Trovagene, Inc.
Form S-3
November 13, 2015
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As filed with the Securities and Exchange Commission on November 13, 2015

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-2004382**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11055 Flintkote Avenue, Suite B
San Diego, CA 92121

(858) 952-7570

(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) 952-7570

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

With copies to:

Jeffrey J. Fessler, Esq.

Sichenzia Ross Friedman Ference LLP

61 Broadway, 32nd Floor

New York, New York 10006

(212) 930-9700

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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.

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as determined by market conditions and other factors.

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

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. x

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. o

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. o

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

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

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 large accelerated filer , accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company
o	x	o (do not check if smaller reporting company)	o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, $0.0001 par value	100,000	$ 4.72(2)	$ 472,000	$ 47.53
Common Stock, $0.0001 par value per share issuable upon exercise of warrants	588,650	$ 5.32(3)	$ 3,131,618	$ 315.35
Total			3,603,618	$ 362.88

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration statement also covers such additional shares as may hereafter be offered or issued to prevent dilution resulting from stock splits, stock dividends, recapitalizations or certain other capital adjustments.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended. In accordance with Rule 457(c) of the Securities Act of 1933, as amended, the price shown is the average of the high and low sales prices of the common stock on November 9, 2015 as reported on The NASDAQ Capital Market.

(3) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(g) of the Securities Act of 1933 based on the exercise price of the warrants. Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(g) of the Securities Act of 1933 based on the exercise price of the warrants.

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 that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

Subject to completion, dated November 13, 2015

PROSPECTUS

TROVAGENE, INC.

688,650 Shares of Common Stock

This prospectus relates to the disposition from time to time of 100,000 shares of common stock and up to 588,650 shares of common stock which are issuable upon the exercise of warrants held by certain of the selling stockholders named in this prospectus. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders. We will, however, receive the net proceeds of any warrants exercised for cash.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section entitled Plan of Distribution on page 21. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or disposition of the shares, or interests therein. We will bear all costs, expenses and fees in connection with the registration of the shares. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is traded on The NASDAQ Capital Market under the symbol TROV. On November 12, 2015, the last reported sale price of our common stock was $5.13 per share.

An investment in our common stock involves a high degree of risk. See Risk Factors on page 6 of this prospectus for more information on these risks.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2015.

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OUR BUSINESS

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

We are a molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based cell-free molecular diagnostic technology for use in disease detection 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 the field of oncology, while our external focus includes entering into collaborations to develop our technology in areas such as infectious disease, transplant medicine, and prenatal genetics. Our goal is to improve treatment outcomes for cancer patients using our proprietary technology to detect and quantitatively monitor cell-free DNA in urine.

We are leveraging our proprietary molecular diagnostic technology for the detection of cell-free DNA originating from diseased cell death that can be isolated and detected from urine, blood, and tissue samples to improve disease management. These genetic materials are also collectively referred to as cell-free nucleic acids , which result when cells in the body die and release their DNA contents into the bloodstream. The circulating fragments of genetic material are eventually filtered through the kidneys and therefore, can be detected and measured in urine. Cell-free nucleic acids can be used as genetic markers of disease. As such, the contents of urine or blood samples represent systemic liquid biopsies that can allow for simple, non-invasive or minimally-invasive sample collection methods. Circulating tumor DNA (ctDNA) is a subtype of cell-free DNA, and represents the mutant cell free DNA that we use to detect and monitor cancer.

Our fundamental ctDNA diagnostic platform, also known as our Precision Cancer Monitoring℠ platform, (PCM) platform is protected by a strong intellectual property portfolio. We have developed significant intellectual property around cell-free nucleic acids in urine, the extraction of cell-free nucleic acids from urine, as well as novel assay designs, particularly our proprietary non-naturally occurring primers. Through this proprietary technology, we believe that we are at the forefront of a shift in the way diagnostic medicine is practiced, using simple, non-invasive or minimally invasive sampling and analysis of nucleic acids, which we believe will ultimately lead to more effective treatment monitoring, better management of serious illnesses such as cancer, and the ability to detect the recurrence of cancer earlier. As of June 30, 2015, our intellectual property portfolio consists of over 60 issued patents and over 55 pending patent applications globally. Our patent estate includes the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in field of oncology. Our PCM platform is designed to offer improved cancer monitoring by tracking and analyzing levels of cell-free DNA from either urine or blood samples, and is intended to provide important clinical information beyond the current standard of care. Using urine as a sample, our cancer monitoring technology enables more frequent, non-invasive monitoring of oncogene mutation status, disease progression and disease recurrence. Our research and development efforts were made commercially feasible following improved next-generation sequencing (NGS) technologies which are now available at a significantly lower cost. This combined with our extensive patent portfolio around cell-free DNA in urine gives us a competitive advantage to leverage an emerging trend toward monitoring cancer using cell-free DNA as a marker of disease status. Our proprietary sample preparation process forms the basis of our PCM platform. It includes novel technology for the extraction and isolation of ctDNA from either a urine or blood sample, proprietary non-naturally occurring primers to enrich the sample for mutant alleles, and the ability to sequence nucleic acids of interest using one of several leading gene sequencing technologies such as NGS or droplet digital PCR. We believe that our quantitative ctDNA detection and monitoring platform offers industry leading sensitivity, featuring single nucleic acid molecule

detection.

