Trovagene, Inc.
Form 424B4
December 15, 2017
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Filed Pursuant to Rule 424(b)(4)
Registration Statement No. 333-221115

PROSPECTUS

14,683,333 Units (each Unit contains One Share of Common Stock and One Common Warrant to Purchase One Share of Common Stock)

316,667 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

(316,667 Shares of Common Stock Underlying the Pre-funded Warrants) and

(15,000,000 Shares of Common Stock Underlying the Common Warrants)

We are offering 14,683,333 units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock (together with the shares of common stock underlying such common warrants). Each common warrant contained in a unit will have an exercise price per share equal to $0.30 per share. The common warrants contained in the units will be exercisable immediately and will expire on the five year anniversary of the original issuance date. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the units.

We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, 316,667 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in a purchaser s beneficial ownership exceeding 4.99% of our outstanding common stock (or at the election of the purchaser, 9.99%). Each pre-funded warrant contained in a pre-funded unit will be exercisable for one share of our common stock. The purchase price of each pre-funded unit is equal to the price per unit being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in the pre-funded unit is $0.01 per share. The pre-funded warrants expire when exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants contained in the pre-funded units sold in this offering. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold. Each common warrant contained in a pre-funded unit will have an exercise price per share equal to $0.30 per share. The common warrants contained in

the pre-funded units will be exercisable immediately and will expire on the five year anniversary of the original issuance date. We are also offering the shares of our common stock that are issuable from time to time upon exercise of the common warrants contained in the pre-funded units.

The units and the pre-funded units will not be issued or certificated. The shares of common stock or pre-funded warrants, as the case may be, and the common warrants can only be purchased together in this offering but the securities contained in the units or pre-funded units will be issued separately.

Our common stock is listed on the Nasdaq Capital Market under the symbol TROV . On December 14, 2017, the closing bid price of our common stock on the Nasdaq Capital Market was $0.43 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

You should read carefully this prospectus and any applicable prospectus supplement or free writing prospectus, together with the additional information described in this prospectus under the headings Incorporation of Certain Information by Reference and Where You Can Find More Information, before you invest in any of our securities.

Investing in our securities involves risks. You should carefully read and consider the Risk Factors beginning on page 8 of this prospectus before investing. You should also consider the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement, before investing in these securities.

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.

We have retained H.C. Wainwright & Co., LLC to act as our exclusive placement agent in connection with this offering. and to use its best efforts to solicit offers to purchase the securities being offered pursuant to this prospectus. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. In addition, because there is no escrow account. and no minimum offering amount in this offering, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan.

	Per Unit	Per Pre-Funded Unit	Total
Public offering price	$ 0.30	$ 0.29	$ 4,496,833
Placement agent fees (1)	$ 0.018	$ 0.018	$ 270,000
Proceeds, before expenses, to us (2)	$ 0.282	$ 0.272	$ 4,226,833

(1)

See Plan of Distribution beginning on page 43 for more information on this offering and the placement agent fees and expenses.

(2) We estimate the total expenses of this offering payable by us, excluding the placement agent fee, will be approximately $275,000. All costs associated with the registration will be borne by us.

Delivery of the securities offered hereby is expected to be made on or about December 19, 2017.

H.C. Wainwright & Co.

The date of this prospectus is December 15, 2017.

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You should rely only on the information contained in this prospectus. We have not, and the placement agent has not, authorized anyone to provide you with any information other than that contained or incorporated by reference in this prospectus or in any applicable prospectus supplement or free writing prospectus prepared by or on behalf of us to which we have referred you. We are offering to sell, and seeking offers to buy, the securities covered hereby only in jurisdictions where offers and sales are permitted. 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. Our business, financial condition, results of operations and prospects may have changed since those dates. We are not, and the placement agent is not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not, and the placement agent has not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby the distribution of this prospectus outside the United States.

We further note that the representations, warranties and covenants made by us in any agreement that is incorporated by reference or filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Information contained in, and that can be accessed through, our web site *www.trovagene.com* shall not be deemed to be part of this prospectus or incorporated herein by reference and should not be relied upon by any prospective investors for the purposes of determining whether to purchase the shares offered hereunder.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

In some cases, you can identify forward-looking statements by terminology, such as expects, anticipates, intends, estimates, plans, believes, seeks, may, should , could or the negative of such terms or other similar 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, 2016 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.

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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 common stock 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. on a consolidated basis with its wholly-owned subsidiary, Trovagene, Srl, as applicable.

Overview

We are a precision medicine biotechnology company developing oncology therapeutics for improved cancer care, optimizing drug development by leveraging our proprietary Precision Cancer Monitoring, or PCM, technology in tumor genomics. Our broad intellectual property and proprietary technology enables us to measure ctDNA in urine and blood to identify and quantify clinically actionable markers for predicting response to cancer therapies. We offer our PCM technology at our CLIA-certified/CAP-accredited laboratory and plan to continue to vertically integrate our PCM technology with the development of precision cancer therapeutics.

We believe we have an opportunity to utilize precision diagnostics to improve treatment outcomes for cancer patients using our proprietary technology to detect clinically actionable mutations and monitor patient response to therapy. On March 15, 2017, we announced the licensing of PCM-075, a Polo-like Kinase 1, or PLK1, inhibitor, from Nerviano Medical Sciences S.r.l., or Nerviano. We have a supplier agreement with NerPharMa, S.r.l., a pharmaceutical manufacturing company and a subsidiary of Nerviano, to manufacture drug product for PCM-075. The agreement covers the clinical and commercial supply of PCM-075, and includes both Active Pharmaceutical Ingredients, or API, and Good Manufacturing Process, or GMP, production of capsules. The licensing of global development and commercialization rights to PCM-075 allows us to execute our strategy to vertically integrate our PCM technology with precision cancer therapeutics, by developing drugs where our deep understanding of tumor genomics may allow for effective targeting of appropriate cancer patients.

We have completed a Phase 1 safety study of PCM-075 in patients with advanced metastatic solid tumors and we received notification from the U.S. Food and Drug Administration, or FDA, that our Phase 1b/2 clinical trial of PCM-075 in patients with Acute Myeloid Leukemia, or AML, may proceed. PCM-075 has positive preclinical data as a single agent and in combination with select chemotherapeutics and targeted agents used in many hematologic and solid cancers, including AML, Non-Hodgkin Lymphoma, metastatic Castration Resistant Prostate Cancer, or mCRPC, Adrenocortical Carcinoma, or ACC, and Triple Negative Breast Cancer, or TNBC.

We have significant experience and expertise with biomarkers and technology in cancer, including AML. We are one of the patent holders of NPM1 for diagnosis and monitoring of patients. NPM1-mutated AML is a genetic marker in leukemia and accounts for approximately one-third of all AML patients. We plan to use our PCM technology to profile other dominant AML markers, such as FLT3, DNMT3A, NRAS, and KIT, as well as to measure PLK1 enzymatic activity to potentially identify patients most likely to respond to PCM-075 and to measure patient therapy

response.

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PCM-075, PLK1 Inhibitor

PLK1 is a serine/threonine protein kinase involved in the entry into, progression through, and exit from mitosis with roles in centrosome maturation, bi-polar spindle formation, chromosome separation, and cytokinesis. Many liquid and solid cancers overexpress PLK1 during the cancer cell growth process. PLK1 is over-expressed in a wide variety of hematologic and solid tumor malignancies including acute myeloid leukemia, prostate, lung, breast, and adrenocortical carcinoma. In addition, several studies have shown that this over-expression correlates with poor prognosis.

