warrants to purchase shares of common stock offered by the selling stockholder.
- (4) Represents shares of common stock issuable upon conversion of outstanding preferred stock offered by the selling stockholder.

**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, 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.**

**Table of Contents**

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

**Subject to Completion, dated February 14, 2019**

**PROSPECTUS**

**Trovogene, Inc.**

**4,000,000 Shares of Common Stock**

This prospectus relates to the resale by the stockholder listed in the section of this prospectus entitled "Selling Stockholder" (the "Selling Stockholder"), of up to 4,000,000 shares of our common stock, par value \$0.0001 per share (the "Common Stock"). The 4,000,000 shares of Common Stock consist of: (i) 1,100,000 shares of Common Stock (the "Shares"), (ii) up to 2,000,000 shares of Common Stock issuable upon conversion of our outstanding Series C Convertible Preferred Stock, par value \$0.0001 per share (the "Series C Preferred Stock") and (iii) up to 900,000 shares of Common Stock issuable upon exercise of outstanding warrants to purchase shares of Common Stock (the "Warrants" and together with the Shares and the Series C Preferred Stock, the "Resale Shares"). The warrants are exercisable at any time until January 25, 2024 at an exercise price of \$0.627 per share.

The Resale Shares may be sold by the Selling Stockholder to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information regarding the methods of sale you should refer to the section entitled "Plan of Distribution" in this Prospectus.

The prices at which the Selling Stockholder may sell the Resale Shares will be determined by the prevailing market price for shares of the Company's Common Stock or in negotiated transactions. We will not receive any proceeds from the sale of the Resale Shares by the Selling Stockholder; provided, however, we will receive the proceeds from any cash exercise of the Warrants.

We will bear all costs relating to the registration of the Resale Shares, other than any Selling Stockholder legal or accounting costs or commissions.

Our Common Stock is presently listed on the Nasdaq Capital Market under the symbol "TROV". The closing price of our Common Stock on February 13, 2019, as reported by Nasdaq, was \$0.57 per share.

**Investing in our Common Stock involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 7 of this prospectus and elsewhere in this prospectus for a discussion of information that should be**

**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 \_\_\_\_\_, 2019.**

**Table of Contents****TABLE OF CONTENTS**

	<b>Page</b>
<u>Cautionary Note Regarding Forward Looking Statements</u>	1
<u>Prospectus Summary</u>	2
<u>Risk Factors</u>	7
<u>Use of Proceeds</u>	8
<u>Selling Stockholders</u>	9
<u>Plan of Distribution</u>	11
<u>Description of Capital Stock</u>	13
<u>Legal Matters</u>	15
<u>Experts</u>	15
<u>Where You Can Find More Information</u>	15
<u>Disclosure of Commission Position on Indemnification for Securities Act Liabilities</u>	15
<u>Incorporation of Certain Information by Reference</u>	16

You should rely only on the information we have provided or incorporated by reference into this prospectus, any applicable prospectus supplement and any related free writing prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

The Selling Stockholder is offering the securities only in jurisdictions where such issuances are permitted. The distribution of this prospectus and the issuance of the securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the issuance of the securities and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, the securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the SEC), under which the Selling Stockholder may offer from time to time up to an aggregate of 4,000,000 shares of our common stock in one or more offerings. If required, each time a Selling Stockholder offers common stock, in addition to this prospectus, we will provide you with a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to that offering. We may also use a prospectus supplement and any related free writing prospectus to add, update or change any of the information contained in this prospectus or in documents we have incorporated by reference. This prospectus, together with any applicable prospectus supplements, any related free writing prospectuses and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified

or superseded by those made in a prospectus supplement. Please carefully read both this prospectus and any prospectus supplement together with the additional information described below under **Important Information Incorporated by Reference** .



**Table of Contents**

**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 of 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, 2017 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.

**Table of Contents****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**, **Trovogene** or the **Company** in this prospectus mean Trovogene, Inc. on a consolidated basis with its wholly-owned subsidiary, Trovogene, Srl, as applicable.*

**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, 3<sup>rd</sup> 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 first PLK1 selective ATP competitive inhibitor administered orally with apparent antitumor activity in different preclinical models currently in clinical development. 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 this over-expression correlates with poor prognosis.

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

cell lines.

