Trovagene, Inc. Form S-8 August 06, 2013 Table of Contents

As filed with the Securities and Exchange Commission on August 6, 2013

Registration No.

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM S-8

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

27-2004382

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

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

(Address of principal executive offices) (Zip Code)

2004 Stock Option Plan

(Full title of the plans)

#### **Antonius Schuh**

#### 1055 Flintkote Avenue, Suite B

San Diego, CA 92121

(Name and Address of agent for service)

(858) 952-7570

(Telephone number, including area code, of agent for service)

With a copy to:

Jeffrey Fessler, Esq.

Sichenzia Ross Friedman Ference LLP

61 Broadway, 32 nd Floor

New York, NY 10006

Phone (212) 930-9700

Fax (212) 930-9725

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o

Accelerated filer o
Smaller Reporting Company x

Non-accelerated filer o

#### **CALCULATION OF REGISTRATION FEE**

**Proposed Maximum Proposed Maximum** Amount to **Title of Securities** Amount of Offering Price Per he **Aggregate Offering** to be Registered Registered (1) Share Price **Registration Fee** Common Stock, \$.0001 par value 6,000,000(2) \$ 9.84(3) \$ 59,040,000 8,053.06

- (1) This Registration Statement shall also cover any additional shares of Common Stock, par value \$0.0001 per share, of Trovagene, Inc. ( Common Stock ) that become issuable under the Trovagene, Inc. 2004 Stock Option Plan (the Plan ) by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of shares of Common Stock.
- (2) Represents shares of common stock issuable pursuant to the Plan.
- (3) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) of the Securities Act of 1933, as amended, using the last sale price reported on The NASDAQ Capital Market on August 5, 2013.

#### **Table of Contents**

#### EXPLANATORY NOTE

This Registration Statement is being filed by Trovagene, Inc. (the Company) in accordance with the requirements of Form S-8 under the Securities Act of 1933, as amended (the Securities Act) in order to register 6,000,000 shares of the Company s common stock, par value \$.001 per share, the amount of shares issuable under the Company s 2004 Stock Option Plan (the Plan).

This Form S-8 includes a reoffer prospectus prepared in accordance with Part I of Form S-3 under the Securities Act. The reoffer prospectus may be used for reoffer and resales of restricted securities (as such term is defined in General Instruction C to Form S-8) acquired pursuant to the Plan.

#### PART I

#### INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

#### Item 1. Plan Information.

The Company will provide each recipient of a grant under the Plan (the Recipients) with documents that contain information related to the Plan, and other information including, but not limited to, the disclosure required by Item 1 of Form S-8, which information is not required to be and are not being filed as a part of this Registration Statement on Form S-8 (the Registration Statement) or as prospectuses or prospectus supplements pursuant to Rule 424 under the Securities Act. The foregoing information and the documents incorporated by reference in response to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act. A Section 10(a) prospectus will be given to each Recipient who receives common stock covered by this Registration Statement, in accordance with Rule 428(b)(1) under the Securities Act.

#### Item 2. Registrant Information and Employee Plan Annual Information.

We will provide to each Recipient a written statement advising of the availability of documents incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) prospectus) and of documents required to be delivered pursuant to Rule 428(b) under the Securities Act without charge and upon written or oral request by contacting:

Antonius Schuh

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

#### **Table of Contents**

#### REOFFER PROSPECTUS

Trovagene, Inc.

3,769,045 Shares of

**Common Stock** 

This reoffer prospectus relates to the sale of up to 3,769,045 shares of our common stock, \$.0001 par value per share that may be offered and resold from time to time by existing selling stockholders identified in this prospectus for their own account issuable pursuant to the Plan. It is anticipated that the selling stockholders will offer common shares for sale from time to time in one or more transactions on The NASDAQ Capital Market, or such other stock market or exchange on which our common stock may be listed or quoted, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated (see Plan of Distribution starting on page 21 of this prospectus). We will receive no part of the proceeds from sales made under this reoffer prospectus. The selling stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the selling stockholders will be borne by us.

The shares of common stock have been issued pursuant to the Plan.

This reoffer prospectus has been prepared for the purposes of registering the common shares under the Securities Act to allow for future sales by selling stockholders on a continuous or delayed basis to the public without restriction.

Investing in our common stock involves risks. See Risk Factors beginning on page 6 of this reoffer prospectus. These are speculative securities.

Our common stock is quoted on The NASDAQ Capital Market under the symbol TROV and the last reported sale price of our common stock on August 5, 2013 was \$9.84 share.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is August 6, 2013

#### TROVAGENE, INC.

#### TABLE OF CONTENTS

	Page
Prospectus Summary	5
Risk Factors	6
Cautionary Note Regarding Forward-Looking Statements	16
Use of Proceeds	16
Selling Stockholders	16
Plan of Distribution	21
Legal Matters	23
Experts	23
Incorporation of Certain Documents by Reference	23
Disclosure of Commission Position on Indemnification For Securities Act Liabilities	24
Additional Information Available to You	24

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS, OTHER THAN THOSE CONTAINED IN THIS PROSPECTUS, IN CONNECTION WITH THE OFFERING MADE HEREBY, AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY OR ANY OTHER PERSON. NEITHER THE DELIVERY OF THIS PROSPECTUS NOR ANY SALE MADE HEREUNDER SHALL UNDER ANY CIRCUMSTANCES CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY SINCE THE DATE HEREOF. THIS PROSPECTUS DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OFFERED HEREBY BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO OR TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION.

#### **Table of Contents**

#### PROSPECTUS SUMMARY

We are a development stage molecular diagnostic company that focuses on the development and commercialization of proprietary diagnostic technologies for use in patient/disease screening and monitoring across a variety of medical disciplines. Our primary internal focus is to leverage our novel urine-based molecular diagnostic platform to facilitate improvements in field of oncology, while our external focus includes developing collaborations in the areas of infectious disease, transplant medicine and prenatal diagnostics.

Our proprietary urine-based molecular diagnostic tests are designed to detect specific nucleic acids in urine which are known as transrenal DNA (TrDNA) and RNA (TrRNA). These are cell-free nucleic acids found in urine as result of normal cell death when DNA and RNA are released to circulate in the bloodstream as fragments and are eventually filtered through the kidneys to allow for the detection and measurement in urine. These transrenal nucleic acids (TrNAs) can be used as genetic markers of disease. The contents of the urine represent a systemic liquid biopsy and provide a simple, non-invasive sample collection method. We believe that our transrenal molecular diagnostic technology may open significant new markets in the molecular diagnostics field.

