

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM S-1

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 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)

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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:

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 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.

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	Amount to be registered(1)	Proposed maximum offering price per share(2)	Aggregate maximum offering price	Amount of Registration Fee
Common stock, par value \$0.0001per share	8,475,746	\$ 1.65	\$ 13,984,981	\$ 1,816

(1) Consists of an aggregate of 8,475,746 shares of the registrant's common stock, including (i) 2,756,340 shares of common stock (or common stock equivalents), (ii) 2,756,340 shares of common stock issuable upon exercise of Series G warrants, (iii) 2,756,340 shares of common stock issuable upon exercise of Series H warrants and (iv) 206,726 shares of common stock issuable upon exercise of placement agent warrants, all of which were acquired by the selling stockholders in a private placement. Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration statement also covers an indeterminate amount of shares of common stock as may become issuable to prevent dilution resulting from stock splits, stock dividends or similar events.

(2) Calculated pursuant to Rule 457(c) of the Securities Act of 1933, as amended, solely for the purpose of computing the amount of the registration fee, on the basis of the average of the high and low prices of the registrant's common stock quoted on The Nasdaq Stock Market on October 29, 2019.

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.

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.

Subject to completion, dated November 1, 2019

PRELIMINARY PROSPECTUS

8,475,746 Shares



Common Stock

This prospectus relates to the resale by the selling security holders identified in this prospectus of up to 8,269,020 shares of our common stock comprised of (i) 2,756,340 shares of common stock (or common stock equivalents) (the “Shares”), (ii) series G warrants to purchase up to 2,756,340 shares of common stock (the “Series G Warrants”), (iii) series H warrants to purchase up to 2,756,340 shares of common stock (the “Series H Warrants”) and (iv) placement agent warrants to purchase up to 206,726 shares of common stock (the “Placement Agent Warrants” and together with the Series G Warrants and the Series H Warrants, the “Warrants”). The Shares and Warrants were issued in connection with a private placement we completed on October 30, 2019.

We will receive none of the proceeds from the sale of the shares by the selling stockholders. 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. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

Our common stock is listed on the Nasdaq Capital Market under the symbol “TROV.” On October 31, 2019, the last reported sale price per share of our common stock on the Nasdaq Capital Market was \$1.81.

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 risks. See “Risk Factors” beginning on page 9 of this prospectus and in the documents incorporated by reference into 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 , 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 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, 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 Cancer Medicine™ (PCM) approach to develop drugs that target mitosis (cell division) for the treatment of various cancers including prostate, colorectal and leukemia. By integrating a biomarker strategy into our development programs, we will be able to identify patients more likely to respond to treatment.

On March 15, 2017, we announced that we licensed onvansertib, a PLK1 inhibitor, from Nerviano, pursuant to a license agreement with Nerviano dated March 13, 2017. This exclusive, world-wide license agreement includes 3 issued patents for onvansertib which cover composition of matter, salt forms of onvansertib and combination of onvansertib with other drugs. Onvansertib was developed to have high selectivity to PLK1 (at low nanomolar IC50 levels), to have ideal pharmacokinetics, including oral bioavailability and administration and a drug half-life of approximately 24 hours, allowing for flexible dosing and scheduling, and is well tolerated and safe with only mild- to moderate side effects reported to-date. A Phase 1 safety study of onvansertib has been successfully completed in patients with advanced metastatic solid tumors and published in 2017 in *Investigational New Drugs*. We currently have three active clinical trials: a Phase 2 open-label clinical trial of onvansertib in combination with abiraterone acetate (Zytiga®) and prednisone in patients with metastatic Castration-Resistant Prostate Cancer (“mCRPC”), being conducted at Beth Israel Deaconess Medical Center (“BIDMC”), Dana-Farber Cancer Institute (“DFCI”), and Massachusetts General Hospital (“MGH”); a Phase 1b/2 open-label clinical trial of onvansertib in combination with FOLFIRI and Avastin® in patients with mCRC with a KRAS mutation, being conducted at USC Norris Comprehensive Cancer Center and The Mayo Clinic; and a Phase 1b/2 open-label clinical trial of onvansertib in combination with standard-of-care chemotherapy in patients with AML, being conducted at eight sites across the U.S.

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

Studies have shown that inhibition of polo-like-kinases can lead to tumor cell death, including a Phase 2 study in Acute Myeloid Leukemia (“AML”) where response rates with a prior PLK inhibitor of up to 31% were observed when used in conjunction with a standard therapy for AML (low-dose cytarabine (“LDAC”)) versus a 13.3% response rate with LDAC alone. We believe the more selective nature of onvansertib to PLK1, its 24-hour half-life and oral bioavailability, as well as its demonstrated safety and tolerability, with only mild- to moderate side effects reported, may prove useful in addressing clinical therapeutic needs across a variety of cancers.

Onvansertib has been tested in-vivo in different xenograft and transgenic models suggesting tumor growth inhibition or tumor regression when used in combination with other therapies. Onvansertib has been tested for antiproliferative activity on a panel of 148 tumor cell lines and appeared highly active with an 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 also appears active in cells expressing multi-drug resistant (“MDR”) transporter proteins and we believe its apparent ability to overcome the MDR transporter resistance mechanism in cancer cells could prove useful in broader drug combination applications.