**Table of Contents**

Onvansertib was developed to have high selectivity to 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 has been successfully completed in patients with advanced metastatic solid tumors and was published in 2017 in *Investigational New Drugs*. We have three active Investigational New Drugs ( IND ), two ongoing clinical studies and a third study planned. 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 (ClinicalTrials.gov Identifier NCT03829410), a Phase 1b/2 open-label clinical trial of Onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for patients with metastatic Colorectal Cancer ( mCRC ), who have a KRAS mutation, planned for initiation in the first half of 2019.

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 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 (interaction of discrete drugs such that the total effect is greater than the sum of the individual effects) 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. The U.S. Food and Drug Administration ( FDA ) recently approved Rydapt® (midostaurin) by Novartis for the treatment of newly diagnosed adult patients with AML that are FLT3 mutation-positive in combination with cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. There are two additional FLT3 inhibitors in ongoing phase 3 trials, including Quizartinib. 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.

## **Table of Contents**

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 with data 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 (formerly known as 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 application 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**

## Edgar Filing: Trovogene, Inc. - Form S-3

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

## **Table of Contents**

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 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.

We announced in February 2018 that the first patient completed the first cycle of dosing with onvansertib in combination with low-dose cytarabine in our Phase 1b/2 multicenter trial of patients with AML. 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

## **Table of Contents**

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 will be 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 Trovogene, 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.trovogene.com](http://www.trovogene.com). The information on our website is not part of this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website.

**Table of Contents**

**RISK FACTORS**

Investing in shares of our securities involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described under "Risk Factors" in in any applicable prospectus supplement and in our most recent Annual Report on Form 10-K, and the updates in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in or incorporated by reference into this prospectus before deciding whether to purchase any of the securities being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of shares of our Common Stock could decline due to any of these risks, and you may lose all or part of your investment.

**Table of Contents**

**USE OF PROCEEDS**

We will receive no proceeds from the sale of the Resale Shares by the Selling Stockholders. We may, however, receive cash proceeds equal to the total exercise price of the Warrants to the extent that the Warrants are exercised for cash. However, the Warrants contain a cashless exercise feature that allow the holders to exercise the Warrants without making a cash payment to us in the event that there is no registration statement registering the Resale Shares. There can be no assurance that any of these Warrants will be exercised by the Selling Stockholders at all or that the Warrants will be exercised for cash rather than pursuant to the cashless exercise feature. To the extent we receive proceeds from the cash exercise of the Warrants, we intend to use such proceeds for working capital purposes.

The Selling Stockholders will pay any underwriting discounts and commissions and any similar expenses they incur in disposing of the Resale Shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the Resale Shares covered by this prospectus. These may include, without limitation, all registration and filing fees, printing fees and fees and expenses of our counsel and accountants.

**Table of Contents****SELLING STOCKHOLDERS**

This prospectus relates to the resale from time to time by the selling security holder identified herein of up to an aggregate of 4,000,000 Resale Shares.

On January 25, 2019, we entered into a Stock and Warrant Subscription Agreement with the Selling Stockholder pursuant to which we sold to the Selling Stockholder (i) 1,100,000 shares of our common stock, (ii) 200,000 shares of our Series C Convertible preferred stock convertible into 2,000,000 shares of our common stock and (iii) a warrant to purchase 900,000 shares of our common stock exercisable at \$0.627 per share.

The Resale Shares were issued or will be issued to the Selling Stockholder in reliance on the exemption from securities registration in Section 4(a)(2) under the Securities Act.

The Resale Shares referred to above are being registered to permit public sales of the Resale Shares, and the Selling Stockholder may offer the shares for resale from time to time pursuant to this prospectus. The Selling Stockholder may also sell, transfer or otherwise dispose of all or a portion of their Resale Shares in transactions exempt from the registration requirements of the Securities Act or pursuant to another effective registration statement covering those shares.

The table below sets forth certain information regarding the Selling Stockholders and the Resale Shares offered in this prospectus. The Selling Stockholder has had no material relationship with us within the past three years other than as described in the footnotes to the table below or as a result of its acquisition of our shares or other securities.

Beneficial ownership is determined in accordance with the rules of the SEC. The selling stockholder's percentage of ownership of our outstanding shares in the table below is based upon 24,129,042 shares of Common Stock outstanding as of February 13, 2019.

