

TrovaGene Inc.  
Form POS AM  
January 30, 2013  
Table of Contents

As filed with the Securities and Exchange Commission on January 30, 2013

Registration Statement No. 333-180810

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1

TO  
**FORM S-1**  
ON

**FORM S-3**

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

**TROVAGENE, INC.**

(Exact name of registrant as specified in its charter)

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

**27-2004382**  
(I.R.S. Employer  
Identification No.)

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**11055 Flintkote Avenue, Suite B  
San Diego, CA 92121  
858-217-4838**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Antonius Schuh, Ph.D  
Chief Executive Officer  
11055 Flintkote Avenue, Suite B  
San Diego, CA 92121  
858-217-4838**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

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**Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.**

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

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

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

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

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

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

Large accelerated filer

Non-accelerated filer  (Do not check if smaller reporting company)

Accelerated filer

Smaller reporting company

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Table of Contents

**EXPLANATORY NOTE**

This Post-Effective Amendment No. 1 to Form S-1 on Form S-3 (this Registration Statement ) is filed in compliance with Section 10(a)(3) of the Securities Act of 1933 and Rule 401(b) under the Securities Act of 1933. This Registration Statement originally covered an offering of units, common stock and warrants (including warrants issued to the underwriter) that was completed in May 2012 and now covers the sale of the shares of our common stock issuable from time to time upon exercise of the warrants held by the holders.

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

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Table of Contents

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

**Subject to completion, dated January 30, 2013**

**Preliminary Prospectus**

**TROVAGENE, INC.**

**1,242,000 Shares of Common Stock Issuable**

**Upon Exercise of Outstanding Warrants**

We are offering up to 1,150,000 shares of our common stock that are issuable at a purchase price of \$5.32 per share from time to time upon exercise of currently outstanding warrants that we issued on May 29, 2012 as part of a public offering of our common stock and warrants. Additionally, we are offering up to 92,000 shares of common stock that are issuable at a purchase price of \$7.00 per share from time to time upon exercise of the outstanding warrants issued to the underwriter and its designees as part of our public offering. No securities are being offered pursuant to this prospectus other than the shares of our common stock that will be issued upon exercise of those currently outstanding warrants.

Our common stock, units and warrants are presently listed on The NASDAQ Capital Market under the symbols TROV, TROVU and TROVW, respectively. On January 29, 2013, the last reported sale price of our common stock, units and warrants was \$7.15, \$20.02 and \$2.40, respectively.

**Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under Risk Factors beginning on page 4 and in the documents incorporated by reference into this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is \_\_\_\_\_, 2013



Table of Contents

TABLE OF CONTENTS

	<b>Page</b>
<u>About This Prospectus</u>	1
<u>Prospectus Summary</u>	2
<u>Risk Factors</u>	4
<u>Disclosure Regarding Forward-Looking Statements</u>	15
<u>Use of Proceeds</u>	15
<u>Dilution</u>	15
<u>Plan of Distribution</u>	16
<u>Description of Capital Stock</u>	16
<u>Legal Matters</u>	20
<u>Experts</u>	20
<u>Where You Can Find More Information</u>	20
<u>Incorporation of Documents by Reference</u>	21

Table of Contents

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC. As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC's website or its offices described below under the heading "Where You Can Find Additional Information".

You should rely only on the information that is contained in this prospectus or that is incorporated by reference into this prospectus. We have not authorized anyone to provide you with information that is in addition to or different from that contained in, or incorporated by reference into, this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it.

The securities offered by this prospectus are not being offered in any jurisdiction where the offer or sale of such securities is not permitted. You should not assume that the information contained in, or incorporated by reference into, this prospectus is accurate as of any date other than the date of this prospectus or, in the case of the documents incorporated by reference, the date of such documents, regardless of the date of delivery of this prospectus or any sale of the securities offered by this prospectus. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.



Table of Contents

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it might not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including Risk Factors beginning on page 4 and our financial statements and related notes thereto incorporated by reference herein, before making an investment decision.*

**Business Overview**

Trovagene, Inc. is referred to throughout this prospectus as Trovogene, we or us.

We are a development stage molecular diagnostic company that focuses on the development and commercialization of proprietary, *in-vitro* 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 sample, by virtue of the collection pathway, make up a liquid biopsy and provide a simple, non-invasive sample collection method. The company believes that its transrenal molecular diagnostic technology will 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 attempting to change 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.