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

We continue to focus on advancing our three active clinical trials with onvansertib in 2019. We have achieved a number of key milestones through the first three quarters of 2019 and anticipate achieving additional milestones through the end of 2019:

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

- Completed Phase 1b dose escalation safety segment of trial, identified the recommended Phase 2 dose (“RP2D”) of onvansertib at 60mg/m².
- Initiated the Phase 2 segment of the AML trial, which will enroll approximately 32 patients, for continued evaluation of safety and efficacy of onvansertib in combination with decitabine.
- Provide safety and preliminary efficacy data on the combination of onvansertib in combination with decitabine in patients treated through the end of 2019.
- Present data from the AML trial at key oncology conferences, including the European Society for Medical Oncology (“ESMO”) and the American Society of Hematology (“ASH”) annual meetings.

Phase 2 Trial of Onvansertib in Combination with Abiraterone Acetate (Zytiga[®]) and Prednisone for the Treatment of Metastatic Castration-Resistant Prostate Cancer

- Completed enrollment and evaluation of the 6 safety lead-in patients in the second arm (2-week dosing schedule) with onvansertib at 24 mg/m² in combination with abiraterone acetate (Zytiga[®]) and prednisone.
- Provide safety and preliminary efficacy data of onvansertib in combination with abiraterone acetate (Zytiga[®]) and prednisone in patients treated through the end of 2019.
- Present data from the mCRPC trial at key oncology conferences throughout 2019, including the Asia-Pacific Prostate Cancer Conference (“APPC”), and first quarter of 2020 including ASCO-GU.

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

- Completed enrollment and evaluation of the initial dose level cohort of onvansertib 12 mg/m² and opened the second dose level (onvansertib 15 mg/m²) cohort to enrollment.

- Provide safety and preliminary efficacy data on the combination of onvansertib + FOLFIRI + Avastin® in patients treated through the end of 2019.

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

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

On October 22, 2019, we announced data demonstrating positive response to treatment in patients enrolled in its Phase 1b/2 trial of onvansertib in combination with FOLFIRI and Avastin® (bevacizumab) for second-line treatment of KRAS-mutated metastatic colorectal cancer (mCRC). Decreases in tumor KRAS mutational burden in response to treatment was observed in all four patients who completed their first cycle of therapy with the combination regimen, as measured by quantitative analysis of circulating tumor DNA (ctDNA).
- Announced data presented at ESMO providing rationale for a clinical trial of onvansertib in subset of patients with Highly-Aggressive Triple Negative Breast Cancer (TNBC).

On October 2, 2019, we announced the presentation of data in a poster at ESMO demonstrating significant tumor regression observed with onvansertib in combination with standard-of-care paclitaxel in models of p53-mutated TNBC. Onvansertib preclinical data provides rationale for conducting a clinical trial targeting the 80% of TNBC that harbors the p53 mutation. The combination has potential to address critical medical need to provide targeted treatment option to overcome resistance to paclitaxel as single agent therapy in TNBC.
- Announced presentation of a poster at ESMO of Phase 1b/2 trial of onvansertib in patients with KRAS-mutated metastatic colorectal cancer (mCRC).

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

On September 30, 2019, we announced positive data from our Phase 1b/2 trial in acute myeloid leukemia (AML) was presented in an oral plenary session at the ESMO conference. The data showed that administration of onvansertib in combination with standard-of-care chemotherapy is safe and well-tolerated and resulted in anti-leukemic activity that appears to be sustainable over time. There is a strong correlation between biomarker positive patients and treatment response; observed in 6 of 9 biomarker positive patients versus 1 of 11 biomarker negative patients. Phase 2 is open to enrolling 32 patients for treatment with onvansertib at the recommended dose of 60 mg/m², in combination with decitabine, to further assess safety and efficacy of the regimen.
- Announced Successful Completion of the AML Phase 1b Trial and Initiation of the Phase 2 Continuation Trial.

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

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

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

- Announced research collaboration with Nektar Therapeutics to evaluate the efficacy of the combination of onvansertib and ONZEALDTM in models of colorectal cancer.

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

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

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

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

On January 23, 2019, we announced the issuance of a new patent (10,155,006), entitled *Combination Therapies and Methods of Use Thereof for Treating Cancer*, by the U.S. Patent and Trademark Office ("USPTO"). This patent broadens previously issued patent (9,566,280), by expanding the use of onvansertib to encompass combination therapies with any anti-androgen and androgen antagonist drug, such as Zytiga®, Xtandi® and Erleada® for the treatment of metastatic and non-metastatic castrate-resistant prostate cancer.

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, PRECISION CANCER MEDICINE, TROVAGENE ONCOLOGY and PIPELINE WITHIN A MOLECULE. 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.trovogeneoncology.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.