	Ownership Before Offering		After Offering (2)	
	Number of Shares of Common stock Beneficially Owned (1)	Number of Shares Offered	Number of Shares of Common Stock Beneficially Owned (1)	Percentage of Common stock Beneficially Owned
Selling Stockholder PoC Capital, LLC (3)	1,207,923(4)	4,000,000(5)	39,100	*

\* Represents less than 1%.

- (1) Under applicable SEC rules, a person is deemed to beneficially own securities which the person has the right to acquire within 60 days through the exercise of any option or warrant or through the conversion of a convertible security. Also under applicable SEC rules, a person is deemed to be the beneficial owner of a security with regard to which the person directly or indirectly, has or shares (a) voting power, which includes the power to vote or direct the voting of the security, or (b) investment power, which includes the power to dispose, or direct the disposition, of the security, in each case, irrespective of the person's economic interest in the security. Each listed Selling Stockholder has the sole investment and voting power with respect to all of the securities shown as

- beneficially owned by such Selling Stockholder, except as otherwise indicated in the footnotes to the table.
- (2) Represents the amount of shares that will be held by the Selling Stockholder after completion of this offering based on the assumptions that (a) all Resale Shares registered for sale by the registration statement of which this prospectus is part will be sold and (b) no other securities are acquired or sold by the Selling Stockholder prior to completion of this offering. However, the Selling Stockholder may sell all, some or none of the Resale Shares offered pursuant to this prospectus and may sell other securities that they may own pursuant to another registration statement under the Securities Act or sell some or all of their securities pursuant to an exemption from the registration provisions of the Securities Act, including under Rule 144.

**Table of Contents**

- To our knowledge there are currently no agreements, arrangements or understanding with respect to the sale of any of the securities that may be held by the Selling Stockholder after completion of this offering or otherwise.
- (3) Daron Evans as Managing Director of PoC Capital, LLC has voting and dispositive power over the securities held by such entity.
  - (4) Includes (i) 1,130,000 shares of Common Stock and (ii) 77,923 shares of Common Stock issuable upon conversion Series C Preferred Stock. Excludes (i) 1,922,077 shares of Common Stock issuable upon conversion of Series C Preferred Stock and (ii) 909,100 shares of Common Stock issuable upon exercise of warrants. The foregoing class of preferred stock and the foregoing warrants contain an ownership limitation such that the holder may not convert or exercise any of such securities to the extent that such conversion or exercise would result in the holder's beneficial ownership being in excess of 4.99% of the Company's issued and outstanding Common Stock together with all shares owned by the holder and its affiliates.
  - (5) Includes (i) 1,100,000 shares of Common Stock, (ii) 2,000,000 shares of Common Stock issuable upon conversion of 200,000 shares of Series C Preferred Stock and (iii) 900,000 shares of Common Stock issuable upon exercise of warrants.

**Table of Contents**

**PLAN OF DISTRIBUTION**

**General**

We are registering the Resale Shares covered by this prospectus to permit the Selling Stockholders to conduct public secondary trading of such shares from time to time after the date of this prospectus. We will not receive any of the proceeds of the sale of the Resale Shares offered by this prospectus. The aggregate proceeds to the Selling Stockholders from the sale of the Resale Shares will be the purchase price of the Resale Shares less any discounts and commissions. Each Selling Stockholder reserves the right to accept and, together with their respective agents, to reject, any proposed purchases of Resale Shares to be made directly or through agents.

Following the date of this prospectus, the Selling Stockholders and any of their pledgees, assignees and successors-in-interest may sell all or a portion of their Resale Shares from time to time in one or more transactions at prevailing market prices or at privately negotiated market prices. The Selling Stockholders may use any one or more of the following methods when selling the Resale Shares offered by this prospectus:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;

broker-dealers may agree with the Selling Stockholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;



under Rule 144, Rule 144A or Regulation S under the Securities Act, if available, rather than under this prospectus; or

any other method permitted pursuant to applicable law.

Our Common Stock is listed on the Nasdaq Capital Market under the symbol TROV. Broker-dealers engaged by the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated.