PCM-075 is the first PLK1 selective adenosine triphosphate, or ATP, competitive inhibitor administered orally to enter clinical trials with apparent antitumor activity in different preclinical models. PCM-075 was developed to have high selectivity to PLK1 (at low nanomolar IC_{50} levels), oral bioavailability, and a relatively short drug half-life of approximately 24 hours compared to another PLK1 inhibitor (volasertib). PCM-075 s reversible hematological toxicities are to be expected based on the mechanism of action of the drug which we believe may prove useful in addressing clinical therapeutic needs in AML, mCRPC, relapse NHL, ACC and other liquid and solid tumors.

PCM-075 has been tested in vivo in different xenograft and transgenic models at times suggesting tumor growth inhibition or tumor regression when used in combination with other therapies. PCM-075 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 IC_{50} values below 1 uM in 133 out of 148 cell lines. PCM-075 also appears active in cells expressing multi-drug resistant, or MDR, transporter proteins and we believe PCM-075 s apparent ability to overcome the MDR transporter resistance mechanism in cancer cells could prove useful in broader drug combination applications.

Combination Therapy

PCM-075 has been evaluated pre-clinically in combination with more than ten different chemotherapeutics, including cisplatin, cytarabine, doxorubicin, gemcitabine and paclitaxel, as well as targeted therapies, such as abiraterone acetate, HDAC inhibitors, FLT3 inhibitors, and bortezomib. These therapeutics are used clinically for treatment of many hematologic and solid cancers, including Acute Myeloid Leukemia, or AML, Non-Hodgkin Lymphoma, or NHL, metastatic Castration-Resistant Prostate Cancer, or mCRPC, Adrenocortical Carcinoma, or ACC, Triple Negative Breast Cancer, or TNBC, Small Cell Lung Cancer, or SCLC, and Ovarian Cancer, or OC.

On August 16, 2017, we announced results of preclinical research indicating potential synergy (interaction of discrete drugs such that the total effect is greater than the sum of the individual effects) of PCM-075 with an investigational FLT3 Inhibitor, Quizartinib by Daiichi Sankyo, in FLT3 mutant xenograft mouse models. This synergy assessment study was conducted for us by a third-party contract research group. Approximately one third of AML patients harbor FLT3-mutated blood cancer cells. The FDA recently approved Rydapt® (midostaurin) by Novartis for the treatment of newly diagnosed adult patients with AML that are FLT3 mutation-positive in combination with cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. There are two additional FLT3 inhibitors in ongoing phase 3 trials, including Quizartinib. We believe that a combination of PCM-075 with a FLT3 inhibitor for AML patients with a FLT3 mutation could extend treatment response and possibly slow or reduce resistance to FLT3 activity.

On August 21, 2017, we announced results of preclinical research indicating potential synergy of PCM-075 with a histone deacetylase, or HDAC, inhibitor in NHL cell lines. This synergy assessment study was conducted by Dr. Steven Grant, Associate Director for Translational Research and co-Leader, Developmental Therapeutics Program, Massey Cancer Center. Patients with relapsed or refractory NHL, such as cutaneous T cell lymphoma and

peripheral T cell lymphoma, may be prescribed approved HDAC inhibitors and we believe this

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continues to be an area of unmet medical need. Dr. Grant s data appeared to indicate that the combination of PCM-075 with Beleodaq® (belinostat), an HDAC inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma, reduced cancer cells by up to 80% in two different forms of NHL (aggressive double-hit B-cell lymphoma and mantle cell lymphoma) cell lines.

On October 11, 2017, we entered into a Patent Option Agreement with Massachusetts Institute of Technology, or MIT, for the exclusive rights to negotiate a royalty-bearing, limited-term exclusivity license to practice world-wide patent rights to US Patent 9,566,280, subject to the rights of MIT (research, testing, and educational purposes), Ortho McNeil Pharmaceuticals-Janssen Pharmaceuticals and its Affiliates (internal research and pre-clinical drug development purposes including some laboratory research) and the federal government (government-funded inventions claimed in any patent rights and to exercise march in rights). This patent is generally directed to combination therapies including an antiandrogen or androgen antagonist and polo-like kinase inhibitor for the treatment of cancer. The Patent Option Agreement expires one-year from the effective date and includes other requirements to maintain the option period.

On October 18, 2017, we announced results of preclinical research indicating potential synergy of PCM-075 with abiraterone acetate in C4-2 prostate cancer cells. This synergy assessment study was conducted by Dr. Michael Yaffe M.D., Ph.D. FACS, David H. Koch Professor of Biology and Biological Engineering at MIT. The results appeared to indicate that the combination of PCM-075 with Zytiga® (abiraterone) decreased cell viability in mCRPC tumor cells and the apparent synergy observed was greater than the expected effect of combining the two drugs. Zytiga is indicated for use in combination with prednisone for the treatment of patients with mCRPC who have received prior chemotherapy containing docetaxel. We believe there is an unmet medical need to improve on the resistance to hormone therapy and extend the benefit of response to abiraterone for mCRPC patients.

PCM-075 Phase 1 Safety Study in Solid Tumors

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

PCM-075 was administered orally, once daily for five consecutive days, every three weeks, to evaluate first cycle dose-limiting toxicities and related maximum tolerated dose in adult subjects with advanced/metastatic solid tumors. The study was also intended to evaluate PCM-075 s pharmacokinetic profile in plasma, its anti-tumor activity, and its ability to modulate intracellular targets in biopsied tissue. The study identified thrombocytopenia and neutropenia as the primary toxicities, which is consistent with the expected mechanism of action of PCM-075 and results from preclinical studies. These hematologic toxicities were reversible, with recovery usually occurring within 3 weeks. One patient experienced a grade 3 constipation adverse event, which the authors conclude may have been due to concomitant treatment with opiates.

We plan to utilize the existing Investigational New Drug, or IND, application to develop PCM-075 as we work to potentially expand our drug development in solid tumors, such as mCRPC.

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PCM-075 Phase 1b/2 Clinical Study in Hematologic Cancers

We submitted an IND application to the FDA on June 26, 2017. This submission included a Phase 1b/2 clinical protocol intended to better characterize the safety profile of PCM-075 in AML patients, provide a preliminary assessment of response to PCM-075 when used in combination with standard of care chemotherapy, study the effect of different clinical dosing regimens, as well as explore the potential of correlative biomarker analyses to select patients more likely to respond. On July 24, 2017, we received notification that the FDA reviewed our IND and our Phase 1b/2 clinical trial of PCM-075 in patients with AML may proceed. Dr. Jorge Cortes, Deputy Department Chair, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center is the principal investigator for the Phase 1b/2 trial. On September 28, 2017, the FDA granted an orphan drug designation to PCM-075 for the treatment of patients with acute myeloid leukemia.

The Phase 1b/2 is an open-label study of the safety and anti-leukemic activity of PCM-075 in combination with standard of care chemotherapy. Phase 1b subjects will be those that have relapsed or had resistant disease to no more than three prior therapeutic regimens. Phase 2 subjects will be those that have received no more than one prior regimen for the treatment of their AML, have either relapsed or refractory disease, and are judged not to be candidates for re-induction therapy that includes hematopoietic cell transplantation. In addition, subjects can be included in Phase 2 if they are newly diagnosed, have not received prior therapy for the treatment of their AML, and are ineligible for, or have refused, standard intensive induction therapy.