RISK FACTORS

An investment in our common stock involves risks. Prior to making a decision about investing in our common stock, you should consider carefully the risks together with all of the other information contained or incorporated by reference in this prospectus, including any risks in the section entitled “Risk Factors” contained in any supplements to this prospectus and in our [Annual Report on Form 10-K for the fiscal year ended December 31, 2018](#) and in our subsequent filings with the SEC. Each of the referenced risks and uncertainties could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities. Additional risks not known to us or that we believe are immaterial may also adversely affect our business, operating results and financial condition and the value of an investment in our securities.

PRIVATE PLACEMENT OF SECURITIES

On October 25, 2019, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain accredited investors (the “Investors”) pursuant to which we sold to the Investors (i) an aggregate of 1,301,268 shares (the “Shares”) of common stock, par value \$0.0001 per share (the “Common Stock”), (ii) pre-funded warrants to purchase an aggregate of 1,455,072 shares of Common Stock (the “Pre-Funded Warrants”), (iii) Series G Warrants to purchase an aggregate of 2,756,340 shares of Common Stock (the “Series G Warrants”) and (iv) Series H Warrants to purchase an aggregate of 2,756,340 shares of Common Stock (the “Series H Warrants”). Assignees of H.C. Wainwright & Co., LLC, as the placement agent, received warrants to purchase 206,726 shares of common stock (the “Placement Agent Warrants” and together with the Pre-Funded Warrants, the Series G Warrants and the Series H Warrants, the “Warrants”). The Shares and the Warrants shall collectively be referred to herein as the “Securities”. The Securities were sold at a price of \$1.814 per Share and associated Warrants for gross proceeds of approximately \$5.0 million.

The Series G Warrants are exercisable immediately until April 30, 2025 at an exercise price of \$1.56 per share. The Series H Warrants are exercisable immediately until April 30, 2021 at an exercise price of \$1.56 per share. The Pre-Funded Warrants are exercisable immediately at an exercise price of \$0.01 per share and shall terminate when exercised in full. The Placement Agent Warrants are exercisable immediately until April 30, 2025 at an exercise price of \$2.2675 per share.

USE OF PROCEEDS

We will not receive any of the proceeds from any sale or other disposition of the common stock covered by this prospectus. All proceeds from the sale of the common stock will be paid directly to the selling stockholders. We will receive proceeds upon the cash exercise of the Warrants for which the underlying Warrant shares are being registered hereunder. Assuming full cash exercise of the Warrants, we would receive proceeds of approximately \$8.4 million. We currently intend to use the cash proceeds from any Warrant exercise for clinical development, working capital and general corporate purposes.

SELLING STOCKHOLDERS

This prospectus covers the resale, from time to time by the selling stockholders identified below, of up to 8,475,746 shares of our common stock issuable upon exercise of certain warrants held by such selling stockholders.

We will not receive any proceeds from the sale of these shares by the selling stockholders. We will bear all costs relating to the registration of these shares of our common stock. We are registering the shares hereby pursuant to the terms of our agreements with certain stockholders, in order to permit the selling stockholders identified in the table below to offer the shares for resale from time to time.

The table below sets forth certain information regarding the selling stockholders and the shares of our common stock offered by them in this prospectus. The selling stockholders have not had a 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 their acquisition of our shares or other securities. To our knowledge, subject to community property laws where applicable, each person named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite such person's name.

Selling Stockholder	Number of Shares Beneficially Owned Prior to this Offering		Number of Shares Being Offered (2)	Number of Shares Beneficially Owned After this Offering	
	Number	Percent (1)		Number	Percent (1)
Armistice Capital Master Fund Ltd.	750,000(3)	9.7	6,615,216	0	—
Lincoln Park Capital Fund, LLC	551,268(4)	7.1	1,653,804	850,000	9.9
Michael Vasinkevich	133,338(5)	1.7	133,338	0	—
Noam Rubinstein	45,480(5)	*	45,480	0	—
Michael Mirsky	19,639(5)	*	19,639	0	—
Mark Viklund	6,202(5)	*	6,202	0	—
Charles Worthman	2,067(5)	*	2,067	0	—

*less than 1%

- (1) Percentages are based on 7,742,355 shares outstanding as of October 31, 2019. Shares of our common stock subject to options, warrants or conversion rights that are currently exercisable or convertible, or exercisable or convertible within 60 days of October 31, 2019 are deemed to be outstanding for the purpose of computing the percentage ownership of the person holding those options, warrants or conversion rights, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.
- (2) Assumes all of the shares of common stock registered on the registration statement of which this prospectus is a part are sold in the offering, that shares of common stock beneficially owned by the selling stockholders but not being offered pursuant to this prospectus (if any) are not sold, and that no additional shares of common stock are purchased or otherwise acquired by the selling stockholders.