In connection with the sale of our Common Stock or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of our Common Stock in the course of hedging the positions they assume. The Selling Stockholders may also sell shares of our Common Stock short and deliver these securities to close out their short positions, or loan or pledge our Common Stock to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

**Table of Contents**

The Selling Stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts. If a Selling Stockholder is deemed to be an underwriter, the Selling Stockholder may be subject to certain statutory liabilities including, but not limited to Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act. Selling Stockholders who are deemed underwriters within the meaning of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

The SEC staff is of a view that Selling Stockholders who are registered broker-dealers or affiliates of registered broker-dealers may be underwriters under the Securities Act. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of Common Stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. We will not pay any compensation or give any discounts or commissions to any underwriter in connection with the securities being offered by this prospectus. The Selling Stockholders have advised us that they have not entered into any written or oral agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the Resale Shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the Resale Shares by the Selling Stockholders.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the Selling Stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act. Each Selling Stockholder has in turn agreed to indemnify us for certain specified liabilities.

In order to comply with the securities laws of some states, if applicable, the shares of Common Stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the shares of Common Stock may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the Resale Shares may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the Common Stock by the Selling Stockholders or any other person. The anti-manipulation rules under the Exchange Act may apply to sales of Common Stock in the market and to the activities of the Selling Stockholders and their affiliates. Regulation M may restrict the ability of any person engaged in the distribution of the Common Stock to engage in market-making activities with respect to the particular shares of common stock being distributed for a period of up to five business days before the distribution. These restrictions may affect the marketability of the Common Stock and the ability of any person or entity to engage in market-making activities with respect to the common stock. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

**Table of Contents**

**DESCRIPTION OF CAPITAL STOCK**

**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 February 13, 2019, a total of 24,129,042 shares of our Common Stock were issued and outstanding, 60,600 shares of our Series A Convertible Preferred Stock were issued and outstanding and 200,000 shares of our Series C Preferred Stock were issued and outstanding.

**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. 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 Stock. 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 and the Certificate of Designation of the Series C Convertible Preferred Stock, each of which has been filed as an exhibit to the registration statement of which this prospectus is a part.*

*Series A Convertible Preferred Stock*

**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, 2017 and 2016, we had \$316,775 and \$292,535, 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, 2017 and 2016, 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 our 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.

## **Table of Contents**

*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 \$25.80 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 \$115.20 per share.

*Automatic Conversion.* If the price of our Common Stock equals \$309.60 per share for 20 consecutive trading days, and an average of 695 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 ten 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**

As of February 13, 2019, we had outstanding warrants to purchase an aggregate of 22,796,043 shares of our Common Stock.

On January 25, 2019, we entered into a Stock and Warrant Subscription Agreement (the SPA ) with an investor pursuant to which we issued to such investor, among other securities, a warrant exercisable for 900,000 shares of our

Common Stock. The warrant is exercisable at any time until January 25, 2024 at an exercise price of \$0.627 per share.

**Table of Contents**

**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, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 incorporated by reference in this prospectus have been so incorporated 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**

This prospectus constitutes a part of the registration statement on Form S-3 that we have filed with the SEC under the Securities Act. As permitted by the SEC's rules, this prospectus and any prospectus supplement, which forms a part of the registration statement, do not contain all of the information that is included in the registration statement. You will find additional information about us in the registration statement. Any statement made in this prospectus or any prospectus supplement concerning legal documents are not necessarily complete and you should read the documents that are filed as exhibits to the registration statement or otherwise filed with the SEC for a more complete understanding of the document or matter.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at <http://www.sec.gov>. We also maintain a website at [www.trovagene.com](http://www.trovagene.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Room 1580, Washington, DC 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. 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.

**DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT  
LIABILITIES**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and persons controlling us pursuant to the provisions described in Item 14 of the registration statement of which this prospectus is a part or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than our payment of expenses incurred or paid by our directors, officers, or controlling persons in the successful defense of any action, suit, or proceeding) is asserted by our directors, officers, or controlling persons in connection with the Common Stock being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question

whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of the issue.



**Table of Contents**

**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus contain important information that you should read about us.

our Annual Report on Form 10-K for the year ended December 31, 2017 filed on February 26, 2018;

our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018 filed on May 5, 2018, for the quarterly period ended June 30, 2018 filed on August 3, 2018 and for the quarterly period ended September 30, 2018 filed on November 11, 2018;

our Current Reports on Form 8-K (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed on March 9, 2018, April 12, 2018, May 30, 2018, June 1, 2018, June 12, 2018, June 22, 2018, September 13, 2018, December 14, 2018, January 29, 2019, January 31, 2019, February 12, 2019 and February 14, 2019;

the Company's prospectus filed on June 11, 2018 pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the Registration Statement on Form S-1, as amended (File No. 333-224808) which contains audited financial statements for the Company's latest fiscal year for which such statements have been filed.

our definitive proxy statement on Schedule 14A relating to our annual meeting of stockholders filed on April 27, 2018;

our definitive proxy statement on Schedule 14A relating to our special meeting of stockholders filed on December 18, 2018; 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, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus and will become a part of this prospectus from the respective dates that such documents are filed with the SEC. 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 or of the related prospectus supplement 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

Edgar Filing: Trovogene, Inc. - Form S-3

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:

Trovogene, Inc.