Company Information

We were incorporated in the State of Florida on April 26, 2002. On July 2, 2004, we acquired Xenomics, a California corporation, which was in business to develop and commercialize urine-based molecular diagnostics technology. In 2007, we changed our fiscal year end from January 31 to December 31 and in January 2010, we re-domesticated our state of incorporation from Florida to Delaware and our name was changed to Trovagene, Inc. We have trademarks for the name TROVAGENE, TROVAGENE PRECISION CANCER MONITORING and TROVAGENE TRANSRENAL MOLECULAR DIAGNOSTICS. 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.trovagene.com. The information on our website is not part of this prospectus supplement. We have included our website address as a factual reference and do not intend it to be an active link to our website.

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SUMMARY OF THE OFFERING

Units offered by us in this offering	14,683,333 units, each consisting of one share of our common stock and one common warrant to purchase one share of our common stock.
Pre-funded units offered by us in this offering	We are also offering to each purchaser whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, 316,667 pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock) in lieu of units that would otherwise result in the purchaser s beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded unit is equal to the price at which the units are being sold to the public in this offering, minus $0.01, and the exercise price of each pre-funded warrant included in each pre-funded unit is $0.01 per share. Because we will issue a common warrant as part of each unit or pre-funded unit, the number of common warrants sold in this offering will not change as a result of a change in the mix of the units and pre-funded units sold. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering.
Common warrants offered by us in the offering	Common warrants to purchase an aggregate of 15,000,000 shares of our common stock. Each unit and each pre-funded unit includes a common warrant to purchase one share of our common stock. Each common warrant will have an exercise price per share equal to $0.30 per share, will be immediately separable from the common stock or pre-funded warrant, as the case may be, will be immediately exercisable and will expire on the five year anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.
Common stock outstanding prior to this offering	38,105,251 shares of common stock.
Common stock outstanding after this offering	52,788,584 shares of common stock (assuming no exercise of the pre-funded warrants and common warrants issued in this offering).
Use of proceeds	We intend to use the proceeds received from this offering to fund our research and development activities and for working capital and general corporate purposes. See Use of Proceeds on page 36 of this prospectus.

Risk factors	Investing in our securities involves a high degree of risk. For a discussion of factors to consider before deciding to invest in our securities, you should carefully review and consider the Risk Factors section of this prospectus, as well as the risk factors described or referred to in any documents incorporated by reference in this prospectus, and in any applicable prospectus supplement.
Trading Symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol TROV . There is no established trading market for the warrants, and we do not expect a trading market to develop. We do not intend to list the warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the warrants will be

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extremely limited. We do not plan on applying to list the pre-funded warrants or the common warrants on the Nasdaq, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the pre-funded warrants or common warrants will be limited.

The number of shares of common stock shown above to be outstanding after this offering is based on 38,105,251 shares outstanding as of September 30, 2017, and excludes as of that date:

- 4,257,031 shares of our common stock issuable upon exercise of outstanding options at a weighted average price of $4.23 per share;
- 1,277,302 shares of our common stock issuable upon vesting of restricted stock units;
- 8,972,503 shares of our common stock issuable upon exercise of outstanding warrants with a weighted-average exercise price of $2.38 per share;
- 63,125 shares of our common stock issuable upon conversion of outstanding shares of Series A Convertible Preferred Stock;
- 3,670,232 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans; and
- 15,316,667 shares of our common stock issuable upon exercise of the common warrants and pre-funded warrants offered hereby.

Unless otherwise indicated, the information in this prospectus assumes no exercise of the warrants offered hereby.

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RISK FACTORS

Any investment in our common stock involves a high degree of risk. Before deciding whether to purchase our common stock, investors should carefully consider the risks described below together with the Risk Factors described in our Annual Report on Form 10-K for the year ended December 31, 2016 and any updates described in our Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, as may be amended, supplemented or superseded from time to time by other reports we file with the Securities Exchange Commission, or SEC as well as any risks and uncertainties described in any applicable prospectus supplement. Our business, financial condition, operating results and prospects are subject to the following material risks as well as those material risks incorporated by reference. Additional risks and uncertainties not presently foreseeable to us may also impair our business operations. If any of the following risks actually occurs, our business, financial condition or operating results could be materially adversely affected. In such case, the trading price of our common stock could decline, and our stockholders may lose all or part of their investment in the shares of our common stock.

Risks Related to our Business

We are a development stage company and may never earn a profit.

We are a development stage company and have incurred losses since our formation. As of September 30, 2017, we have an accumulated total deficit of approximately $170 million. For the fiscal year ended December 31, 2016 and the nine months ended September 30, 2017, we had a net loss attributable to common stockholders of approximately $39.2 million and $22.4 million, respectively. To date, we have experienced negative cash flow from development of our product candidate PCM-075 and our cell-free molecular diagnostic technology. We have generated limited revenue from operations, and we expect to incur substantial net losses for the foreseeable future as we seek to further develop and commercialize PCM-075 and our cell-free molecular diagnostic technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from PCM-075 and our cell-free molecular diagnostic technology or attain profitability, we will not be able to sustain operations.

Because of the numerous risks and uncertainties associated with developing and commercializing PCM-075 and our cell-free molecular diagnostic technology and tests, we are unable to predict the extent of any future losses or when we will attain profitability, if ever. We may never become profitable and you may never receive a return on an investment in our common stock. An investor in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of PCM-075 and tests in the medical diagnostic industry. We may never successfully commercialize PCM-075 and our cell-free molecular diagnostic technology or any future tests we may develop, and our business may not be successful.

We will need to raise substantial additional capital to develop and commercialize PCM-075 and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

As of September 30, 2017, our cash balance and short-term investments was approximately $7.4 million and our working capital was approximately $3.4 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. At September 30, 2017, we had $1.5 million outstanding under debt agreements. In order to raise additional capital, we may seek to sell additional equity and/or debt securities or obtain a credit facility or other loan, which we may not be able to do on favorable terms, or at

all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or

discontinue the development and/or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unfavorable terms.

Our financial statements include an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern, indicating the possibility that we may not be able to operate in the future.

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

Recent events of default have forced us to repay outstanding indebtedness sooner than expected.

On June 1, 2017, we received a Notice of Event of Default (the Notice) from Oxford Finance LLC (Oxford) with respect to the Loan Agreement dated as of June 30, 2014 (as amended, restated, supplemented or otherwise modified from time to time, the Loan Agreement), by and among Oxford, as Collateral Agent, Oxford, as a Lender, Silicon Valley Bank, as a Lender (SVB) and together with Oxford, the Lenders) and us. The Notice stated that Events of Default had occurred and are continuing under Sections 8.2(a) and 8.2(b) (Covenant Defaults) (as a result of violations of Section 5.2, 7.1 and 7.2), Section 8.3 (Material Adverse Change), Section 8.6 (Other Agreements) and Section 8.8 (Misrepresentations) of the Loan and Security Agreement. The Notice further stated that all of the obligation under the Loan and Security Agreement are immediately due and payable. On June 6, 2017, the Lenders withdrew approximately $16.6 million out of our bank accounts which satisfies all of our outstanding obligations under the Loan Agreement. On March 31, 2017, we had approximately $28.8 million of cash and short-term investments. As of September 30, 2017, we had approximately $7.4 million of cash. We need to raise substantial additional capital to operate our business and our failure to obtain financing will force us to delay, reduce or eliminate our product development programs or collaboration efforts and would have a material adverse effect on our business.