Our fundamental intellectual property is focused on the discovery that cell-free DNA, RNA and other types of nucleic acids pass through the kidney into the urine. Cell free fragments of nucleic acids from normal cell death that circulate in the blood can cross the kidney barrier and be detected in urine. These transrenal nucleic acids can be diagnostic of diseases such as cancer and infection. Through this proprietary technology, we are at the forefront of a paradigm shift in the way diagnostic medicine is practiced, using simple, non-invasive sampling and analysis of these nucleic acids which we believe will ultimately lead to earlier detection, more effective treatment monitoring, and better management of serious illnesses. As of August 5, 2013, our property portfolio consists of 60 issued patents and 47 pending applications globally. The patent estate includes the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation and prenatal testing.

#### **Corporate Information**

We were incorporated in the State of Florida on April 26, 2002 under the name Used Kar Parts, Inc. Our name was changed to Trovagene, Inc. and we redomesticated our state of incorporation from Florida to Delaware in January 2010. Our principal executive offices are located at 11055 Flintkote Avenue, Suite B, 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. We have included our website address as a factual reference and do not intend it to be an active link to our website.

5

**Table of Contents** 

#### RISK FACTORS

Investing in our common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below and other information contained in this prospectus, before purchasing shares of our common stock. There are numerous and varied risks that may prevent us from achieving our goals. If any of these risks actually occur, our business, financial condition and results of operations may be materially adversely affected. In that case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

**Risks Related to Our Business** 

We are a development stage company and may never commercialize any of our products or services or earn a profit.

We are a development stage company and have incurred losses since we were formed. As of March 31, 2013 and December 31, 2012, we have an accumulated total deficit of approximately \$56.3 million and \$55.2 million, respectively. For the fiscal year ended December 31, 2012, we had a net loss and comprehensive loss attributable to common stockholders of approximately \$11.6 million. For the fiscal quarter ended March 31, 2013, we had a net loss and comprehensive loss attributable to common stockholders of approximately \$1.1 million. To date, we have experienced negative cash flow from development of our transrenal molecular technology. We currently have no products ready for commercialization, have not generated any revenue from operations except for licensing, milestone and royalty income and expect to incur substantial net losses for the foreseeable future to further develop and commercialize the transrenal molecular 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 the transrenal molecular technology or attain profitability, we will not be able to sustain operations.

Because of the numerous risks and uncertainties associated with developing and commercializing our transrenal molecular technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, 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 tests in the medical diagnostic industry. We may never successfully commercialize transrenal molecular technology or any future tests, and our business may fail.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

In their report dated April 1, 2013 our independent registered public accountants stated that our financial statements for the year ended December 31, 2012 were prepared assuming that we would continue as a going concern. The doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing, is an issue raised as a result of recurring losses from operations. We continue to experience net operating losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, increasing sales or obtaining loans and grants from various financial institutions where possible. Our continued net operating losses increase the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

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

As of December 31, 2012 and March 31, 2013 our cash balance was approximately \$10.8 million and \$9.1 million, respectively, and our working capital was approximately \$10.3 million and \$8.2 million, respectively. 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 sales of our equity and issuances of notes to fund our operations. We currently have no credit facility or committed sources of capital. During the next 12 months, we will have to raise additional funds to continue the development and commercialization of our transrenal molecular technology. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, 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 unattractive terms.

Our ability to successfully commercialize our technology will depend largely upon the extent to which third-party payors reimburse our tests.

Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid pay a substantial portion of the test price.

#### **Table of Contents**

Reimbursement by a thi	ird-party payor may depend on a number of factors, including a payor s determination that our product candidates are:
•	not experimental or investigational;
•	effective;
•	medically necessary;
•	appropriate for the specific patient;
•	cost-effective;
•	supported by peer-reviewed publications; and
•	included in clinical practice guidelines.

Market acceptance, sales of products based upon the TrDNA or TrRNA technology, and our profitability may depend on reimbursement policies and health care reform measures. Several entities conduct technology assessments of medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. The levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, may reimburse the price patients pay for such products could affect whether we are able to commercialize our products. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement of the test. Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals may be a time-consuming and costly process. We cannot be sure that reimbursement in the U.S. or elsewhere will be available for any of our products in the future. If reimbursement is not available or is limited, we may not be able to commercialize our products.

If we are unable to obtain reimbursement approval from private payors and Medicare and Medicaid programs for our product candidates, or if the amount reimbursed is inadequate, our ability to generate revenues could be limited. Even if we are being reimbursed, insurers may withdraw their coverage policies or cancel their contracts with us at any time, stop paying for our test or reduce the payment rate for our test, which would reduce our revenue. Moreover, we may depend upon a limited number of third-party payors for a significant portion of our test revenues and if these or other third-party payors stop providing reimbursement or decrease the amount of reimbursement for our test, our revenues could decline.

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community.

The use of the transrenal molecular technology has never been commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not order diagnostic tests based upon the TrDNA or TrRNA technology, in which event we may be unable to generate significant revenue or become profitable. Acceptance of the transrenal molecular technology will depend on a number of factors including:

•	acceptance of products based upon the TrDNA or TrRNA technology by physicians and patients;
•	successful integration into clinical practice;
•	adequate reimbursement by third parties;
•	cost effectiveness;
•	potential advantages over alternative treatments; and
•	relative convenience and ease of administration.

We will need to make leading physicians aware of the benefits of tests using our technology through published papers, presentations at scientific conferences and favorable results from our clinical studies. In addition, we will need to gain support from thought leaders who believe that testing a urine specimen for these molecular markers will provide superior performance. Ideally, we will need these individuals to publish support papers and articles which will be necessary to gain acceptance of our products. There is no guarantee that we will be able to obtain this support. Our failure to be successful in these efforts would make it difficult for us to convince medical practitioners to order TrDNA tests for their patients and consequently our revenue and profitability will be limited.

If our potential medical diagnostic tests are unable to compete effectively with current and future medical diagnostic tests targeting similar markets as our potential products, our commercial opportunities will be reduced or eliminated.