We intend to develop and expand our transrenal molecular technology into a pipeline of potentially groundbreaking commercial medical testing and screening products. The recent acquisition and expansion of our Clinical Laboratory Improvement Amendments of 1998 (CLIA)-certified, College of American Pathologists (CAP)-accredited laboratory in San Diego provides an ideal platform from which to commercialize our testing services and launch our growing pipeline of innovative diagnostic tests. Transrenal molecular diagnostics can provide relevant diagnostic information across multiple therapeutic and clinical areas, and may lead to improvements in patient management.

Targeting transrenal markers will allow for the development of genetic tests that use non-invasive and easy-to-obtain urine samples rather than other more traditional, more invasive methods. These methods include blood testing, bone marrow and tissue biopsy. We are exploring a broad range of clinical utilities where transrenal nucleic acid technology holds the potential to replace complex and less robust earlier technologies

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based on circulating cells and nucleic acids in blood. We are leveraging our technology to develop faster, more effective, non-invasive diagnostics, aligned with the current industry shift into personalized medicine. Transrenal molecular tests can make it easier to address important health problems worldwide - and may lead to significant advancements in patient care.

Our patented technology uses safe, non-invasive, cost effective and simple urine collection and can be applied to a broad range of testing including tumor detection and monitoring, infectious disease screening, transplantation monitoring and prenatal diagnostics. We believe that our technology is ideally suited to be used in developing molecular diagnostic assays that will allow physicians to provide very simple, non-invasive and convenient screening and monitoring tests for their patients by identifying specific biomarkers involved in a disease process. Our novel assays will facilitate much improved testing compliance resulting in earlier diagnosis of disease, more targeted treatment which can be more cost-effective, and improvements in the quality of life for the patient.

In order to facilitate early availability and use of our products and technologies, on February 1, 2012, we acquired the CLIA laboratory assets of MultiGEN Diagnostics, Inc., or MultiGEN, which included CLIA approval and licensing documentation, laboratory procedures, customer lists and marketing materials. A CLIA lab is a clinical reference laboratory that can perform high complexity diagnostic assays (e.g. those requiring PCR amplification). Through this CLIA laboratory we are able to offer laboratory developed tests, or LDTs, in compliance with

Table of Contents

CLIA guidelines, and, depending on the diagnostic assay, without the need for FDA review. This will make our tests and technology available to physicians to order for their patient management.

We will determine on a case-by-case basis whether an eventual FDA review of a given diagnostic assay is necessary. This decision will, amongst other factors, be based on the desired route of commercialization (e.g., in vitro diagnostic product vs. laboratory testing service) and the specific nature of the respective diagnostic test. We plan to make and sell our products and services in the U.S. with our own direct commercial sales force. In order to provide our products globally, we plan to establish business partnerships with diagnostic or pharmaceutical companies in Europe, Asia, South America, and other international markets.

**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 Trovagine, 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.trovagine.com](http://www.trovagine.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.

**The Offering**

<b>Securities being offered by us</b>	1,150,000 shares of common stock issuable upon the exercise of the warrants issued as a part of the securities sold in our May 2012 public offering which are exercisable until May 29, 2017 at an exercise price of \$5.32 per share and 92,000 shares of common stock issuable upon the exercise of the warrants issued to the underwriter and its designees in connection with our May 2012 public offering which are exercisable until May 29, 2017 at an exercise price of \$7.00 per share..
<b>Common stock to be outstanding after this offering if all of the warrants are exercised</b>	16,758,400 shares
<b>Use of proceeds</b>	We intend to use the net proceeds of this offering to fund our research and development activities and for working capital and general corporate purposes. See <i>Use of Proceeds</i> for further information.
<b>Risk Factors</b>	See <i>Risk Factors</i> , as well as other information included in this prospectus, for a discussion of factors you should read and consider carefully before investing in our securities.
<b>Trading Market</b>	Our common stock is traded on The Nasdaq Capital Market under the symbol TROV. Our warrants and units are also traded on The Nasdaq Capital Market under the symbols TROVW and TROVU, respectively.

The number of shares of our common stock to be outstanding after this offering as shown above is based on 15,516,400 shares outstanding as of January 29, 2013 and excludes:

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- 78,100 shares of common stock issuable upon conversion of outstanding Series A Convertible Preferred Stock;
- 3,734,616 shares of our common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$4.71 per share as of January 29, 2013; and
- 6,989,237 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$3.96 per share as of January 29, 2013.