On June 20, 2017, we received a Notice of Event of Default (the Equipment Notice) from SVB with respect to that certain Loan and Security Agreement in the aggregate principal amount of $1.5 million dated as of November 17, 2015 (as amended, restated, supplemented or otherwise modified from time to time, the Equipment Loan Agreement), between SVB and us. The Equipment Notice stated that Events of Default had occurred and are continuing under Sections 8.2(a) (Covenant Defaults) (as a result of violations of Section 7.1 and 7.2), Section 8.3 (Material Adverse Change), Section 8.6 (Other Agreements) and Section 8.8 (Misrepresentations) of the Equipment Loan Agreement. The Equipment Loan Agreement is substantially similar to the Loan and Security Agreement which also was the subject of a Notice of Event of Default on June 1, 2017. Both Notices of Event of Default are substantially similar, except that the Equipment Notice further stated that SVB intends to monitor the default situation very carefully and will decide in their sole discretion on a day-by-day basis whether or not to exercise rights and remedies. As of September 30, 2017, approximately $1.5 million of principal and accrued interest was outstanding under the equipment loan. We are currently discussing with SVB a waiver of the defaults. In the event that we cannot agree with SVB on a waiver of the defaults, SVB may accelerate the amounts outstanding under the Equipment Loan Agreement which will cause us to repay such amounts sooner than expected and could have a material adverse effect on our business.

Our product candidate PCM-075 is in the early stages of development and its commercial viability remains subject to the successful outcome of PCM-075 , current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed.

In the near-term, failure to successfully advance the development of our product candidate may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully

advance the development of our product candidate through preclinical studies and clinical trials, have the product candidate approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidate successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidate, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidate.

Our product candidate must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete its clinical development or it can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our product candidate. Despite these efforts, our product candidate may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidate. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidate may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidate demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application, or NDA or a biologics license application, or BLA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Our product candidate will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that our product candidate will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidate to be commercialized by us or collaborators for at least several years.

Our product candidate may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval, or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidate to obtain regulatory approval to further advance clinical development or to market it. Even if our product candidate demonstrates biologic activity and clinical efficacy, any unacceptable adverse side

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effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. In preclinical studies and clinical trials we have conducted to date, our product candidate s safety profile is based on studies and trials that have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the results of preclinical studies or clinical trials for our product candidate, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business.

In order to further advance the development of, and ultimately receive regulatory approval to sell, our product candidate, we must conduct extensive preclinical studies and clinical trials to demonstrate its safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities (including an Institutional Review Board or Ethical Committee) or IRB or EC, not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting patients or participants dropping out of our clinical trials at a higher rate than we anticipated;
- our third party contractors, upon whom we rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks;

IRBs, ECs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and

the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a favorable safety and efficacy profile, such results may not be sufficient to support the submission

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of a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidate may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidates and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for PCM-075.

As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidate.

We, and our collaborators, must comply with extensive government regulations in order to advance our product candidate through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

The product candidate that we, or our collaborators, are developing require regulatory approval to advance through clinical development and to ultimately be marketed and sold, and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biopharmaceutical products. Our product candidate is also subject to similar regulation by foreign governments to the extent we seek to develop or market it in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data

supporting an acceptable manufacturing process, that appropriately demonstrate our product candidate s safety and efficacy before it can be approved for the targeted indications. Our product candidate has not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates we are developing or

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plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidate based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA s or other similar foreign regulatory authorities policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidate through clinical development, and ultimately commercialize them, may:

- adversely impact our ability to raise sufficient capital to fund the development of our product candidate;
- adversely affect our ability to further develop or commercialize our product candidate;
- diminish any competitive advantages that we or our collaborators may have or attain; and
- adversely affect the receipt of potential milestone payments and royalties from the sale of our products or product revenues.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including:

- delays, suspension or termination of clinical trials related to our products;
- refusal by regulatory authorities to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving

appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks.

We have limited experience in the development of therapeutic product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.

We have limited experience in the discovery, development and manufacturing of therapeutic compounds. In order to successfully develop our product candidate, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of a number of responsibilities and key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidate. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel, and directors to develop, implement and execute our business strategy, operate the company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidate, we need to retain or attract certain personnel, consultants or advisors with experience in drug development activities that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems. We are highly dependent upon our senior management and scientific staff, particularly William Welch, our Chief Executive Officer. The loss of services of Mr. Welch or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidate.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key managers or employees, or are unable to attract and retain qualified key personnel, directors, advisors or consultants, the development of our product candidate could be delayed or terminated and our business may be harmed.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our product candidate may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidate, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidate for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidate, and if those assumptions are incorrect it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all.

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Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate s clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidates or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

Our product candidate could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidate, which would significantly harm our business, results of operations and prospects.

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In addition, even if we were to obtain approval, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

We have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for our product candidate, and we cannot be certain that our product candidate will be successful in clinical trials or receive regulatory approval. Further, our product candidate may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for our product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidate are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval and to commercialize our product candidate, directly or with a collaborator, worldwide including the United States, the European Union and other additional foreign countries which we have not yet identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidate.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering our product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidate for any or all targeted indications. Ultimately, our product candidate may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the

referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidate.

We need FDA approval prior to marketing our product candidate in the United States. If we fail to obtain FDA approval to market our product candidate, we will be unable to sell our product candidate in the United States and we will not generate any revenue.

The FDA s review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre- clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical

product. We cannot predict if or when we will submit an NDA for approval for our product candidate currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidate for

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the claimed intended uses. Following any regulatory approval of our product candidate, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidate in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidate is unable to compete effectively with marketed drugs targeting similar indications as our product candidate, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidate. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If approved and commercialized, PCM-075 would compete with several currently approved prescription therapies for the treatment of AML. To our knowledge, other potential competitors are in earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for PCM-075.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully identify and develop key points of product differentiations from currently available therapies;

successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;

maintain a proprietary position for our products and manufacturing processes and other related product technology;

attract and retain key personnel;

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develop relationships with physicians prescribing these products; and

build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed drugs, we may never generate meaningful revenue. If a competitor markets the same drug for the treatment of AML, before us, we may not receive orphan drug marketing exclusivity.

If the manufacturers upon whom we rely fail to produce our product candidate, in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate.

We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of PCM-075, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We continue to pursue active pharmaceutical ingredients, or API, and drug product supply agreements with other manufacturers. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and good manufacturing practices or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidate.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We will be responsible for ensuring that each of our future contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer s compliance with GMP requirements. We will be responsible for regularly assessing a contract manufacturer s compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers our product candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

While we will oversee compliance by our contract manufacturers, ultimately we will not have control over our manufacturers compliance with these regulations and standards. A failure to comply with these

requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of our product candidate is compromised due to a manufacturers failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of PCM-075 or other product candidates, entail higher costs or result in us being unable to effectively commercialize our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidate in commercial quantities, which would prevent us from commercializing our product candidate.

To date, our product candidate has been manufactured in small quantities for preclinical studies and clinical trials. If our product candidate is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for our product candidate in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidate requires precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidate may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidate.

We rely on Nerviano to purchase from third-party suppliers the materials necessary to produce bulk APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidate would be delayed, which may significantly impact our ability to develop the product candidate. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidate, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If our product candidate is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

demonstration of safety and efficacy;

changes in the practice guidelines and the standard of care for the targeted indication;

relative convenience and ease of administration;

the prevalence and severity of any adverse side effects;

budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;

pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;

effectiveness of our or any of our partners sales and marketing strategies;

the product labeling or product insert required by the FDA or regulatory authority in other countries; and

the availability of adequate third-party insurance coverage or reimbursement.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our product.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed product.