The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. In each of our potential product areas, we face significant competition from large biotechnology, medical diagnostic and other companies. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain molecular diagnostics companies have established technologies that may be competitive to our product candidates and any future tests that we develop. Some of these tests may use different approaches or means to obtain diagnostic results, which could be more effective or less expensive than our tests for similar indications. Moreover, these and other future competitors have or may have considerably greater resources than we do in terms of technology, sales, marketing, commercialization and capital resources. These competitors may have substantial advantages over us in terms of research and development expertise, experience in clinical studies, experience in regulatory issues, brand name exposure and expertise in sales and marketing as well as in operating central laboratory services. Many of these organizations have financial, marketing and human resources greater than ours; therefore, there can be no assurance that we can successfully compete with present or potential competitors or that such competition will not have a materially adverse effect on our business, financial position or results of operations.

Since the transrenal molecular diagnostic (TrDNA or TrRNA) technology is under development, we cannot predict the relative competitive position of any product based upon the transrenal molecular technology. However, we expect that the following factors will determine our ability to compete effectively: safety and efficacy; product price; turnaround time; ease of administration; performance; reimbursement; and marketing and sales capability.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new diagnostic tools or develop existing technologies to compete with the transrenal molecular diagnostic technology. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, are more convenient or are less expensive than our products.

Our failure to obtain human urine samples from medical institutions for our clinical studies will adversely impact the development of our transrenal molecular technology.

We will need to establish relationships with medical institutions in order to obtain urine specimens from patients who are testing positive for a relevant infectious disease or from patients that have been diagnosed with solid tumors. We must obtain a sufficient number in order to statistically prove the equivalency of the performance of our assays versus existing assays that are already on the market.

If our clinical studies do not prove the superiority of our technologies, we may never sell our products and services.

The results of our clinical studies may not show that tests using our transrenal molecular technology are superior to existing testing methods. In that event, we will have to devote significant financial and other resources to further research and development, and commercialization of tests using our technologies will be delayed or may never occur. Our earlier clinical studies were small and included samples from high-risk patients. The results from these earlier studies may not be representative of the results we obtain from any future studies, including our next two clinical studies, which will include substantially more samples and a larger percentage of normal-risk patients.

Our inability to establish strong business relationships with leading clinical reference laboratories to perform TrDNA/TrRNA tests using our technologies will limit our revenue growth.

A key step in our strategy is to sell diagnostic products that use our proprietary technologies to leading clinical reference laboratories that will perform TrDNA or TrRNA tests. We currently have no business relationships with these laboratories and have limited experience in establishing these business relationships. If we are unable to establish these business relationships, we will have limited ability to obtain revenues beyond the revenue we can generate from our limited in-house capacity to process tests.

We depend upon our officers, 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 such as our current key employee, Dr. Antonius Schuh, Chief Executive Officer. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire, 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. 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 future tests could be delayed or negatively impacted.

#### **Table of Contents**

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

We are a small company with 13 full-time employees as of August 5, 2013. Future growth will impose significant added 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 transrenal molecular technology. Our future financial performance and our ability to commercialize TrDNA and TrRNA assays 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.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

If we do not receive regulatory approvals, we may not be able to develop and commercialize our transrenal molecular technology.

We may need FDA approval to market products based on the transrenal molecular technology for diagnostic uses in the United States and approvals from foreign regulatory authorities to market products based on the TrDNA or TrRNA technology outside the United States. We have not yet filed an application with the FDA to obtain approval to market any of our proposed products. If we fail to obtain regulatory approval for the marketing of products based on the TrDNA or TrRNA technology, we will be unable to sell such products and will not be able to sustain operations.

We believe the estimated molecular diagnostics market for many diseases in Europe is approximately as large as that of the United States. If we seek to market products or services such as a urine-based HPV test in Europe, we need to receive a CE Mark. If we do not obtain a CE Mark for our urine-based HPV DNA test, we will be unable to sell this product in Europe and countries that recognize the CE Mark.

The regulatory review and approval process, which may include evaluation of preclinical studies and clinical trials of products based on the TrDNA or TrRNA technology, as well as the evaluation of manufacturing processes and contract manufacturers facilities, is lengthy, expensive and uncertain. Securing regulatory approval for products based upon the transrenal molecular technology may require the submission of extensive preclinical and clinical data and supporting information to regulatory authorities to establish such products safety and effectiveness for each indication. We have limited experience in filing and pursuing applications necessary to gain regulatory approvals.

Regulatory authorities generally have substantial discretion in the approval process and may either refuse to accept an application, or may decide after review of an application that the data submitted is insufficient to allow approval of any product based upon the transrenal molecular technology. If regulatory authorities do not accept or approve our applications, they may require that we conduct additional clinical, preclinical or manufacturing studies and submit that data before regulatory authorities will reconsider such application. We may need to expend substantial resources to conduct further studies to obtain data that regulatory authorities believe is sufficient. Depending on the extent of these studies, approval of applications may be delayed by several years, or may require us to expend more resources than we may have available. It is also possible that additional studies may not suffice to make applications approvable. If any of these outcomes occur, we may be forced to abandon our applications for approval, which might cause us to cease operations.

In addition, if we do not comply with various state and federal licensing requirements and accreditation standards, our CLIA certification could be put at risk, which would have a detrimental impact on our operations.

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 United States 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 health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products and services which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and 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, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new

#### **Table of Contents**

healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA. This law will substantially change the way health care is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential 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, they could have a material adverse effect on our business and financial condition.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, 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 trials 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.

If the FDA were to begin regulating LDTs, or if we decide to market our products as a medical device rather than a LDT, we could be forced to delay commercialization of our current product candidates, experience significant delays in commercializing any future tests, incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval and/or experience decreased demand for or reimbursement of our test.

We intend to develop products that are considered to be medical devices and are subject to federal regulations including those covering Quality System Regulations (QSR) and Medical Device Reporting (MDR).

The QSR includes requirements related to the methods used in and the facilities and controls used for designing, purchasing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices. Manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements. The quality systems for FDA-regulated products are known as current good manufacturing practices (cGMPs) as described in the Code of Federal Regulations, part 820 (21 CFR part 820). Among the cGMP requirements are those requiring manufacturers to have sufficient appropriate personnel to implement required design controls and other portions of the OSR guidelines.

Design controls include procedures that describe the product design requirements (design goals) and compare actual output to these requirements, including documented Design Reviews. Required Design History Files (DHFs) for each device will document the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the QSRs.

QSRs also include stipulation for control of all documents used in design and production, including history of any changes made. Production and process controls include stipulations to ensure products are in fact produced as specified by controlled documents resulting from the controlled design phase, using products and services purchased under controlled purchasing procedures.

Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA under the Medical Device Reporting (MDR) program. In addition, certain malfunctions must also be reported. The MDR regulation is a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.