- (3) Consists of shares of common stock. Does not include (i) 1,455,972 shares of common stock issuable upon exercise of pre-funded warrants, (ii) 2,205,072 shares of common stock issuable upon exercise of Series G warrants and (iii) 2,205,072 shares of common stock issuable upon exercise of Series H warrants, all which include a 9.9% beneficial ownership limitation. Stephen Boyd is deemed to be the beneficial owner of all the shares of common stock owned by Armistice. The address for Armistice Capital Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, New York 10022.
- (4) Consists of shares of common stock. Does not include (i) 12,731 shares of common stock issuable upon exercise of December 19, 2017 warrants, (iii) 200,000 shares of common stock issuable upon exercise of June 12, 2018 warrants, (iv) 382,166 shares of common stock issuable upon exercise of Series B warrants, (v) 458,015 shares of common stock issuable upon exercise of Series D warrants, (vi) 551,268 Series G warrants and (vii) 551,268 Series H warrants, all of which include a 9.9% beneficial ownership limitation. Joshua Scheinfeld and Jonathan Cope, the principals of Lincoln Park are deemed to be beneficial owners of all the shares of common stock owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and disposition power over the shares being offered. The address for Lincoln Park Capital Fund, LLC is 440 N. Wells St., Suite 410, Chicago, IL 60654.
- (5) Address is c/o H.C. Wainwright & Co., LLC, 430 Park Ave., New York, NY 10022. Consists of shares of common stock underlying the Placement Agent warrants.

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 October 31, 2019, a total of 7,742,355 shares of our common stock were issued and outstanding, 60,600 shares of our Series A Convertible 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. Except for a stockholder who has the right to participate, until August 20, 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. 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, 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.

Warrants

Description of Series G Warrants

The material terms and provisions of the Series G Warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the Series G Warrants is not complete. For the complete terms of the Series G Warrants, you should refer to the form of Warrant filed as an exhibit to the registration statement of which this prospectus forms a part.

The Series G Warrants are exercisable immediately until April 30, 2025 at an exercise price of \$1.56 per share. The holder of a Series G Warrant will not be deemed a holder of our underlying common stock until the Series G Warrant is exercised, except as set forth in the Series G Warrant.

Pursuant to the terms of the Series G Warrants, a holder of Series G Warrants will not have the right to exercise any portion of its Series G Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) (the "Beneficial Ownership Limitations") of the shares of our common stock then outstanding after giving effect to such exercise; provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial

Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the Series G Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The Series G Warrant holders must pay the exercise price in cash upon exercise of the Series G Warrants, unless such Series G Warrant holders are utilizing the cashless exercise provision of the Series G Warrants.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series G Warrants will be entitled to receive upon exercise of such Series G Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their Series G Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series G Warrants.

Upon the holder's exercise of a Series G Warrant, we will issue the shares of common stock issuable upon exercise of the Series G Warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any Series G Warrants to purchase common stock, holders of the Series G Warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

We intend to use commercially reasonable efforts to have the registration statement, of which this prospectus forms a part, effective when the Series G Warrants are exercised. The Series G Warrant holders must pay the exercise price in cash upon exercise of the Series G Warrants, provided that, if there is not an effective registration statement, the Series G Warrants may be exercised via a "cashless" exercise provision in the Series G Warrants.

Description of Series H Warrants

The material terms and provisions of the Series H Warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the Series H Warrants is not complete. For the complete terms of the Series H Warrants, you should refer to the form of Warrant filed as an exhibit to the registration statement of which this prospectus forms a part.

The Series H Warrants are exercisable immediately until April 30, 2021 at an exercise price of \$1.56 per share. The holder of a Series H Warrant will not be deemed a holder of our underlying common stock until the Series H Warrant is exercised, except as set forth in the Series H Warrant.

Pursuant to the terms of the Series H Warrants, a holder of Series H Warrants will not have the right to exercise any portion of its Series H Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise; provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation; provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the Series H Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The Series H Warrant holders must pay the exercise price in cash upon exercise of the Series H Warrants, unless such Series H Warrant holders are utilizing the cashless exercise provision of the Series H Warrants.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Series H Warrants will be entitled to receive upon exercise of such Series H Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their Series H Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Series H Warrants.

Upon the holder's exercise of a Series H Warrant, we will issue the shares of common stock issuable upon exercise of the Series H Warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any Series H Warrants to purchase common stock, holders of the Series H Warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

We intend to use commercially reasonable efforts to have the registration statement, of which this prospectus forms a part, effective when the Series H Warrants are exercised. The Series H Warrant holders must pay the exercise price in cash upon exercise of the Series H Warrants, provided that, if there is not an effective registration statement, the Series H Warrants may be exercised via a "cashless" exercise provision in the Series H Warrants.

Description of Placement Agent Warrants

The material terms and provisions of the Placement Agent Warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the Placement Agent Warrants is not complete. For the complete terms of the Placement Agent Warrants, you should refer to the form of Warrant filed as an exhibit to the registration statement of which this prospectus forms a part.

The Placement Agent Warrants are exercisable immediately until April 30, 2025 at an exercise price of \$2.2675 per share. The holder of a Placement Agent Warrant will not be deemed a holder of our underlying common stock until the Placement Agent Warrant is exercised, except as set forth in the Placement Agent Warrant.