If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidate do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidate could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;

our contract manufacturers failing to manufacture our product candidate according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;

our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidate. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidate. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;

our contract manufacturers placing a priority on the manufacture of their own products, or other customers products;

our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and

our contract manufacturers plants being closed as a result of regulatory sanctions or a natural disaster.

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

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

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

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

If in the future we decide to further expand our pipeline, we will be dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third-parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical

companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds

that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

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

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently do not have product liability insurance coverage for our proposed clinical trials but we intend to obtain such insurance. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If we materially breach or default under the Nerviano Agreements, Nerviano will have the right to terminate the agreement and we could lose critical license rights, which would materially harm our business.

Our business is substantially dependent upon certain intellectual property rights that we license from Nerviano. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under the Agreement. The Agreement provides the right to terminate if the Agreement for an uncured breach by us, or if we are insolvent or the subject of a bankruptcy proceeding, or potentially other reasons. We expect that other technology in-licenses that we may enter into in the future will contain similar provisions and impose similar obligations on us. If we fail to comply with any such obligations such licensor will likely terminate their out-licenses to us, in which case we would not be able to market products covered by these licenses, including our PCM-075 asset. The loss of our license with Nerviano with respect to the PCM-075, and potentially other licenses that we enter into in the future, would have a material adverse effect on our business. In addition, our failure to comply with obligations under our material in-licenses may cause us to become subject to litigation or other potential disputes under any such license agreements.

In addition, the Nerviano Agreement requires us to make certain payments, including license fees, milestone payments royalties, and other such terms typically required under licensing agreements and these types of technology in-licenses generally could make it difficult for us to find corporate partners and less profitable for us to develop product candidates utilizing these existing product candidates and technologies.

We may delay or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

Even though the results of preclinical studies and clinical trials that have been conducted or may conduct in the future may support further development of our product candidate, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

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We depend upon our officers and other key employees, and if we are not able to retain them or recruit additional qualified personnel, the commercialization of our product candidates and any future tests that we develop could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers, especially William J. Welch, our Chief Executive Officer, and other key employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field and, in order to pursue our test development and commercialization strategies, we will need to attract, hire and retain, or engage as consultants, additional personnel with specialized experience in a number of disciplines, including assay development, bioinformatics and statistics, laboratory and clinical operations, clinical affairs and studies, government regulation, sales and marketing, billing and reimbursement and information systems. Additionally, there is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any tests we may develop in the future could be delayed or negatively impacted.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 16 full-time employees as of September 30, 2017. Future growth of our company will impose significant additional responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of our product candidates and our cell-free molecular diagnostic technology. Our future financial performance and our ability to commercialize our product candidates and cell-free molecular diagnostic tests and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

manage our clinical studies effectively;

integrate additional management, administrative, manufacturing and regulatory personnel;

maintain sufficient administrative, accounting and management information systems and controls; and

hire and train additional qualified personnel.

There is no guarantee that we will be able to accomplish these tasks, and our failure to accomplish any of them could materially adversely affect our business, prospects and financial condition.

All of our diagnostic technology and services are performed at a single laboratory, and in the event this facility is affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.

We are performing all of our diagnostic services in our laboratory located in San Diego, California. Despite precautions taken by us, any future natural or man-made disaster at this laboratory, such as a fire, flood, earthquake or terrorist act, could cause substantial delays in our operations, damage or destroy our equipment and urine samples or

cause us to incur additional expenses.

In addition, we are leasing the facilities where our laboratory operates. We are currently in compliance with all of our lease obligations, but should the lease terminate for any reason, or if the laboratory is moved due to conditions outside of our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of our laboratory, we may be unable to perform our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could materially adversely affect our operating results and financial condition.

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Further, if we have to use a substitute laboratory while our facility is closed, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA-certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to certification under CLIA and licensure by various states, which would take a significant amount of time and expense and result in delays in our ability to continue our personalized medicine services operations.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers and partners proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, the Health Insurance Portability and Accountability Act, or HIPAA, imposes limitations on the use and disclosure of an individual s healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual s health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed: notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

General economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the U.S. and other countries have contributed to increased volatility and diminished expectations for the global economy. If the economic climate does not improve, or if it

deteriorates, our business, including our access to patient samples and the addressable market for tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party

payors, could be negatively impacted, which could materially adversely affect our business, prospects and financial condition.

We incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, and the Nasdaq Stock Market LLC. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. For example, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There is significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

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

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

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

The establishment and operation of our laboratory is subject to regulation by numerous federal, state and local governmental authorities in the U.S. Our laboratory holds a CLIA certificate of compliance and is licensed by every state (other than the State of New York) and the District of Columbia, as required, which enables us to provide testing services to residents of almost every state. Failure to comply with state regulations or changes in state regulatory requirements could result in a substantial curtailment or even prohibition of the operations of our laboratory and could materially adversely affect our business. CLIA is a federal law that regulates clinical laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease. To renew CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of these laboratories. If we were to lose our CLIA certification or our state licenses, whether as a result of a revocation, suspension or limitation of our license, we would no longer be able to continue our testing operations, which would materially adversely affect our business, prospects and financial condition. Potential sanctions for violations of these statutes and regulations also include significant fines, the

suspension or loss of various licenses, certificates and authorizations, or product suspension or recalls.

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We are subject to other regulation in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- the Federal Anti-kickback Law and state anti-kickback prohibitions;
- the Federal physician self-referral prohibition, commonly known as the Stark Law, and the state equivalents;
- the Federal Health Insurance Portability and Accountability Act of 1996;
- the Medicare civil money penalty and exclusion requirements;
- the Federal False Claims Act civil and criminal penalties and state equivalents; and
- the Foreign Corrupt Practices Act, the United Kingdom Anti-bribery Act and the European Data Protection Directive, all of which apply to our international activities.

We have adopted policies and procedures designed to comply with these laws. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could materially adversely affect our business, prospects and financial

condition. Moreover, in the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Changes in healthcare policy could subject us to additional regulatory requirements that may delay the commercialization of our tests and increase our costs.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of our diagnostic products and tests in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products and services that we believe are fair, which may impact our ability to generate revenues and achieve and maintain profitability.

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New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and judicial decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue or force us to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging for several reasons, including policies advanced by the current executive administration in the U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, has substantially changed the way healthcare is financed by both government health plans and private insurers. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our revenues in the future. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, such provisions could materially adversely affect our business, prospects and financial condition.

The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical studies of products, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical studies and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products, all of which could materially adversely affect our business, prospects and financial condition.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property effectively, we may be unable to prevent third parties from using our technologies, which would impair our competitive advantage.

We rely on patent protection as well as a combination of trademark, copyright and trade secret protection, and other contractual restrictions, to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We may not be successful in defending challenges made in connection with our patents and patent applications. If we fail to protect our intellectual property, we will be unable to prevent third parties from using our technologies and they will be able to compete more effectively against us.

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and our employees are also required to sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights. Any failure to protect our intellectual property rights could materially adversely affect our business, prospects and financial condition.