We may be required to participate in MDR through two routes. As a manufacturer of products for sale within the United States, we would be required to report to the FDA any deaths, serious injuries and malfunctions, and events requiring remedial action to prevent an unreasonable risk of substantial harm to the public health. Our CLIA lab offering services for sale is already currently required to report suspected medical device related deaths to both the FDA and the relevant manufacturers of products we purchase and use.

Clinical laboratory tests like our current product offerings are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We expect that, upon the commencement of commercialization, our product candidates will be an LDT and not a diagnostic kit. As a result, we believe that our product candidates should not be subject to regulation under current FDA policies, however there is no assurance that it will not be subject to such regulation in the future. Further, if we decide to market our products as a diagnostic kit rather than a LDT, our products would be subject to FDA regulation as a medical device. The container we expect to provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation and while we expect that it will be exempt from pre-market review by FDA, there is no certainty in that respect.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our LDT product candidates, either through new policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will

be enacted into law and may result in increased regulatory burdens for us to offer or continue to offer our product as a clinical laboratory service.

If pre-market review is required, our business could be negatively impacted until such review is completed and clearance to market or approval is obtained, and the FDA could require that we stop selling. If pre-market review of our LDTs is required by the FDA, there can be no assurance that our product offerings will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations, such as the Quality System Regulation and Medical Device Reporting, would increase the cost of conducting our business, and subject us to inspection by the FDA and to the requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA pre-market review of our product offerings if we determine that doing so would be appropriate. Some competitors may develop competing tests cleared for marketing by the FDA. There may be a marketing differentiation or perception that an FDA-cleared test is more desirable than our product offerings, and that could discourage adoption and reimbursement of our test.

Should any of the reagents obtained by us from vendors and used in conducting our clinical laboratory service be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents necessary to perform testing.

If the FDA decides to regulate our LDTs, it may require that we conduct extensive pre-market clinical studies prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical studies, whether using retrospectively collected and banked samples or prospectively collected samples, delays in the commencement or completion of clinical studies could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval.

The commencement of clinical studies may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical studies, which might increase the cost of the studies. We will also depend on clinical investigators, medical institutions and contract research organizations to perform the studies properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, FDA requirements or for other reasons, our clinical studies may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our test. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

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. 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.

We cannot assure you that any of our currently pending or future patent applications will result in issued patents, or that any patents issued to us will not be challenged, invalidated or held unenforceable. We cannot guarantee you that we will be successful in defending challenges made in connection with our patents and patent applications.

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 employees to also 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.

We cannot guarantee that the patents issued to us will be broad enough to provide any meaningful protection nor can we assure you that one of our competitors may not develop more effective technologies, designs or methods without infringing our intellectual property rights or that one of our competitors might not 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 the transrenal molecular 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 currently we do not generate revenues.

We cannot rely solely on our current patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent office s use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same and 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 we attempt to enforce them and 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 which 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 transrenal molecular 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 diversion of financial resources and technical and management personnel. 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 financial 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 application that covers mutations in the NPM-1 gene related to acute myeloid leukemia, an anonymous third party has filed Observations against the claims prior to allowance of the patent. Observations concern the patentability of the invention to which a European patent application or patent relates and are considered by the examining or opposition division of the European Patent Office.

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 products or processes. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States 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 if any, awarded against us 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 become subject to injunctions against the further development and use of our technology, which would have a material adverse effect on our business, financial condition and results of operations.

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 have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Ownership of our Common Stock

In preparing our consolidated financial statements, our management determined that our disclosure controls and procedures and internal controls were ineffective as of March 31, 2013 and December 31, 2012 and if they continue to be ineffective could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. As of March 31, 2013 and December 31, 2012, our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process.

We intend to implement remedial measures designed to address the ineffectiveness of our disclosure controls and procedures and internal controls. If these remedial measures are insufficient to address the ineffectiveness of our disclosure controls and procedures and internal controls, or if material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures and internal controls continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation, and our common stock could be delisted from The NASDAQ Capital Market. Any failure to address the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the ineffectiveness of our disclosure controls and procedures or that any material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in

strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

If we continue to fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, 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 of 2002 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 to 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. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

We recently filed past due Federal and state tax returns for fiscal year 2006 through 2011. We do not know the amount of any interest and penalties we may owe.

In March 2013, we filed past due federal and state returns for fiscal year 2006 through 2011. The amount of any interest and penalties that could arise since fiscal year 2006 for these periods is de minimus as of December 31, 2012.

Our Series A Convertible Preferred Stock contains a covenant that limits our ability to pay dividends.

Our Series A Convertible Preferred Stock includes a covenant limiting our ability to pay dividends while the Series A Convertible Preferred Stock is outstanding. This covenant may limit us in raising additional capital, competing effectively, or taking advantage of new business opportunities.

The rights of the holders of 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 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 which could adversely affect the voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be utilized as a method of discouraging, delaying or preventing a change of control. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to issue any additional shares of preferred stock or to create any new series of preferred stock and the certificate of designation relating to the Series A Convertible Preferred Stock restricts our ability to issue additional series of preferred stock, we may issue such shares in the future. Without the consent of the holders of the outstanding shares of Series A Convertible Preferred Stock we may not alter or change adversely the rights of the holders of the Series A

Convertible Preferred Stock or increase the number of authorized shares of Series A Convertible Preferred Stock, create a class of stock which is senior to or on a 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.

	7 7 7	1101		1 . 1 . 11		c .
Our common stock price may	be volatile and	could fluctuate	e widelv in price.	which could resul	lt in substantial losses	tor investors.

The market price of our countries which are beyond our countries.	r common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of control, including:
•	technological innovations or new products and services by us or our competitors;
•	clinical trial results relating to our tests or those of our competitors;
•	commercial acceptance of our products, if approved or cleared;
•	coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
•	FDA, CMS and comparable ex-U.S. agency regulation and oversight of our products and services;
•	the establishment of partnerships with clinical reference laboratories;
•	health care legislation;
•	intellectual property disputes;

13

# Table of Contents

•	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.		
Because we are a development stage company with no revenues to date, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the above.			
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 August 5, 2013, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 24.0% 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 might harm the market price of our common stock by:

•	delaying, deferring or preventing a change in corporate control;
•	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.
	ends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable investment may be limited to the value of our common stock.
operations and growth. upon our profitability a not pay dividends, our of	been paid on our common stock. We expect that any income received from operations will be devoted to our future. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do common stock may be less valuable because a return on an investor s investment will only occur if our stock price in our common stock should not rely on an investment in our company if they require dividend income.
-	v analysts do not publish research or reports about our business, or if they change their recommendations regarding r stock price and trading volume could decline.
our business. We do no commence coverage of analysts who cover us of	our common stock will be influenced by the research and reports that industry or securities analysts publish about us or t currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the lowngrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our larly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price one.
Delaware law and our that stockholders may o	corporate charter and bylaws will contain anti-takeover provisions that could delay or discourage takeover attempts consider favorable.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. For example, our board of directors have 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

#### **Table of Contents**

adversely affect the market price of our common stock. Our bylaws require that any stockholder proposals or nominations for election to our board of directors must meet specific advance notice requirements and procedures, which make it more difficult for our stockholders to make proposals or director nominations.

Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. These provisions may prohibit or restrict large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These provisions in our certificate of incorporation and bylaws and under Delaware law could discourage potential takeover attempts and could reduce the price that investors might 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, despite certain increases of trading volume from time to time, there have been periods when it could be considered thinly-traded, meaning that the number of persons 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 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 intend to 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 become involved in securities class action litigation that could divert management s attention and harm our business.

#### Our common stock is subject to volatility.

There can be no assurance that the market price for our common stock will remain at its current level and a decrease in the market price could result in substantial losses for investors. The market price of our common stock may be significantly affected by one or more of the following factors:

- announcements or press releases relating to the industry or to our own business or prospects;
- regulatory, legislative, or other developments affecting us or the industry generally;

- sales by holders of restricted securities pursuant to effective registration statements or exemptions from registration; and
- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally.

15

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expects, plans, anticipates, could, int projects, contemplates, believes, estimates, predicts, potential or continue or the negative of these terms or other similar words. These are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. We discuss many of the risks in greater detail under the heading Risk Factors. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. Except as required by law, we assume no obligation to update any forward-looking statements after the date of this prospectus.

This prospectus also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other industry data. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified the statistical and other industry data generated by independent parties and contained in this prospectus and, accordingly, we cannot guarantee their accuracy or completeness. In addition, projections, assumptions and estimates of our future performance and the future performance of the industries in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Risk Factors and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

#### USE OF PROCEEDS

This prospectus relates to sale of shares of common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds from the sale of shares by the selling stockholders.

#### SELLING STOCKHOLDERS

The selling stockholders named in this prospectus (the Selling Stockholders ) are offering 3,769,045 shares offered through this prospectus that were granted to the selling stockholders pursuant to the Plan.

The following table provides, as of August 5, 2013, information regarding the beneficial ownership of our common shares held by each of the selling stockholders, including:

- 1. the total number of common shares owned by each selling stockholder prior to this offering;
- 2. the total number of common shares that are to be offered by each selling stockholder;
- 3. the total number of common shares that will be owned by each selling stockholder upon completion of the offering; and
- 4. the percentage owned by each selling stockholder, prior to and upon completion of the offering.

Information with respect to beneficial ownership is based upon information obtained from the selling stockholders. Because the selling stockholders may offer all or part of the common shares, which they own pursuant to the offering contemplated by this reoffer prospectus, and because its offering is not being underwritten on a firm commitment basis, no estimate can be given as to the amount of shares that will be held upon termination of this offering. The common shares currently owned offered by this reoffer prospectus may be offered from time to time by the selling stockholders named below. However, information with respect to Shares Beneficially Owned Upon Completion the Offering assumes the sale of all of the common shares offered by this prospectus and no other purchases or sales of our common shares by the selling stockholders. Except as described below and to our knowledge, the named selling stockholder beneficially owns and has sole voting and investment power over all common shares or rights to these common shares.

NAME	SHARES BENEFICIAL PRIOR TO THIS OFI NUMBER		NUMBER SHARES BENEFICIALLY OWN OF SHARES BEING COMPLETION OF THE OFFERI OFFERED NUMBER PERCE		ON
1121121	11011221	121(21(1(2)	OTT EALLS	1,0111211	121(221(1(2)
Hovsep S. Melkonyan	150,000**	*	150,000	0	0
L. David Tomei	358,477(37)	1.97	202,083	156,394	*
Gabriele M. Cerrone	1,544,204(36)	8.19	524,761	1,019,443	5.56
Samuil Umansky	307,718(9)	1.69	227,083	80,635	0
Donald Picker	36,833**	*	36,833	0	0
Natalie Cooper	278**	*	278	0	0
Annie Picinich	1,667**	*	1,667	0	0
Vladimir Scheinker	2,000**	*	2,000	0	0
Eugene Shekhtman	2,000**	*	2,000	0	0
Eric Meyer	667**	*	667	0	0
Elysia Preston	500**	*	500	0	0
Bernard Denoyer	4,167**	*	4,167	0	0
David Ladner	6,667**	*	6,667	0	0
Gary Jacob	210,138(32)	1.13	86,970(28)	133,500	*
Uma Kavita	667**	*	667	0	0
Dr. Zhenghan Xin	1,333**	*	1,333	0	0
Dr. William John Feaver	667**	*	667	0	0
David Robbins	69,792**	*	69,592	200	*
Christoph Bruening	6,667**	*	6,667	0	0
John Brancaccio	92,289(33)	*	79,815(29)	27,666	*
Subhash Patel	10,833**	*	10,833	0	0
Frederick Larcombe	11,111**	*	11,111	0	0
Thomas Adams	642,816(34)	3.5	323,281(3)	319,222	1.77
Jim Goode	10,000**	*	10,000	0	0
Riccardo Dalla-Favera	2,778(4)**	*	4,167(4)	0	0
Brunangelo Falini	2,778(5)**	*	4,167(5)	0	0