Pursuant to the terms of the Placement Agent Warrants, a holder of Placement Agent Warrants will not have the right to exercise any portion of its Placement Agent Warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) (the "Beneficial Ownership Limitations") of the shares of our common stock then outstanding after giving effect to such exercise; provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the Placement Agent Warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The Placement Agent Warrant holders must pay the exercise price in cash upon exercise of the Placement Agent Warrants, unless such Placement Agent Warrant holders are utilizing the cashless exercise provision of the Placement Agent Warrants.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the Placement Agent Warrants will be entitled to receive upon exercise of such Placement Agent Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised their Placement Agent Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the Placement Agent Warrants.

Upon the holder's exercise of a Placement Agent Warrant, we will issue the shares of common stock issuable upon exercise of the Placement Agent Warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision). Prior to the exercise of any Placement Agent Warrants to purchase common stock, holders of the Placement Agent Warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

We intend to use commercially reasonable efforts to have the registration statement, of which this prospectus forms a part, effective when the Placement Agent Warrants are exercised. The Placement Agent Warrant holders must pay the exercise price in cash upon exercise of the Placement Agent Warrants, provided that, if there is not an effective registration statement, the Placement Agent Warrants may be exercised via a "cashless" exercise provision in the Placement Agent Warrants.

Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, Bylaws and the DGCL

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. This provision generally prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date the stockholder became an interested stockholder, unless:

- prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of a corporation, or an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of a corporation at any time within three years prior to the time of determination of interested stockholder status; and any entity or person affiliated with or controlling or controlled by such entity or person.

These statutory provisions could delay or frustrate the removal of incumbent directors or a change in control of our Company. They could also discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such event would be favorable to the interests of stockholders.

Our amended and restated certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, our certificate of incorporation and bylaws, as applicable, among other things:

- provide our board of directors with the ability to alter our bylaws without stockholder approval; and
- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

Such provisions may have the effect of discouraging a third-party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of our Company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our Company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms.

However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

Disclosure of SEC Position on Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the “Securities Act”), may be permitted for directors, officers and persons controlling our Company, we understand that it is the SEC’s opinion that such indemnification is against public policy as expressed in the Securities Act and may therefore be unenforceable.

PLAN OF DISTRIBUTION

The selling security holders, including their transferees, donees, pledgees, assignees and successors-in-interest, may, from time to time, sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus from time to time on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price, at varying prices determined at the time of sale or at negotiated prices. The selling security holders may use any one or more of the following methods when selling shares:

- 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 date of this prospectus;
- broker-dealers may agree with the selling security holders to sell a specified number of the shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any of these methods of sale; or
- any other method permitted pursuant to applicable law.

The selling security holders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling security holders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling security holders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each selling security holder does not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling security holders 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 our common stock by the selling security holders or any other person. We have advised the selling security holders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling security holders and their affiliates. In addition, we will make copies of this prospectus available to the selling security holders for the purpose of satisfying the prospectus delivery requirements of the Securities Act 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.

In connection with the sale of our common stock or interests therein, the selling security holders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling security holders may also sell

shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling security holders 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 these broker-dealers or other financial institutions of shares offered by this prospectus, which shares these broker-dealers or other financial institutions may resell pursuant to this prospectus (as supplemented or amended to reflect these transactions).

The selling security holders 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 these sales. In this event, any commissions received by these 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 under the Securities Act. Each selling security holder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

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 security holders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against certain liabilities, including liabilities arising under the Securities Act.

Because selling security holders may be deemed to be “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the shares by the selling security holders.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus forms a part effective until the earlier of (1) the date on which all the shares have been sold thereunder or pursuant to Rule 144 or (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

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 the years then ended incorporated by reference in this prospectus and in the registration statement 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

We have filed a registration statement on Form S-1 with the SEC under the Securities Act of 1933, as amended. This prospectus is part of the registration statement but the registration statement includes additional information and exhibits. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The website address is www.sec.gov. The information on the SEC's website is not part of this prospectus, and any references to this website or any other website are inactive textual references only.

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 Reports on Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019, filed on [May 7, 2019](#) and [August 8, 2019](#), respectively;
- our [definitive proxy statement on Schedule 14A, filed on April 19, 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](#), [May 13, 2019](#), [May 31, 2019](#), [June 6, 2019](#), [July 9, 2019](#), [July 22, 2019](#), [August 8, 2019](#), [August 15, 2019](#), [August 21, 2019](#), [August 26, 2019](#), [September 3, 2019](#), [September 19, 2019](#), [September 30, 2019](#), [October 1, 2019](#), [October 2, 2019](#), [October 22, 2019](#) and [October 28, 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.](#)

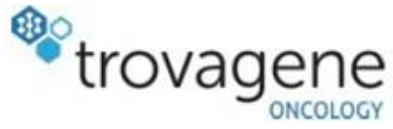
We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, including those made after the date of the 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 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.

8,475,746 Shares



Common Stock

PROSPECTUS

, 2019

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PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

The following table sets forth the costs and expenses paid by us in connection with the issuance and distribution of the securities being registered. None of the following expenses are payable by the selling stockholders. All of the amounts shown are estimates, except for the SEC registration fee.