Our currently pending or future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated or held unenforceable. Furthermore, we cannot be certain that we were the first to make the invention claimed in our issued patents or pending patent applications in the U.S., or that we were the first to file for protection of the inventions claimed in our foreign issued patents or pending patent applications. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, or the PTO, which may have a significant impact on our ability to protect our technology and enforce our

intellectual property rights. For example, in September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. from a first-to-invent system to a first-to-file system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs

surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, we may become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine our entitlement to patents, and these proceedings may conclude that other patents or patent applications have priority over our patents or patent applications. It is also possible that a competitor may successfully challenge our patents through various proceedings and those challenges may result in the elimination or narrowing of our patents, and therefore reduce our patent protection. Accordingly, rights under any of our issued patents, patent applications or future patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes.

The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs or methods without infringing our intellectual property rights and one or more of our competitors may design around our proprietary technologies.

If we are not able to protect our proprietary technology, trade secrets and know-how, our competitors may use our inventions to develop competing products. We own certain patents relating to our cell-free molecular diagnostic technology. However, these patents may not protect us against our competitors, and patent litigation is very expensive. We may not have sufficient cash available to pursue any patent litigation to its conclusion because we currently do not generate revenues other than licensing, milestone and royalty income.

We cannot rely solely on our current patents to be successful. The standards that the PTO and foreign patent offices use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same, are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have been issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries.

We cannot be certain of the level of protection, if any, that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. In addition, the type and extent of any patent claims that may be issued to us in the future are uncertain. Any patents that are issued may not contain claims that will permit us to stop competitors from using similar technology.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our cell-free molecular diagnostic technology.

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the attention of our technical and management personnel will be diverted. An adverse determination may subject us to significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required to pay substantial monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights. In our European patent that covers using microRNAs to detect in vivo cell death, an anonymous third party has recently filed an opposition against the claims in the patent. Oppositions against the patentability of claims in a European patent are considered by a panel of examiners at the European Patent Office, and we are considering the full range of options available for defending against the opposition.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further

require us to obtain rights to issued patents covering such technologies. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our potential products or processes. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions. In addition, we cannot assure you that we would prevail in any of these suits or that the damages or other remedies that we are ordered to pay, if any, would not be substantial. Claims of intellectual property infringement may require us to enter into royalty or license agreements with third parties that may not be available on acceptable terms, if at all. We may also be subject to injunctions against the further development and use of our technology, which could materially adversely affect our business, prospects and financial condition.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations.

Certain rights that we in-license from third-parties are not within our control, and we may be negatively impacted it we lose those rights.

We license some of the technology that is necessary for our products and services from third. In connection with such in-licenses, we may agree to pay the licensor royalties based on sales of our products, which become a cost of product revenues and impact the margins on our products and services. We may need to in-license other technologies in the future to commercialize on our products and services. We may also need to negotiate licenses after launching our products and services. Our business may suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid, or if we are unable to enter into necessary licenses on acceptable terms.

Risks Related to Ownership of Our Common Stock

If we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act, related to disclosure controls and procedures, or if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important in helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. We previously identified a material weakness in our internal control over financial reporting as of December 31, 2012, which was remedied in the year ended December 31, 2013. We cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

The rights of the holders of our common stock may be impaired by the potential issuance of preferred stock.

Our certificate of incorporation gives our board of directors the right to create one or more new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights that could adversely affect the voting power and equity interests of

the holders of our common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be used to discourage, delay or prevent a change of control of our company, which could materially adversely affect the price of our common stock. Without the consent of the holders of the outstanding shares of our Series A Convertible Preferred Stock, we may not adversely alter or change the rights

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of the holders of the Series A Convertible Preferred Stock or increase the number of authorized shares of Series A Convertible Preferred Stock, create a class of stock that is senior to or on parity with the Series A Convertible Preferred Stock, amend our certificate of incorporation in breach of these provisions or agree to any of the foregoing.

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

The market price of our common stock historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. For example, during the year ended December 31, 2016, the closing bid price of our common stock ranged from a low of $2.00 to a high of $6.88. These fluctuations may be due to various factors, many of which are beyond our control, including:

- technological innovations or new products and services introduced by us or our competitors;
- clinical trial results relating to our product candidates or those of our competitors;
- announcements or press releases relating to the industry or to our own business or prospects;
- coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
- regulation and oversight of our product candidates and services, including by the FDA, Centers for Medicare & Medicaid Services and comparable foreign agencies;
- the establishment of partnerships with clinical reference laboratories;
- healthcare legislation;
- intellectual property disputes;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to integrate operations, technology, products and services;

our ability to execute our business plan;

operating results below expectations;

loss of any strategic relationship;

industry developments;

economic and other external factors; and

period-to-period fluctuations in our financial results.

In addition, market fluctuations, as well as general political and economic conditions, could materially adversely affect the market price of our securities. Because we are a development stage company with no revenue from operations to date, other than licensing, milestone and royalty income, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the foregoing.

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Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of September 30, 2017, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially owned approximately 8.7% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

We have never paid any cash dividends on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors that our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor s investment will only occur if our stock price appreciates. In addition, under the terms of our Loan and Security Agreement and the Equipment Line of Credit, we are precluded from paying cash dividends without the prior written consent of the Lenders, and the terms of the Series A Convertible Preferred Stock prohibit us from paying dividends to the holders of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid. Investors in our common stock should not rely on an investment in our company if they require dividend income.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control of our company or changes in our management. For example, our board of directors has the authority to issue up to 20,000,000 shares of preferred stock in one or more series and to fix the powers, preferences and rights of each series without stockholder approval. The ability to issue preferred stock could discourage unsolicited acquisition proposals or make it more difficult for a third party to gain control of our company, or otherwise could materially adversely affect the market price of our common stock.

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Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware. This provision may prohibit or restrict large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us, which could discourage potential takeover attempts, reduce the price that investors may be willing to pay for shares of our common stock in the future and result in our market price being lower than it would without these provisions.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

Our common stock is traded on the Nasdaq Capital Market and could be considered thinly-traded, meaning that the number of investors interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

If our stockholders sell, or the market perceives that our stockholders may sell for various reasons, including the ending of restriction on resale, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

We may be subject to stockholder litigation, thereby diverting our resources, which could materially adversely affect our profitability and results of operations.

The market for our common stock is characterized by significant price volatility, and we expect that our share price will continue to be at least as volatile for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price for its securities. In addition, stockholders may bring actions against companies relating to past transactions or other matters. Any such actions could give rise to substantial damages and thereby materially adversely affect our consolidated financial position, liquidity or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could materially adversely affect our business, prospects and financial condition. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management s time and attention away from business operations, which could harm our business.

Risks Related to this Offering

Our management has broad discretion as to the use of the net proceeds from this offering.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering, and these uses may vary from our current plans. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in Use of Proceeds. Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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You will experience immediate and substantial dilution in the net tangible book deficit per share of the common stock included in the units or issuable upon exercise of the common warrants or pre-funded warrants in this offering.

Since the effective price per share of common stock included in the units or issuable upon exercise of the common warrants or the pre-funded warrants being offered is substantially higher than the net tangible book deficit per share of our common stock outstanding prior to this offering, you will suffer immediate and substantial dilution in the net tangible book deficit of the common stock included in the units or issuable upon the exercise of the common warrants or the pre-funded warrants issued in this offering. See the section titled Dilution below for a more detailed discussion of the dilution you will incur if you purchase units in this offering.