17

# Table of Contents

Sinuhe Hahn	2,778(6)**	*	4,167(6)	0	0
Antonius Schuh	316,666**	2.52	833,333(7)	0	0
Steve Zaniboni	41,667**	*	226,667(8)	0	0
Charles Rodi	41,666(10) **	*	166,667(10)	0	0
Carlo Croce	33,334(11)**	*	100,000(11)	0	0
Mike Terry	25,000(12) **	*	100,000(12)	0	0
Brian Keith McCormick	18,750(13) **	*	75,000(13)	0	0
Brigitte Lindsay	12,500(14) **	*	50,000(14)	0	0
Mark Erlander	1,667(15) **	*	215,000(15)	0	0
Paul Billings	0(16)	0	15,000(16)	0	0
Anna Lorieta Leppin	4,167	0	4,167	0	0
Latifa Teriki-Hassaine	0(17)	0	13,000(17)	0	0
Adriana Muniz-Fernandez	0(18)	0	10,000(18)	0	0
Elizabeth Anderson	0(19)	0	15,000(19)	0	0
Amy Caterina	0(20)	0	15,000(20)	0	0
Dana Hosseini	0(21)	0	40,000(21)	0	0
Kunwar Shailubhai	0(22)	0	15,000(22)	0	0
Rebecca Campbell	0(23)	0	8,000(23)	0	0
Karena Kosco	0(24)	0	12,000(24)	0	0
Maya Kiss	0(25)	0	10,000(25)	0	0
Jason Poole	0(26)	0	12,000(26)	0	0
Cecile Rose Vibat	0(27)	0	18,000(27)	0	0
Stanley Tennant	229,097(35)	1.26	26,903(30)	219,374	1.2
Christopher McGuigan	0(31)	*	16,165(31)	0	0

<sup>\*</sup> less than one percent

<sup>\*\*</sup>Represents options to purchase shares of Common Stock

#### **Table of Contents**

- (1) The number and percentage of shares beneficially owned is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any shares as to which the selling stockholder has sole or shared voting power or investment power and also any shares which the selling stockholder has the right to acquire within 60 days.
- (2) Based on 18,029,905 shares of common stock outstanding as of August 5, 2013.
- (3) 56,806 options remain unvested and shall vest on August 5, 2014. 1,667 options remain unvested and shall vest on January 26, 2014 and 833 options remain unvested and shall vest on January 26, 2015. 7,832 options remain unvested and vest as follows: 2,611 option on each of February 14, 2014 and 2015 and 2,610 options on February 14, 2016.
- (4) 2,778 of such options remain unvested and shall vest in equal installments on each of September 19, 2013 and 2014.
- (5) 2,778 of such options remain unvested and shall vest in equal installments on each of September 19, 2013 and 2014.
- (6) 2,778 of such options remain unvested and shall vest in equal installments on each of September 19, 2013 and 2014.
- (7) 474,999 of such options remain unvested and shall vest in equal installments on each of October 4, 2013, 2014 and 2015. 200,000 of such options remain unvested and shall vest in equal installments of 50,000 options on each of June 24, 2014, 2015, 2016 and 2017.
- (8) 125,001 of such options remain unvested and shall vest in equal installments of 41,667 options on each of February 1, 2014, 2015 and 2016. 60,000 of such options remain unvested and shall vest in equal installments of 15,000 options on each of June 24, 2014, 2015, 2016 and 2017.
- (9) Includes 80,635 shares of Common Stock
- (10) 125,001 of such options remain unvested and shall vest in equal installments of 41,667 options on each of February 1, 2014, 2015 and 2016.
- (11) 66,666 of such options remain unvested and shall vest in equal 33,333 installments on each of April 26, 2014 and 2015.
- (12) 100,000 of such options remain unvested and shall vest in four equal installments of 25,000 options each on September 13, 2013, 2014, 2015 and 2016.
- (13) 75,000 of such options remain unvested and shall vest in four equal installments of 18,750 options each on September 13, 2013, 2014, 2015 and 2016.
- (14) 50,000 of such options remain unvested and shall vest in four equal installments of 12,500 options each on September 13, 2013, 2014, 2015 and 2016.
- 5,000 of such options remain unvested and shall vest as follows: 1,667 on each of September 13, 2013 and 2014 and 1,666 on September 13, 2105. 10,000 of such options remain unvested and shall vest as follows: 3,333 on each of December 10, 2013 and 2014 and 3,334 on December 10, 2015. 200,000 of such options remain unvested and shall vest in equal installments of 50,000 options on each of January 28, 2014, 2015, 2016 and 2017.
- (16) 15,000 of such options remain unvested and shall vest in full on November 18, 2013.
- (17) 13,000 options remain unvested and shall vest in four equal installments of 3,250 options each on December 10, 2013, 2014, 2015 and 2016.
- (18) 10,000 options remain unvested and shall vest in four equal installments of 2,500 options each on December 10, 2013, 2014, 2015 and
- (19) 15,000 options remain unvested and shall vest in four equal installments of 3,750 options each on December 10, 2013, 2014, 2015 and 2016.

- (20) 15,000 options remain unvested and shall vest in four equal installments of 3,750 options each on December 10, 2013, 2014, 2015 and 2016.
- (21) 40,000 options remain unvested and shall vest in four equal installments of 5,000 options each on December 10, 2013, 2014, 2015 and 2016.

19

#### **Table of Contents**

- (22) 15,000 options remain unvested and shall vest in equal installments of 5,000 options on each of January 4, 2014, 2015 and 2016.
- 8,000 options remain unvested and shall vest in equal installments of 2,000 options on each of June 24, 2014, 2015, 2016 and 2017.
- (24) 12,000 options remain unvested and shall vest in equal installments of 3,000 options on each of June 24, 2014, 2015, 2016 and 2017.
- (25) 10,000 options remain unvested and shall vest in equal installments of 2,500 options on each of June 24, 2014, 2015, 2016 and 2017.
- (26) 12,000 options remain unvested and shall vest in equal installments of 3,000 options on each of June 24, 2014, 2015, 2016 and 2017.
- (27) 18,000 options remain unvested and shall vest in equal installments of 4,500 options on each of June 24, 2014, 2015, 2016 and 2017.
- (28) 2,500 options remain unvested and shall vest as follows: 1,667 options on January 26, 2014 and 833 options on January 26, 2015. 7,832 options remain unvested and vest as follows: 2,611 options on each of February 14, 2014 and 2015 and 2,610 options on February 14, 2016.
- (29) 2,500 options remain unvested and shall vest as follows: 1,667 options on January 26, 2014 and 833 options on January 26, 2015. 7,832 options remain unvested and vest as follows: 2,611 options on each of February 14, 2014 and 2015 and 2,610 options on February 14, 2016.
- (30) 2,777 options remain unvested and shall vest on December 30, 2013. 2,500 of such options remain unvested and shall vest as follows: 1,667 options on January 26, 2014 and 833 options on January 26, 2015. 7,832 options remain unvested and vest as follows: 2,611 options on each of February 14, 2014 and 2015 and 2,610 options on February 14, 2016.
- (31) 8,333 options remain unvested and shall vest as follows: 2,778 options on each of January 14, 2014 and 2015 and 2,777 options on January 14, 2016. 7,832 options remain unvested and vest as follows: 2,611 options on each of February 14, 2014 and 2015 and 2,610 options on February 14, 2016.
- (32) Includes (i) 70,999 shares of common stock issuable upon exercise of stock options and (ii) 10,500 shares of common stock issuable upon exercise of warrants.
- (33) Includes (i) 53,790 shares of common stock issuable upon exercise of stock options and (ii) 13,833 shares of common stock issuable upon exercise of warrants.
- (34) Includes (i) 251,444 shares of common stock issuable upon exercise of stock options and (ii) 45,686 shares of common stock issuable upon exercise of warrants.
- (35) Includes 75,000 shares of common stock issuable upon exercise of warrants and 13,794 shares of common stock exercisable upon exercise of stock options.
- (36) Consists of (i) 719,526 shares of common stock held by Panetta Partners, Ltd., (ii) 6,250 shares of common stock held by Mr. Cerrone, (iii) 524,761 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, (iv) 287,417 shares of common stock issuable upon exercise of warrants held by Panetta and (v) 6,250 shares of common stock issuable upon exercise of warrants held by Mr. Cerrone. Mr. Cerrone is a director of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta, despite him having only a small pecuniary interest in such securities.
- (37) Includes 156,394 shares of Common Stock.