	Amount
SEC registration fee	\$ 1,816
Accounting fees and expenses	15,000
Legal fees and expenses	50,000
Miscellaneous fees and expenses	3,184
Total expenses	<u>\$ 70,000</u>

ITEM 14. 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 15. Recent Sales of Unregistered Securities.

The Company has sold the securities described below within the past three years which were not registered under the Securities Act. All of the sales listed below were made pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act and Regulation D thereunder.

On July 13, 2017, the Company entered into a securities purchase agreement, whereby the Company issued and sold to certain purchasers warrants to purchase up to 64,496 shares of common stock with an exercise price of \$101.52 per share.

On April 4, 2019, the Company entered into a Securities Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company offered to LPC, in a registered direct offering, an aggregate of (i) 225,813 shares (the "Shares") of common stock, par value \$0.0001 per share ("Common Stock") and (ii) 156,353 Series A warrants to purchase shares of our common stock (the "Series A Warrants"). In a concurrent private placement, we also sold to LPC Series B warrants (the "Series B Warrants") to purchase one share of our Common Stock for each Share and for each Series A Warrant purchased for cash in the registered direct offering. The Series B Warrants will be exercisable six months following the date of issuance at an exercise price of \$3.80 per share and will expire 5.5 years following the date of issuance.

On May 10, 2019, the Company entered into a Securities Purchase Agreement with LPC, pursuant to which the Company offered to LPC, in a registered direct offering, an aggregate of (i) 196,104 shares (the “Shares”) of common stock, par value \$0.0001 per share (“Common Stock”) and (ii) 261,911 Series C warrants to purchase shares of our common stock (the “Series C Warrants”). In a concurrent private placement, we also sold to LPC Series D warrants (the “Series D Warrants”) to purchase one share of our Common Stock for each Share and for each Series C Warrant purchased for cash in the registered direct offering. The Series D Warrants will be exercisable six months following the date of issuance at an exercise price of \$3.15 per share and will expire 5.5 years following the date of issuance.

On August 20, 2019, the Company entered into a Securities Purchase Agreement with LPC, pursuant to which the Company offered to LPC, in a registered direct offering, an aggregate of (i) 271,7444 shares (the “Shares”) of common stock, par value \$0.0001 per share (“Common Stock”) and (ii) 456,058 Series E warrants to purchase shares of our common stock (the “Series E Warrants”). In a concurrent private placement, we also sold to LPC Series F warrants (the “Series F Warrants”) to purchase one share of our Common Stock for each Share and for each Series E Warrant purchased for cash in the registered direct offering. The Series F Warrants will be exercisable six months following the date of issuance at an exercise price of \$1.936 per share and will expire 5.5 years following the date of issuance.

On October 25, 2019 the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain accredited investors (the “Investors”) pursuant to which it sold to the Investors (i) an aggregate of 1,301,268 shares (the “Shares”) of common stock, par value \$0.0001 per share (the “Common Stock”), (ii) pre-funded warrants to purchase an aggregate of 1,455,072 shares of Common Stock (the “Pre-Funded Warrants”), (iii) Series G Warrants to purchase an aggregate of 2,756,340 shares of Common Stock (the “Series G Warrants”) and (iv) Series H Warrants to purchase an aggregate of 2,756,340 shares of Common Stock (the “Series H Warrants” and together with the Pre-Funded Warrants and the Series G Warrants, the “Warrants”) (the “Offering”). The Shares and the Warrants shall collectively be referred to herein as the “Securities”. The Securities were sold at a price of \$1.814 per Share and associated Warrants for gross proceeds of approximately \$5.0 million.

The Series G Warrants are exercisable immediately for a period of 5.5 years from the date of issuance at an exercise price of \$1.56 per share. The Series H Warrants are exercisable immediately for a period of 18 months from the date of issuance at an exercise price of \$1.56 per share. The Pre-Funded Warrants are exercisable immediately at an exercise price of \$0.01 per share and shall terminate when exercised in full.

ITEM 16. Exhibits and Financial Statement Schedules.

- (a) The exhibits listed under the caption “Exhibit Index” following 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.

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;

(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; and

(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) 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 Exchange Act that are incorporated by reference in the Registration Statement.

(2) that, for the purpose of determining any liability under the Securities Act, 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, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. 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 time of contract of sale prior to such first use, 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 date of first use.

(5) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 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.

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Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed on March 20, 2012).
3.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Form 10-12G filed on November 25, 2011).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 12, 2018).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 29, 2019).
3.7	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on January 31, 2019).
3.8	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on February 20, 2019).
4.1	Form of Common Stock Certificate of Trovagene, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 10-12G filed on November 25, 2011).
4.2+	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on July 19, 2004).
4.4	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).
4.5	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 1, 2014).
4.6+	Trovagene, Inc. 2014 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on July 23, 2014).
4.7	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on July 26, 2016).
4.8	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 4.1 to Form 8-K filed on June 12, 2018).
4.9	Form of Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on January 29, 2019).
4.10	Form of Series A Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on April 5, 2019).
4.11	Form of Series B Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on April 5, 2019).
4.12	Form of Series C Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on May 13, 2019).
4.13	Form of Series D Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on May 13, 2019).
4.14	Form of Series E Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on August 21, 2019).
4.15	Form of Series F Warrant (incorporated by reference to Exhibit 10.3 to Form 8-K filed on August 21, 2019).
4.16	Form of Series G, H, Pre-Funded Warrant and Placement Agent Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on October 28, 2019).
5.1**	Opinion of Sheppard Mullin Richter & Hampton LLP
10.1	Summary of Terms of Lease Agreement dated as of October 28, 2009 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.3 to the Company's Form 10-12G/A filed on February 15, 2012).