If we fail to comply with the continued minimum closing bid requirements of the Nasdaq Capital Market LLC (Nasdaq) or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

On September 5, 2017, we received a written notice (the Notice) from the Nasdaq Stock Market LLC (Nasdaq) that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the minimum bid price of our common stock has been below $1.00 per share for 30 consecutive business days. The Notice had no immediate effect on the listing of our common stock, and our common stock continues to trade on the Nasdaq Capital Market under the symbol TROV . In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until March 5, 2018, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for at least 10 consecutive business days during this 180 calendar day period. In the event we do not regain compliance by March 5, 2018, we may be eligible for an additional 180 calendar day grace period if we meet the initial listing standards, with the exception of bid price, for the Nasdaq Capital Market, and we provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we do not regain compliance within the allotted compliance period(s), including any extensions that may be granted by Nasdaq or fail to comply with or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of your warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock.

A large number of shares issued in this offering may be sold in the market following this offering, which may depress the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market following this offering could cause the market price of our common stock to decline. If there are more shares of common stock offered for sale than buyers are willing to purchase, then the market price of our common stock may

decline to a market price at which buyers are willing to purchase the offered shares of common stock and sellers remain willing to sell the shares. All of the shares of common stock issued in the offering will be freely tradable without restriction or further registration under the Securities Act of 1933.

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The warrants issued in this offering may not have any value.

Each common warrant will have an exercise price equal to $0.30 and will expire on the fifth anniversary of the date they first become exercisable. In the event our common stock price does not exceed the exercise price of the common warrants during the period when the warrants are exercisable, the common warrants may not have any value.

There is no public market for the common warrants or the pre-funded warrants to purchase shares of our common stock included in the units and the pre-funded units being offered by us in this offering.

There is no established public trading market for the common warrants or the pre-funded warrants included in the units and the pre-funded units being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the common warrants and the pre-funded warrants will be limited.

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USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately $4.0 million, from the sale of our securities in this offering, after deducting the placement agent fees and estimated offering expenses payable by us. The public offering price per unit was negotiated between us and the placement agent based on market conditions at the time of pricing, and represents a discount to the current market price of our common stock. This amount excludes the proceeds, if any, from the exercise of the common warrants and pre-funded warrants issued pursuant to this offering. If all of the common warrants and pre-funded warrants sold in this offering were to be exercised in cash at an exercise price of $0.30 and $0.01 per share, respectively, we would receive additional net proceeds of approximately $4.5 million. We cannot predict when or if these common warrants will be exercised. It is possible that these common warrants may expire and may never be exercised.

We intend to use the net proceeds received from this offering to fund our research and development activities and for working capital and general corporate purposes.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, we will retain broad discretion over the use of these proceeds. Pending any use as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

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DILUTION

If you purchase our securities in this offering, you will experience dilution in the net tangible book value per share of the common stock you purchase to the extent of the difference between the combined public offering price per share and related warrants and the net tangible book value per share of our common stock immediately after this offering. The net tangible book value of our common stock on September 30, 2017, was approximately $3.7 million or approximately $0.10 per share. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the aggregate number of shares of our common stock outstanding.

After giving effect to the sale by us of 14,683,333 units and 316,667 pre-funded units in this offering at a public offering price of $0.30 and $0.29 per unit and pre-funded unit, respectively, after deducting estimated placement agent s fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2017, would have been approximately $7.6 million, or approximately $0.14 per share. This represents an immediate increase in net tangible book value of approximately $0.04 per share to existing stockholders and an immediate dilution of approximately $0.16 per share to new investors purchasing shares of our common stock and warrants in this offering. The following table illustrates this per share dilution:

Public offering price per unit		$ 0.30
Net tangible book value per share as of September 30, 2017	$0.10	
Increase in net tangible book value per share attributable to this offering	0.04	
As adjusted net tangible book value per share after this offering		0.14
Dilution in as adjusted net tangible book value per share to new investors		$ 0.16

This table does not take into account further dilution to new investors that could occur upon the exercise of the warrants offered hereby or outstanding options and warrants having a per share exercise price less than the public offering price per share in this offering. To the extent that outstanding options or warrants are exercised, or restricted stock units vest and settle, investors purchasing our common stock will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The table and discussion above are based on 38,105,251 shares issued and outstanding as of September 30, 2017 and excludes as of that date:

- 4,257,031 shares of our common stock issuable upon exercise of outstanding options at a weighted average price of $4.23 per share;
- 1,277,302 shares of our common stock issuable upon vesting of restricted stock units;
- 8,972,503 shares of our common stock issuable upon exercise of outstanding warrants with a weighted-average exercise price of $2.38 per share;

63,125 shares of our common stock issuable upon conversion of outstanding shares of Series A Convertible Preferred Stock;

3,670,232 shares of our common stock that are reserved for equity awards that may be granted under our equity incentive plans; and

15,316,667 shares of our common stock issuable upon exercise of the common warrants and pre-funded warrants offered hereby.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of December 11, 2017 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all of our current directors and executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

The percentage ownership information under the column entitled Before Offering is based upon 38,105,460 shares of common stock outstanding as of December 14, 2017. The percentage ownership information under the column entitled After Offering gives effect to the sale of 14,683,333 units and 316,667 pre-funded units in this offering. and assumes no exercise of the common warrants and pre-funded warrants issued pursuant to this offering. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or exercisable within 60 days of December 14, 2017 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

Beneficial Owner[1]	Shares Beneficially Owned		
	Number	Percentage	
		Before Offering	After Offering
Named executive officers and directors:			
Thomas H. Adams, Ph.D.	755,827[2]	2.0	1.4
William Welch	1,078,267[3]	2.8	2.0
Dr. Paul Billings	89,728[4]	*	*
John Brancaccio	172,774[5]	*	*
Gary S. Jacob, Ph.D.	290,126[6]	*	*
Dr. Stanley Tennant	377,552[7]	1.0	*
Dr. Rodney S. Markin	74,173[8]	*	*
Dr. Athena Countouriotis	0	-	-
Mark Erlander, Ph.D.	745,408[9]	1.9	1.4
All Executive Officers and Directors as a Group (9 persons)	3,583,855[10]	8.9	6.5

* less than 1%

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

(2) Includes (i) 374,849 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017, and (ii) 45,686 shares of common stock issuable upon exercise of warrants that are exercisable within 60 days after December 14, 2017.

(3)

Includes 328,125 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017.

(4) Includes 83,230 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017.

(5) Includes (i) 132,441 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017, and (ii) 13,833 shares of common stock issuable upon exercise of warrants that are exercisable within 60 days after December 14, 2017.

(6) Includes (i) 147,339 shares of common stock issuable upon exercise of stock options that are exercisable

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within 60 days after December 14, 2017, and (ii) 10,500 shares of common stock issuable upon exercise of warrants that are exercisable within 60 days after December 14, 2017.

(7) Includes (i) 93,158 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017, and (ii) 75,000 shares of common stock issuable upon exercise of warrants that are exercisable within 60 days after December 14, 2017.

(8) Includes 68,230 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017.

(9) Includes 684,375 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017.

(10) Includes (i) 1,911,747 shares of common stock issuable upon exercise of stock options that are exercisable within 60 days after December 14, 2017 and (ii) 145,019 shares of common stock issuable upon exercise of warrant to purchase shares of common stock.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering 14,683,333 units, each unit consisting of one share of our common stock and one common warrant to purchase one share of our common stock, and 316,667 pre-funded units, each pre-funded unit consisting of one pre-funded warrant to purchase one share of our common stock and one common warrant to purchase one share of our common stock. The share of common stock and accompanying common warrant included in each unit will be issued separately, and the pre-funded warrant to purchase one share of common stock and the accompanying common warrant included in each pre-funded unit will be issued separately. Units will not be issued or certificated. We are also registering the shares of common stock included in the units and the shares of common stock issuable from time to time upon exercise of the pre-funded warrants included in pre-funded units and common warrants included in the units and the pre-funded units offered hereby.