Table of Contents

**RISK FACTORS**

*Investing in our securities involves risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our company. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed below and under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading "Risk Factors" included in our most recent annual report on Form 10-K, as revised or supplemented by our most recent quarterly report on Form 10-Q, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future.*

**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 December 31, 2011 and September 30, 2012, we have an accumulated total deficit of \$43,598,431 and \$48,866,386, respectively. For the fiscal year ended December 31, 2011 and the nine months ended September 30, 2012, we had net losses and comprehensive losses attributable to common stockholders of \$2,277,452 and \$5,267,955, respectively. 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 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 March 30, 2012 our independent registered public accountants stated that our financial statements for the year ended December 31, 2011 were prepared assuming that we would continue as a going concern. 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 our cash balance was \$10.8 million and our working capital was \$10.3 million. At our current burn rate, we estimate that our existing capital resources will fund our operations for at least the next 12 months. We estimate that we will require approximately \$8.0 million over the next 12 months in order to sustain our operations and implement our business strategy. Consequently, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. This amount will be sufficient to launch our products in the marketplace currently under development as LDTs. 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

Table of Contents

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.

Reimbursement by a third-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

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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



Table of Contents

- 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.

Table of Contents

***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.

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

We are a small company with ten full-time employees as of January 28, 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.***

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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.

Table of Contents

***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 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).

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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 QSR 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 (DHF) 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.

Table of Contents

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

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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



Table of Contents

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 offices 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

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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.

Table of Contents

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 December 31, 2011 and continue to be ineffective which 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 December 31, 2011, 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 have not filed any Federal, state or foreign tax returns since fiscal year 2006, except for Delaware franchise tax returns and we do not know the amount of any tax liability, interest and penalties we may owe.*

We have not filed any federal, state or foreign tax returns since fiscal year 2006, except for Delaware franchise tax returns. The amount of any tax liability, interest and penalties that could arise since inception is undetermined as of December 31, 2012. We intend to file all tax returns that are currently due as soon as possible.

*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

Table of Contents

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.

*Our stockholders may experience significant dilution as a result of the sale of securities offered by this prospectus.*

To the extent that we raise additional funds through the sale of securities offered by this prospectus, our stockholders may experience significant dilution. Sale of additional equity and/or convertible securities at prices below certain levels will trigger anti-dilution provisions with respect to certain securities we have previously sold. If additional funds are raised through a credit facility or the issuance of preferred stock, lenders under the credit facility or holders of preferred stock would likely have rights that are senior to the rights of holders of our common stock, and any credit facility or additional securities could contain covenants that would restrict our operations.

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

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our 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;

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- the establishment of partnerships with clinical reference laboratories;
- health care legislation;
- intellectual property disputes;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- loss of any strategic relationship;
- industry developments;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

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.



Table of Contents

***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 January 29, 2013, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 24.1% 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.

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

No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income.

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

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.



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

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control 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 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

Table of Contents

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.

Table of Contents

**DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

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

You should read this prospectus and any accompanying prospectus supplement and the documents that we reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the front cover of this prospectus or such prospectus supplement only. Because the risk factors referred to above, as well as the risk factors referred to on page 4 of this prospectus and incorporated herein by reference, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

**USE OF PROCEEDS**

We estimate that the net proceeds of this offering will be approximately \$6.1 million. We expect to use the net proceeds received from this offering to fund our research and development activities and for working capital and general corporate purposes.

We cannot currently determine with absolute certainty how we will use the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering. We will pay all of the costs associated with registering the securities covered by this prospectus.

**DILUTION**

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Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of September 30, 2012.

Our pro forma net tangible book value at September 30, 2012 was \$8,737,385, or \$0.56 per share, after giving effect to the issuance and sale of 1,288,650 shares of common stock and 1,288,650 warrants in November and December 2012 by us in a private placement. After giving effect to the sale of 1,150,000 shares of common stock in this offering at an exercise price of \$5.32 per share, our pro forma as adjusted net tangible book value as of September 30, 2012 would have been \$14.9 million, or approximately \$0.89 per share of our common stock. This represents an immediate increase in net tangible book value of \$0.33 per share of common stock to our already existing stockholders and an immediate dilution in net tangible book value of \$4.43 per share of common stock to purchasers in this offering. The following table illustrates this per share dilution:

Public offering price per share		\$	5.32
Pro forma net tangible book value per share as of September 30, 2012	\$	0.56	
Increase per share attributable to this offering	\$	0.33	
Pro forma as adjusted net tangible book value per share as of September 30, 2012	\$	0.89	
Dilution per share to investors participating in this offering	\$	4.43	

Table of Contents

The above discussion and table are based on 15,469,376 shares of our common stock issued and outstanding as of September 30, 2012 on a pro forma basis giving effect to the issuance of 1,288,650 shares in November and December 2012 in a private placement and excludes the following:

- 99,583 shares of common stock issuable upon conversion of outstanding Series A Convertible Preferred Stock;
- 3,734,616 shares of our common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$4.71 per share as of January 29, 2013; and
- 6,989,237 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$3.96 per share as of January 29, 2013.

To the extent that any outstanding options or warrants are exercised, new options are issued under our 2004 Stock Option Plan, or we otherwise issue additional shares of common stock in the future, at a price less than the public offering price, there will be further dilution to new investors.

**PLAN OF DISTRIBUTION**

We will deliver shares of our common stock upon exercise of the warrants we issued in May 2012. As of the date of this prospectus, these warrants were exercisable for a total of 1,242,000 shares of our common stock, and no more of these warrants will be issued. We will not issue fractional shares upon exercise of these warrants. Each of these warrants contains instructions for exercise. In order to exercise any of these warrants, the holder must deliver to us or our transfer agent the information required in the warrants, along with payment for the exercise price of the shares to be purchased. We will then deliver shares of our common stock in the manner described below in the section titled *Description of Capital Stock May 2012 Warrants* and *Description of Capital Stock Underwriter Warrants*.

**DESCRIPTION OF CAPITAL STOCK**

**General**

As of December 31, 2012, our authorized capital stock consisted of 150,000,000 shares of common stock, \$0.0001 par value per share, and 20,000,000 shares of preferred stock, \$0.001 par value per share. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of January 29, 2013, there are 15,516,400 shares of our common stock issued and outstanding and 78,100 shares of Series A Convertible Preferred Stock are issued and outstanding.

**Common Stock**

Holders of our common stock are entitled to one vote per share. Our certificate of incorporation does not provide for cumulative voting. Holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds. However, the current policy of our board of directors is to retain earnings, if any, for the operation and expansion of the Company and, the consent of the holders of our Series A Convertible Preferred Stock is required for the payment of any such dividends on our common stock. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities and the liquidation preference of any outstanding Series A Convertible Preferred Stock. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

**Preferred Stock**

Our certificate of incorporation provides that our board of directors is authorized to provide for the issuance of shares of preferred stock in one or more series and, by filing a certificate of designations pursuant to the applicable law of the State of Delaware (hereinafter referred to as a Preferred Stock Designation ), to establish from time to time for each such series the number of shares to be included in each such series and to fix the designations, powers, rights and preferences of the shares of each such series, and the qualifications, limitations and restrictions thereof. The authority of the board of directors with respect to each series of Preferred Stock includes, but is not limited to, determination of the following:

Table of Contents

- the designation of the series, which may be by distinguishing number, letter or title;
- the number of shares of the series, which number the board of directors may thereafter (except where otherwise provided in the Preferred Stock Designation) increase or decrease (but not below the number of shares thereof then outstanding);
- whether dividends, if any, shall be paid, and, if paid, the date or dates upon which, or other times at which, such dividends shall be payable, whether such dividends shall be cumulative or noncumulative, the rate of such dividends (which may be variable) and the relative preference in payment of dividends of such series;
- the redemption provisions and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund or similar fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of our corporation;
- whether the shares of the series shall be convertible into shares of any other class or series, or any other security, of our corporation or any other corporation, and, if so, the specification of such other class or series of such other security, the conversion price or prices, or rate or rates, any adjustments thereto, the date or dates on which such shares shall be convertible and all other terms and conditions upon which such conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of shares of the series.