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- 10.2 [Form of First Amendment to Standard Industrial Net Lease dated September 28, 2011 between Trovogene, Inc. and BMR-Sorrento West LLC \(incorporated by reference to Exhibit 10.4 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.3 [Form of Second Amendment to Standard Industrial Net Lease dated October 2011 between Trovogene, Inc. and BMR-Sorrento West LLC \(incorporated by reference to Exhibit 10.5 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.4 [Form of Third Amendment to Standard Industrial Net Lease dated October 22, 2012 between Trovogene, Inc. and BMR-Sorrento West, LP. \(incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on March 12, 2015\).](#)
 - 10.5 [Form of Fourth Amendment to Standard Industrial Net Lease dated December 2, 2013 between Trovogene, Inc. and BMR-Coast 9 LP. \(incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 12, 2015\).](#)
 - 10.6 [Form of Fifth Amendment to Standard Industrial Net Lease dated May 14, 2014 between Trovogene, Inc. and BMR-Coast 9 LP. \(incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed on March 12, 2015\).](#)
 - 10.7 [Sixth Amendment to Standard Industrial Net Lease dated June 11, 2015 between Trovogene, Inc. and BMR-Coast 9 LP \(incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015\).](#)
 - 10.8 [Co-Exclusive Sublicense Agreement dated October 22, 2007 between Trovogene, Inc. and Asuragen, Inc. \(incorporated by reference to Exhibit 10.6 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.9 [Amendment to Co-Exclusive Sublicense Agreement dated June 1, 2010 between Trovogene, Inc. and Asuragen, Inc. \(incorporated by reference to Exhibit 10.7 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.10 [Sublicense Agreement dated as of August 27, 2007 between Trovogene, Inc. and Ipsogen SAS \(incorporated by reference to Exhibit 10.8 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.11 [Amendment to Co-Exclusive Sublicense Agreement dated as of September 1, 2010 between Trovogene, Inc. and Ipsogen SAS \(incorporated by reference to Exhibit 10.9 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.12 [Sublicense Agreement dated as of July 20, 2011 between Trovogene, Inc. and Fairview Health Services \(incorporated by reference to Exhibit 10.11 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.13 [Sublicense Agreement dated as of December 1, 2008 by and between Trovogene, Inc. and InVivoScribe Technologies, Inc. \(incorporated by reference to Exhibit 10.13 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.14 [Sublicense Agreement dated as of August 25, 2008 by and between Trovogene, Inc. and Laboratory Corporation of America Holdings \(incorporated by reference to Exhibit 10.14 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.15 [Form of Sublicense Agreement effective as of February 8, 2011 by and between Trovogene, Inc. and MLL Munchner Leukamielabor GmbH \(incorporated by reference to Exhibit 10.15 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.16 [Sublicense Agreement effective as of June 15, 2010 by and between Trovogene, Inc. and Skyline Diagnostics BV \(incorporated by reference to Exhibit 10.16 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.17 [Exclusive License Agreement effective as of December 12, 2011 by and between Columbia University and Trovogene, Inc. \(incorporated by reference to Exhibit 10.20 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
 - 10.18 [Form of Exclusive License Agreement effective as of October 2011 by and between Gianluca Gaidano, Robert Foa and Davide Rossi and Trovogene, Inc. \(incorporated by reference to Exhibit 10.21 to the Company's Form 10-12G/A filed on February 15, 2012\).](#)
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10.19	Exclusive License Agreement effective as of May 2006 by and between Brunangelo Falini, Cristina Mecucci and Trovogene, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Form 10-12G/A filed on February 15, 2012).
10.20	Form of First Amendment to Exclusive License Agreement effective as of August 2010 by and among Brunangelo Falini, Cristina Mecucci and Trovogene, Inc. (incorporated by reference to Exhibit 10.24 to the Company's Form 10-12G/A filed on February 15, 2012).
10.21+	Form of Indemnification Agreement to be entered into between the Company and its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 15, 2015).
10.22***	Patent Assignment and License Agreement dated April 23, 2014 between Trovogene, Inc. and GenSignia IP Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2014).
10.23+	Employment Agreement, dated February 18, 2016, by and between the Company and Mark Erlander (incorporated by reference to Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2016).
10.24	Form of Seventh Amendment to Standard Industrial Net Lease dated April 4, 2016 between Trovogene, Inc. and BMR-Coast 9 LP (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 4, 2016).
10.25***	License Agreement dated as of March 13, 2017 between Nerviano Medical Sciences S.r.l. and Trovogene, Inc. (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on March 15, 2017).
10.26	Form of Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 28, 2019)
10.27	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to Form 8-K filed on October 28, 2019)
23.1**	Consent of BDO USA, LLP
23.2**	Consent of Sheppard Mullin Richter & Hampton LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page hereto).