#### PLAN OF DISTRIBUTION

## **Timing of Sales**

The selling stockholders may offer and sell the shares covered by this prospectus at various times. The selling stockholders will act independently of our company in making decisions with respect to the timing, manner and size of each sale.

## No Known Agreements to Resell the Shares

To our knowledge, no selling stockholder has any agreement or understanding, directly or indirectly, with any person to resell the common shares covered by this prospectus.

## **Offering Price**

The sales price offered by the selling stockholders to the public may be:

- 1. the market price prevailing at the time of sale;
- 2. a price related to such prevailing market price; or
- 3. such other price as the selling stockholders determine from time to time.

## Manner of Sale

The common shares may be sold by means of one or more of the following methods:

1. a block trade in which the broker-dealer so engaged will attempt to sell the common shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

2. Purchases by a broker-dealer as principal and resale by that broker-dealer for its account pursuant to this prospectus;

3. ordinary brokerage transactions in which the broker solicits purchasers;
4. through options, swaps or derivatives;
5. in transactions to cover short sales;
6. privately negotiated transactions; or
7. in a combination of any of the above methods.
The selling stockholders may sell their common shares directly to purchasers or may use brokers, dealers, underwriters or agents to sell their common shares. Brokers or dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate. Brokers or dealers may receive commissions, discounts or concessions from the selling stockholders, or, if any such broker-dealer acts as agent for the purchaser of common shares, from the purchaser in amounts to be negotiated immediately prior to the sale. The compensation received by brokers or dealers may, but is not expected to, exceed that which is customary for the types of transactions involved.
Broker-dealers may agree with a selling stockholder to sell a specified number of common shares at a stipulated price per common share, and, the extent the broker-dealer is unable to do so acting as agent for a selling stockholder, to purchase as principal any unsold common shares at the price required to fulfill the broker-dealer commitment to the selling stockholder.
Broker-dealers who acquire common shares as principal may thereafter resell the common shares from time to time in transactions, which may involve block transactions and sales to and through other broker-dealers, including transactions of the nature described above, on The NASDAC Capital Market or otherwise at prices and on terms then prevailing at the time of sale, at prices then related to the then-current market price or in negotiated transactions. In connection with resales of the common shares, broker-dealers may pay to or receive from the purchasers of shares commissions as described above.
If our selling stockholders enter into arrangements with brokers or dealers, as described above, we are obligated to file a post-effective amendment to this registration statement disclosing such arrangements, including the names of any broker-dealers acting as underwriters.
21

#### **Table of Contents**

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of the common shares may be deemed to be underwriters within the meaning of the Securities Act. In that event, any commissions received by broker-dealers or agents and any profit on the resale of the common shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We will make copies of this prospectus available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act.

#### Sales Pursuant to Rule 144

Any common shares covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus.

Accordingly, during such times as a selling stockholder may be deemed to be engaged in a distribution of the common stock, and therefore be considered to be an underwriter, the selling stockholder must comply with applicable law and, among other things:

- 1. may not engage in any stabilization activities in connection with our common stock;
- 2. may not cover short sales by purchasing shares while the distribution is taking place; and
- 3. may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities other than as permitted under the Exchange Act.

#### **State Securities Laws**

Under the securities laws of some states, the common shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the common shares may not be sold unless the shares have been registered or qualified for sale in the state or an exemption from registration or qualification is available and is complied with.

## **Expenses of Registration**

We are bearing all costs relating to the registration of the common stock. These expenses are estimated to be \$5,000, including, but not limited to, legal, accounting, printing and mailing fees. The selling stockholders, however, will pay any commissions or other fees payable to brokers or dealers in connection with any sale of the common stock.

#### **LEGAL MATTERS**

The validity of the common stock has been passed upon, for us by Sichenzia Ross Friedman Ference LLP, New York, New York.

#### **EXPERTS**

The financial statements of Trovagene, Inc. as of December 31, 2012 and 2011 and for each of the years then ended and for the period from August 4, 1999 (inception) to December 31, 2012 incorporated by reference in this Prospectus have been so incorporated in reliance upon the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in accounting and auditing.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The Securities and Exchange Commission (SEC) allows us to incorporate by reference certain of our publicly filed documents into this prospectus, which means that such information is considered part of this prospectus. Information that we file with the SEC subsequent to the date of this prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, until the selling stockholders have sold all of the shares offered hereby or such shares have been deregistered.

The following documents filed by us with the SEC are incorporated herein by reference:

- Reference is made to our report on Form10-Q filed with the SEC on May 14, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form10-K filed with the SEC on April 1, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on January 16, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on March 4, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on April 2, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on April 26, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on May 15, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on June 25, 2013, which is hereby incorporated by reference

- Reference is made to our report on Form 8-K filed with the SEC on July 19, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on July 31, 2013, which is hereby incorporated by reference
- The description of our common stock in our Registration Statement on Form 8-A, filed with the SEC on May 23, 2012, which is hereby incorporated by reference

We will provide without charge to each person to whom a copy of this prospectus has been delivered, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, other than exhibits to such documents. Written or oral requests for such copies should be directed to Antonius Schuh at the Company.