On July 13, 2005, we closed a private placement of 277,100 shares of Series A Convertible Preferred Stock (the Series A Convertible Preferred Stock ) and 64,442 warrants to certain investors for aggregate gross proceeds of \$2,771,000 pursuant to a Securities Purchase Agreement dated as of July 13, 2005. The warrants sold to the investors were immediately exercisable at \$19.50 per share and were exercisable at any time within five years from the date of issuance. These investor warrants had a fair value of \$567,085 on the date of issuance using a market price of \$14.40 on that date. In addition we paid an aggregate \$277,102 and issued an aggregate 17,572 warrants to purchase common stock to certain selling agents. The warrants issued to the selling agents are immediately exercisable at \$15.00 per share and will expire five years after issuance. The material terms of the Series A Convertible Preferred Stock consist of:

1) *Dividends.* Holders of the Series A Convertible Preferred Stock shall be entitled to receive cumulative dividends at the rate per share of 4% per annum, payable quarterly on March 31, June 30, September 30 and December 31, beginning with September 30, 2005. Dividends shall be payable, at our sole election, in cash or shares of common stock. As of December 31, 2011 and 2010, we had recorded \$152,960 and \$114,720, respectively, in accrued cumulative unpaid preferred stock dividends, included in Accrued Expenses in our consolidated balance sheets, and \$38,240 was recorded for each of the years ended December 31, 2011 and 2010.

2) *Voting Rights.* Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of the shares of Series A Convertible Preferred Stock then outstanding, (a) adversely change the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend our articles of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock, or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.

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- 3) *Liquidation.* Upon any liquidation, dissolution or winding-up of our company, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is equal to \$10 per share plus any accrued and unpaid dividends.
- 4) *Conversion Rights.* Each share of Series A Convertible Preferred Stock shall be convertible at the option of the holder into that number of shares of common stock determined by dividing the Stated Value, currently \$10 per share, by the conversion price, originally \$12.90 per share.
- 5) *Automatic Conversion.* Beginning July 13, 2006, if the price of the common stock equals \$25.80 per share for 20 consecutive trading days, and an average of 8,333 shares of common stock per day shall have been traded during the 20 trading days, we shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price

### Warrants

#### *May 2012 Warrants*

*Exercisability.* The warrants are exercisable beginning on June 4, 2012 and at any time up to the date that is five years from the date of issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Unless otherwise specified in the warrant, the holder will not have the right to exercise any portion of the



Table of Contents

warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

*Cashless Exercise.* In the event that a registration statement covering shares of common stock underlying the warrants, or an exemption from registration, is not available for the resale of such shares of common stock underlying the warrants, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. In no event shall we be required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of common stock underlying the warrants.

*Exercise Price.* The initial exercise price per share of common stock purchasable upon exercise of the warrants is \$5.32 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Certain Adjustments.* The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.

*Transferability.* Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to us together with the appropriate instruments of transfer.

*Fundamental Transaction.* If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a Fundamental Transaction, then upon any subsequent exercise of the warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of warrant shares then issuable upon exercise of the warrant, and any additional consideration payable as part of the Fundamental Transaction.

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

*Underwriter Warrants*

In connection with our May 2012 public offering, we issued to the underwriter, Aegis Capital Corp., the representative warrants to purchase up to a total of up to 92,000 shares of common stock. The warrants are exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing on May 29, 2013. The warrants are exercisable at \$7.00 per share. The warrants have been deemed compensation by FINRA and are therefore subject to a 180 day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative (or permitted assignees under Rule 5110(g)(1)) agreed to not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of the closing of the public offering. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from May 29, 2012 in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from May 29, 2012 in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock and warrants is Philadelphia Stock Transfer, Inc.

Table of Contents

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

*Delaware Law*

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

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

Section 203 defines a business combination to include:

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

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

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

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

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

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

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

Table of Contents

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

**LEGAL MATTERS**

The validity of the securities being offered hereby will be passed upon by Sichenzia Ross Friedman Ference LLP, New York, New York.

**EXPERTS**

The financial statements as of December 31, 2011 and 2010 and for the two years in the period ended December 31, 2011, and the period from August 4, 1999 (inception) to December 31, 2011 incorporated by reference in this prospectus have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

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

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read, without charge, and copy the documents we file at the SEC's public reference rooms in Washington, D.C. at 100 F Street, NE, Room 1580, Washington, DC 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our SEC filings are also available to the public at no cost from the SEC's website at <http://www.sec.gov>.