** Filed herewith.

*** The U.S. Securities and Exchange Commission (SEC) has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

+ Indicates a management contract or compensatory plan or arrangement.

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 1st day of November 2019.

TROVAGENE, INC.

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

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas H. Adams, his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his 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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Thomas H. Adams</u> Thomas H. Adams	Chief Executive Officer and Chairman (Principal Executive Officer)	November 1, 2019
<u>/s/ Brigitte Lindsay</u> Brigitte Lindsay	VP, Finance (Principal Financial Officer)	November 1, 2019
<u>/s/ John P. Brancaccio</u> John P. Brancaccio	Director	November 1, 2019
<u>/s/ Gary S. Jacob</u> Gary S. Jacob	Director	November 1, 2019
<u>/s/ Rodney S. Markin</u> Rodney S. Markin	Director	November 1, 2019
<u>Athena Countouriotis</u>	Director	November 1, 2019



Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112-0015
212.653.8700 main
212.653.8701 fax
www.sheppardmullin.com

November 1, 2019

VIA ELECTRONIC MAIL

Trovagene, Inc.
11055 Flintkote Avenue
San Diego, CA 92121

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Trovagene, Inc., a Delaware corporation (the "Company"), in connection with the issuance of this opinion which relates to a Registration Statement on Form S-1 (the "Registration Statement") filed by the Company with the Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement covers the resale of 8,475,746 shares of the Company's common stock, \$0.0001 par value per share ("Common Stock"), consisting of (i) 2,756,340 shares of Common Stock (the "Shares") and (ii) 5,719,406 shares of Common Stock (the "Warrant Shares" and together with the Shares, the "Securities") issuable upon exercise of outstanding warrants to purchase shares of Common Stock (the "Warrants") issued to the selling stockholders.

This opinion letter is being delivered in accordance with the requirements of Item 601(b)(5)(i) of Regulation S-K under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement.

In connection with the issuance of this opinion letter, we have examined originals or copies, certified or otherwise identified to our satisfaction, of:

- a. the Registration Statement, including the prospectus contained therein and all exhibits thereto;
- b. the Warrants;
- c. the Amended and Restated Certificate of Incorporation of the Company, as amended and presently in effect (the "Charter");
- e. the Bylaws of the Company, as presently in effect (the "Bylaws"); and
- f. certain resolutions adopted by the Board of Directors of the Company relating to the issuance of the Shares, Warrant Shares and the Warrants.

We have also examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates and receipts of public officials, certificates of officers or other representatives of the Company and others, and such other documents as we have deemed necessary or appropriate as a basis for the opinions stated below.

In our examination, we have assumed the genuineness of all signatures, including endorsements, the legal capacity and competency of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies. As to any facts relevant to the opinions stated herein that we did not

independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and others and of public officials.

For the purposes of this opinion letter, we have assumed that at the time of issuance of each Warrant Share, the Charter, the Bylaws and the Warrants, will not have been modified or amended and will be in full force and effect. In addition, it is understood that this opinion is to be used only in connection with the offer and sale of the securities being registered while the Registration Statement is effective under the Securities Act.

Based upon and subject to the foregoing and to the other qualifications and limitations set forth herein, we are of the opinion that the Securities have been duly authorized, and if, as, and when issued by the Company in accordance with and in the manner described in prospectus set forth in the Registration Statement (as amended and supplemented through the date of issuance) and, in the case of the Warrant Shares, when issued in accordance with the terms of the applicable Warrants, will be validly issued, fully paid and non-assessable and, with respect to the Warrants, will be legally binding obligations of the Company in accordance with their terms except: (a) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally and by general equitable principles (regardless of whether enforceability is considered in a proceeding in equity or at law); (b) as enforceability of any indemnification or contribution provision may be limited under the Federal and state securities laws; and (c) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

The opinion which we render herein is limited to those matters governed by the Delaware General Corporation Law as of the date hereof. Our opinion expressed herein is as of the date hereof, and we assume no obligation to revise or supplement the opinion rendered herein should the above-referenced laws be changed by legislative or regulatory action, judicial decision or otherwise. We express no opinion as to whether, or the extent to which, the laws of any particular jurisdiction apply to the subject matter hereof.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. We also hereby consent to the reference to our firm under the heading "Legal Matters" in the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the General Rules and Regulations under the Securities Act.

Very truly yours,

/s/ Sheppard, Mullin, Richter & Hampton LLP

SHEPPARD, MULLIN, RICHTER &
HAMPTON LLP

Consent of Independent Registered Public Accounting Firm

Trovagene, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our report dated March 6, 2019, relating to the consolidated financial statements of Trovagene, Inc. (the “Company”), which is incorporated by reference in that Prospectus. Our report contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

We also consent to the reference to us under the caption “Experts” in the Prospectus.

/s/ BDO USA, LLP

San Diego, California
November 1, 2019