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION

## FOR SECURITIES ACT LIABILITIES

As permitted by the Delaware General Corporation Law, we have adopted provisions in our certificate of incorporation and by-laws to be in effect at the closing of this offering that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

• any breach of the director s duty of loyalty to us or our stockholders;
• any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
• any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
• any transaction from which the director derived an improper personal benefit.
These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedisuch as an injunction or rescission.
In addition, our by-laws provide that:
• we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted to the Delaware General Corporation Law; and
• we will advance expenses, including attorneys fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or

omissions in their capacities as directors or officers, including liabilities under the Securities Act.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

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

#### ADDITIONAL INFORMATION AVAILABLE TO YOU

This prospectus is part of a Registration Statement on Form S-8 that we filed with the SEC. Certain information in the Registration Statement has been omitted from this prospectus in accordance with the rules of the SEC. We file annual, quarterly and special reports, proxy statements and other information with the SEC. You can inspect and copy the Registration Statement as well as reports, proxy statements and other information we have filed with the SEC at the public reference room maintained by the SEC at 100 F Street N.E. Washington, D.C. 20549. You can obtain copies from the public reference room of the SEC at 100 F Street N.E. Washington, D.C. 20549, upon payment of certain fees. You can call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed through the SEC s World Wide Web site at http://www.sec.gov.

Т	ab	le	of	Cor	itents

TROVAGENE, INC.	
3,769,045 SHARES OF COMMON STOCK	
PROSPECTUS	
August 6, 2013	
11ugust 0, 2013	
25	

#### **PART II**

#### INFORMATION NOT REQUIRED IN THE PROSPECUTS

#### Item 3. Incorporation of Documents by Reference.

The Registrant hereby incorporates by reference into this Registration Statement the documents listed below. In addition, all documents subsequently filed pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934 (the Exchange Act ), prior to the filing of a post-effective amendment which indicates that all securities offered have been sold or which deregisters all securities then remaining unsold, shall be deemed to be incorporated by reference into this Registration Statement and to be a part hereof from the date of filing of such documents:

- Reference is made to our report on Form10-Q filed with the SEC on May 14, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form10-K filed with the SEC on April 1, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on January 16, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on March 4, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on April 2, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on April 26, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on May 15, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on June 25, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on July 19, 2013, which is hereby incorporated by reference
- Reference is made to our report on Form 8-K filed with the SEC on July 31, 2013, which is hereby incorporated by reference
- The description of our common stock in our Registration Statement on Form 8-A, filed with the SEC on May 23, 2012, which is hereby incorporated by reference

## Item 4. Description of Securities.

Not applicable.

## Item 5. Interests of Named Experts and Counsel.

No expert or counsel named in this Registration Statement as having prepared or certified any part of this Registration Statement or having given an opinion upon the validity of the securities being registered or upon other legal matters in connection with the registration or offering of the common stock was employed on a contingency basis or had, or is to receive, in connection with the offering, a substantial interest, directly or indirectly, in the registrant or any of its parents or subsidiaries.

#### Item 6. Indemnification of Directors and Officers.

As permitted by the Delaware General Corporation Law, we have adopted provisions in our certificate of incorporation and by-laws to be in effect at the closing of this offering that limit or eliminate the personal liability of our directors. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- · any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

## Table of Contents

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our by-laws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the Delaware General Corporation Law; and
- we will advance expenses, including attorneys fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings, subject to limited exceptions.

We also maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, a stockholder s investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. We believe that these provisions, the indemnification agreements and the insurance are necessary to attract and retain talented and experienced directors and officers.

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

## Item 7. Exemption from Registration Claimed.

Up to 6,000,000 shares of common stock being registered pursuant to this Registration Statement may be issued under the Plan. The 3,769,045 shares underlying options already issued were issued pursuant to the exemption from registration provided by Section 4(2) of the Securities Act.

#### Item 8. Exhibits.

<b>Exhibit Number</b>	Description
4.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to Form
	10-12G filed on November 25, 2011).
4.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by
	reference to Appendix B to Trovagene, Inc. s Proxy Statement on Schedule 14A filed March 20, 2012).
4.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to Form 10-12G filed on November 25, 2011).
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
23.1	Consent of BDO USA LLP.
23.2	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)
99.1	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to Form 8-K filed July 19, 2004).
99.2	Amendment to 2004 Stock Option Plan (incorporated by reference to the Definitive Proxy Statement filed on March 20,
	2012.
99.3	Amendment to 2004 Stock Option Plan (incorporated by reference to the Definitive Proxy Statement filed on May 29,
	2013)

Table of Contents
Item 9. Undertakings.
(a) The undersigned Registrant hereby undertakes:
(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:
(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
(ii) to reflect in the prospectus any facts or events arising after the effective date of this Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in this Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;
(iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;
<i>Provided, however</i> , that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in this Registration Statement.
(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be

deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be

the

deemed to be the initial bona fide offering thereof.

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

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Form S-8 to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 6th day of August 2013.

TROVAGENE, INC.

By: /s/ ANTONIUS SCHUH, PH.D

Antonius Schuh, Ph.D

Chief Executive Officer and Director

By: /s/ STEPHEN ZANIBONI

Stephen Zaniboni Chief Financial Officer

#### POWER OF ATTORNEY

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

Signature	Title	Date
/s/ ANTONIUS SCHUH Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	August 6, 2013
/s/ STEPHEN ZANIBONI Stephen Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	August 6, 2013
/s/ THOMAS H. ADAMS Thomas H. Adams	Chairman of the Board	August 6, 2013
/s/ JOHN P. BRANCACCIO John P. Brancaccio	Director	August 6, 2013
/s/ GARY S. JACOB Gary S. Jacob	Director	August 6, 2013

/s/ STANLEY N. TENNANT Stanley N. Tennant	Director	August 6, 2013
/s/ CHRISTOPHER MCGUIGAN Christopher McGuigan	Director	August 6, 2013

## Table of Contents

## EXHIBIT INDEX

Exhibit Number	Description
4.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to Form
	10-12G filed on November 25, 2011).
4.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by
	reference to Appendix B to Trovagene, Inc. s Proxy Statement on Schedule 14A filed March 20, 2012).
4.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to Form 10-12G filed on November 25, 2011).
5.1	Opinion of Sichenzia Ross Friedman Ference LLP
23.1	Consent of BDO USA LLP.
23.2	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)
99.1	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to Form 8-K filed July 19, 2004).
99.2	Amendment to 2004 Stock Option Plan (incorporated by reference to the Definitive Proxy Statement filed on March 20,
	2012.
99.3	Amendment to 2004 Stock Option Plan (incorporated by reference to the Definitive Proxy Statement filed on May 29,
	2013)