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. Other than the purchasers in this offering as further described below, 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.

Pre-Funded Warrants

The following summary of certain terms and provisions of pre-funded warrants included in the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant will have an initial exercise price per share equal to $0.01. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying common warrants included in the pre-funded units, and may be transferred separately immediately thereafter.

Exercisability

The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days prior notice

from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder s pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is

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determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded units in this offering may also elect prior to the issuance of the pre funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder.

Except as otherwise provided in the pre-funded warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Common Warrants

The following summary of certain terms and provisions of common warrants included in the units and the pre-funded units that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

Duration and Exercise Price

Each common warrant included in the units and the pre-funded units offered hereby will have an initial exercise price per whole share equal to $0.30. The common warrants will be immediately exercisable and will expire on the fifth

anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock included in the units, or the pre-funded warrants included in the pre-funded units, as the case may be, and may be transferred separately immediately thereafter. A common warrant to purchase one share of our common stock will be included in each unit or pre-funded unit purchased in this offering.

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Exercisability

The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder s common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants.

Cashless Exercise

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the common warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Transferability

Subject to applicable laws, a common warrant may be transferred at the option of the holder upon surrender of the common warrant to us together with the appropriate instruments of transfer.

Exchange Listing

We do not intend to list the common warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder

Except as otherwise provided in the common warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Fundamental Transaction

In the event of a fundamental transaction which is approved by our Board, the holders of the common warrants have the right to require us or a successor entity to redeem the common warrant for cash in the amount of the Black Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the common

warrants have the right to require us or a successor entity to redeem the common warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the common warrant on the date of the consummation of the fundamental transaction.

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PLAN OF DISTRIBUTION

H.C. Wainwright & Co., LLC (the Placement Agent or Wainwright) has agreed to act as our exclusive placement agent in connection with the offering pursuant to the terms and conditions of an engagement agreement. The Placement Agent is not purchasing or selling any securities offered by this prospectus, and is not required to arrange for the purchaser or sale of any specific number or dollar amount of securities, but will use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. We will enter into a securities purchase agreement directly with certain institutional investors. The Placement Agent may retain one or more brokers, dealers or sub-agents in connection with the offering.

Fees and Expenses

	Per Unit	Per Pre-Funded Unit
Placement Agent Fees	$ 0.018	$ 0.018
Total	$ 264,300	$ 5,700

We have agreed to pay to the Placement Agent a placement agent fee equal to six percent (6%) of the aggregate gross proceeds to us from the sale of the securities in the offering. In addition, we have agreed to reimburse the placement agent for offering expenses in the non-accountable sum of $25,000 and for legal fees and expenses in an amount up to $75,000, subject to compliance with FINRA Rule 5110(f)(2)(D)(i).

Lock-Up Agreements

We have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock for a period of 60 days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Wainwright.

In addition, each of our officers and directors have agreed not to offer, pledge, sell, contract to sell, grant any option or contract to purchase, purchase any option or contract to sell, or otherwise dispose of, directly or indirectly, any shares of common stock or any securities convertible into, exercisable for, or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock for a period of 90 days after the effective date of the registration statement of which this prospectus is a part without the prior written consent of Wainwright.

Wainwright may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the Placement Agent will consider, among other factors, the security holder s reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Right of First Refusal

We have agreed to grant Wainwright, for the 3-month period following the closing of this offering, a right of first refusal to act as co-book running manager, co-underwriter or co-placement agent, as the case may be.

Indemnification

The engagement agreement provides that we will indemnify the Placement Agent against specified liabilities, including liabilities under the Securities Act of 1933, as amended. The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the shares sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Shares Act. As an underwriter, the Placement

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Agent would be required to comply with the Securities Act and the Securities Exchange Act of 1934, as amended (Exchange Act), including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock, overallotment purchase rights and warrants by the Placement Agent acting as principal. Under these rules and regulations, the Placement Agent:

- may not engage in any stabilization activity in connection with our shares; and
- may not bid for or purchase any of our shares or attempt to induce any person to purchase any of our shares, other than as permitted under the Exchange Act, until it has completed its participation in the distribution of shares in this offering.

Listing of Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol TROV .

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LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon for us by Sheppard Mullin Richter & Hampton LLP, New York, New York. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel for the placement agent in connection with this offering.

EXPERTS

The consolidated financial statements as of December 31, 2016 and 2015 and for each of the three years in the period ended December 31, 2016 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2016 incorporated by reference in this Prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, 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 with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock and warrants to purchase shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement of which this prospectus is a part and the exhibits to such registration statement. For further information with respect to us and the common stock and warrants offered by this prospectus, we refer you to the registration statement of which this prospectus is a part and the exhibits to such registration statement. Statements contained in this prospectus as to the contents of any contract or any other document are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document incorporated by reference or filed as an exhibit to the registration statement of which this prospectus is a part. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part, as well as our reports, proxy statements and other information, at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Trovagene, Inc. The SEC s Internet site can be found at *http://www.sec.gov*. You may also request a copy of these filings, at no cost, by writing us at 11055 Flintkote Avenue, San Diego, CA 92121 or telephoning us at (858) 952-7570.

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with this law, file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC s public reference facilities and the website of the SEC referred to above. We also maintain a website at *www.trovagene.com*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

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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, 2016 filed on March 15, 2017;
- our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2017 filed on May 10, 2017, for the quarterly period ended June 30, 2017 filed on August 9, 2017 and for the quarter ended September 30, 2017 filed on November 9, 2017;
- our Current Reports on Form 8-K or Form 8-K/A (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed on January 9, 2017, January 12, 2017, January 24, 2017, February 28, 2017, March 2, 2017, March 7, 2017, March 21, 2017, March 27, 2017, April 14, 2017, April 25, 2017, April 26, 2017, May 23, 2017, May 25, 2017, June 2, 2017, June 7, 2017, June 12, 2017, June 13, 2017, June 22, 2017, June 23, 2017, June 26, 2017, June 27, 2017, June 29, 2017, July 6, 2017, July 10, 2017, July 12, 2017, July 17, 2017, July 25, 2017, July 28, 2017, July 31, 2017, August 16, 2017, August 18, 2017, August 21, 2017, August 31, 2017, September 8, 2017, September 20, 2017, October 10, 2017, October 18, 2017, November 13, 2017, December 8, 2017 and December 12, 2017.
- our definitive proxy statement on Schedule 14A relating to our 2017 annual meeting of stockholders filed on April 28, 2017; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the Commission on May 23, 2012.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus and will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies 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.trovagene.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.

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

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14,683,333 Units (each Unit contains One Share of Common Stock and One

Common Warrant to Purchase One Share of Common Stock)

316,667 Pre-funded Units (each Pre-funded Unit contains One Pre-funded Warrant to Purchase One Share of Common Stock and One Common Warrant to purchase One Share of Common Stock)

(316,667 Shares of Common Stock Underlying the Pre-funded Warrants) and

(15,000,000 Shares of Common Stock Underlying the Common Warrants)

PROSPECTUS

H.C. Wainwright & Co.

December 15, 2017