Table of Contents

**INCORPORATION OF DOCUMENTS BY REFERENCE**

This prospectus is part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. The Securities and Exchange Commission permits us to incorporate by reference the information contained in documents we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus. Information that is incorporated by reference is considered to be part of this prospectus and you should read it with the same care that you read this prospectus. Information that we file later with the Securities and Exchange Commission will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus, and will be considered to be a part of this prospectus from the date those documents are filed. We have filed with the Securities and Exchange Commission, and incorporate by reference in this prospectus:

- Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 30, 2012;
- Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2012, June 30, 2012 and September 30, 2012 filed on May 15, 2012, August 14, 2012 and November 14, 2012, respectively.
- Current Reports on Form 8-K (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed on January 6, 2012, February 3, 2012, February 15, 2012, April 16, 2012, May 1, 2012, August 15, 2012, November 28, 2012, December 11, 2012 and January 16, 2013; and
- The description of our common stock contained in our Form 8-A filed on May 23, 2012.

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the initial filing date of the registration statement of which this prospectus is a part until the offering of the particular securities covered by a prospectus supplement or term sheet has been completed. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

You may request, and we will provide you with, a copy of these filings, at no cost, by calling us at (858) 952-7570 or by writing to us at the following address:

Trovagene Inc.

11055 Flintkote Avenue, Suite B  
San Diego, CA 92121

Attn.: Corporate Secretary

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

We estimate that expenses payable by us in connection with the offering described in this registration statement will be as follows:

Nature of Expense	Amount
SEC registration fee	\$ 4,507.60
FINRA filing fee	\$ 4,33.33
NASDAQ initial listing fee	\$ 75,000
Accounting fees and expenses	\$ 250,000
Legal fees and expenses	\$ 90,000
Transfer agent s fees and expenses	\$ 65,000
Printing and related fees	\$ 3,000
Miscellaneous	\$ 18,059.07
<b>Total</b>	<b>\$ 510,000</b>

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

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses including attorneys' fees, judgments, fines and amounts paid in settlement in connection with various actions, suits or proceedings, whether civil, criminal, administrative or investigative other than an action by or in the right of the corporation, a derivative action, if they acted in good faith and in a manner they reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, if they had no reasonable cause to believe their conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses including attorneys' fees incurred in connection with the defense or settlement of such actions, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's certificate of incorporation, bylaws, agreement, a vote of stockholders or disinterested directors or otherwise.



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The Company's Certificate of Incorporation and By-Laws provide that it will indemnify and hold harmless, to the fullest extent permitted by Section 145 of the Delaware General Corporation Law, as amended from time to time, each person that such section grants us the power to indemnify.

The Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- payments of unlawful dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

The Company's Certificate of Incorporation and By-Laws provide that, to the fullest extent permitted by applicable law, none of our directors will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director. Any repeal or modification of this provision will be prospective only and will not adversely affect any limitation, right or protection of a director of our company existing at the time of such repeal or modification.

Table of Contents

**Item 16. Exhibits.**

(a) The following exhibits are filed as part of this Registration Statement:

**Exhibit  
Number**

**Description of Document**

a) Exhibits.

**Exhibit Number**

**Description of Document**

3.1	Amended and Restated Certificate of Incorporation of Trovogene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovogene, Inc. (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed March 20, 2012)
3.3	Bylaws of Trovogene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011)
5.1	Opinion of Sichenzia Ross Friedman Ference LLP as to the legality of the securities being registered.*
23.1	Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1).*
23.2	Consent of BDO USA, LLP**
24.1	Power of Attorney (included on signature pages to the registration statement).*

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\*Previously Filed

\*\*Filed herewith

Table of Contents

**Item 17. Undertakings.**

(a) The undersigned Registrant hereby undertakes:

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

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

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

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

*provided, however*, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) above 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 and Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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

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

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

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

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

Table of Contents

(5) That, for the purpose of determining liability of the Registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this Registration Statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the Registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in 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 deemed to be the initial bona fide offering thereof.

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

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### Table of Contents

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 Post-Effective Amendment No. 1 to Form S-1 on Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 30th day of January 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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ ANTONIUS SCHUH Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	January 30, 2013
/s/ * Stephen Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	January 30, 2013
/s/ * Thomas H. Adams	Chairman of the Board	January 30, 2013
/s/ * John Brancaccio	Director	January 30, 2013
/s/ * Gary S. Jacob	Director	January 30, 2013
/s/ * Gabriele M. Cerrone	Director	January 30, 2013
/s/ * Stanley Tennant	Director	January 30, 2013
Christopher McGuigan	Director	January 30, 2013

By: /s/ Antonius Schuh  
Antonius Schuh  
Attorney-in-Fact