11055 Flintkote Avenue

San Diego, CA 92121

Telephone: (858) 952-7570

You also may access these filings on our Internet site at [www.trovogene.com](http://www.trovogene.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.

**Table of Contents**

This prospectus is part of a registration statement we filed with the SEC. We have incorporated exhibits into the registration statement of which this prospectus is a part. You should read the exhibits carefully for provisions that may be important to you. We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery.

**Table of Contents**

4,000,000 Shares of Common Stock

PROSPECTUS

, 2019

Neither we nor the Selling Stockholder has authorized any dealer, salesperson or other person to give any information or to make any representations not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information. This prospectus is not an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. The information in this prospectus is current as of the date of this prospectus. You should not assume that this prospectus is accurate as of any other date.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the costs and expenses payable by Trovogene, Inc. (the Registrant, the Company, we or us) in connection with the issuance and distribution of the securities being registered hereunder. All amounts are estimates except the SEC registration fee.

SEC registration fees	\$ 277
Printing expenses	\$ 5,000
Accounting fees and expenses	\$ 10,000
Legal fees and expenses	\$ 25,000
Miscellaneous	\$ 1,723
Total	\$ 42,000

**Item 15. Indemnification of Directors and Officers.**

The Company's amended and restated certificate of incorporation eliminates the personal liability of directors to the fullest extent permitted by the Delaware General Corporation Law and, together with the Company's bylaws, provides that the Company shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it may be amended or supplemented, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Company or, while a director or officer of the Company, is or was serving at the request of the Company as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person.

We have also obtained a liability insurance policy that insures our directors and officers, within the limits and subject to the limitations of the policy, against certain expenses in connection with the defense of actions, suits or proceedings, and certain liabilities that might be imposed as a result of such actions, suits or proceedings, to which they are parties by reason of being or having been directors or officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, this indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) The exhibits listed under the caption Exhibit Index preceding the signature page are filed herewith or incorporated by reference herein.

(b) Financial Statement Schedules

No financial statement schedules are provided because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

II-1

---

**Table of Contents**

**Item 17. Undertakings.**

(a) The undersigned Registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however, That:*

Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the

initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a

II-2



**Table of Contents**

time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, as amended, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

---

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
4.1	<u>Form of Common Stock Certificate of Trovogene, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 10-12G filed on November 25, 2011).</u>
4.2+	<u>2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on July 19, 2004)</u>
4.3	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 28, 2012).</u>
4.4	<u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 1, 2014).</u>
4.5+	<u>Trovogene, Inc. 2014 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Proxy Statement on Schedule 14A filed on April 27, 2018)</u>
4.6	<u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to Form 8-K filed on July 26, 2016).</u>
4.7	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on June 12, 2018).</u>
4.8	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 29, 2019).</u>
4.9	<u>Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2019)</u>
5.1*	<u>Opinion of Sheppard Mullin Richter &amp; Hampton LLP</u>
23.1*	<u>Consent of BDO USA, LLP</u>
23.2*	<u>Consent of Sheppard Mullin Richter &amp; Hampton LLP (included as part of Exhibit 5.1)</u>
24.1*	<u>Power of Attorney (included on signature page hereto).</u>

\* Filed herewith.

+ Indicates a management contract or compensatory plan or arrangement.

**Table of Contents****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 14th day of February 2019.

TROVAGENE, INC.

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

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Adams, his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him/her and in his/her name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Thomas Adams	Chief Executive Officer and Chairman	February 14, 2019
Thomas Adams	(Principal Executive Officer and Principal Financial Officer)	
/s/ Gary Jacob	Director	February 14, 2019
Gary Jacob		
/s/ Rodney S. Markin	Director	February 14, 2019
Rodney S. Markin		
/s/ Athena Countouriotis	Director	February 14, 2019

Athena Countouriotis

/s/ John Brancaccio

Director

February 14, 2019

John Brancaccio