Our PCM platform is poised to overcome a significant clinical dilemma in the area of cancer treatment. Recent scientific evidence supports the molecular basis of cancer, and has resulted in a paradigm shift in the way cancer is treated. Researchers and clinicians are now focused on specific oncogene mutations that are believed to be the molecular drivers of cancer, and, as a result, there is a trend in the pharmaceutical research community toward developing targeted therapies. As such, there is a need for oncologists to have an ability to track the mutational status of their patients, including a given patient s response to treatments that are designed to target driver oncogene mutations. Current monitoring tools such as imaging procedures, tissue biopsy, and circulating tumor cells are insufficient to meet the challenge of monitoring oncogene mutations. Cancer imaging provides a rough indication of tumor size, but provides no information to oncologists regarding mutational status which is important for the use of molecular targeted therapies. Tissue biopsy usually involves a major surgical procedure and, in many cases, is not repeatable as there are limitations related to access for serial biopsies. In some cases, biopsies may not be feasible, significantly increasing the need to determine mutational status using an alternative method. In addition, tumor heterogeneity is important, as the surgeon may not obtain the proper tissue from the tumor sample. With circulating tumor cells, which are typically measured using blood tests, sensitivity is low, and such tests are technically difficult and can be expensive.

While an improvement over chemotherapy in many cases, targeted drug therapies are not without issues, such as their high cost and potential side effect. In order to measure effectiveness of these therapies, repeated monitoring is needed and imaging and serial biopsies have their challenges or may not be optimal. If resistance develops to a targeted cancer therapy, fast and accurate detection of emerging or changing oncogene mutations can provide critical information early. Our PCM platform provides a novel

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solution for early detection of cancer progression using urine, a non-invasive, plentiful sample source. We continue to build a growing body of evidence supporting the clinical utility of our technology to monitor cancer using ctDNA.

Our accumulated deficit through September 30, 2015 is $101,500,333. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and commercial expansion. During 2015, we have advanced our business with the following activities:

- We formed the Trovagene Research Institute in Europe with Alberto Bardelli, Ph.D., an internationally recognized leader in cell-free DNA cancer research, and currently affiliated with the Department of Oncology, Torino Medical School and the Candiolo Cancer Institute in Italy. We appointed Bardelli as the Scientific Director and transferred core technologies from University of Torino. Trovagene Research Institute intends to improve cancer care through advanced genomic solutions with the mission of accelerating adoption of our PCM platform in translational research and clinical applications.

- Clinical study results were presented by Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the 2015 European Lung Cancer Conference. In that study, our urinary ctDNA assay identified 100% of tissue biopsy confirmed *EGFR T790M* mutations (n=10) in metastatic lung cancer patients. Our assay also detected *T790M* mutations in three subjects that Dr. Husain speculated may have been tissue biopsy false negatives. In addition, data from the study suggest that our assay may be capable of detecting cancer progression earlier than standard imaging and may be useful in determining patient response to novel *EGFR T790M* inhibitors.

- Clinical study results from a second large-scale clinical trial for our urine-based HPV test were presented by Adriana Lorenzi, a research fellow at the Institute of Education and Research and Molecular Oncology Research Center, Barretos Cancer Hospital - Pio XII Foundation, Barretos, Brazil at the 30th International Papillomavirus Conference. In the trial, urine samples collected from women prior to treatment of cervical pre-cancer lesions (referral population) were tested with our HPV HR Test, and results were compared to Roche s cobas® HPV Test results from cervical samples. The trial results were consistent with previously reported Predictors 4 data, which demonstrated that sensitivity with our HPV HR Test for the detection of cervical intraepithelial neoplasia Grade Two or higher (CIN2+) and Grade Three or higher (CIN3+) were comparable to other established cervical screening tests. In the Brazilian cohort, 271 cases of CIN2+ and 202 cases of CIN3+ disease were tested.

- Clinical study results for our PCM platform were presented by Julia Johansen, M.D. at Herlev Hospital, Copenhagen, and Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the European Cancer Congress. Results demonstrated that quantitative detection and monitoring of ctDNA and driver mutations can be used to rapidly detect treatment response

- We completed an underwritten public offering of 4,600,000 shares of common stock with net proceeds of approximately $37.4 million in July 2015.

- We entered into a clinical collaboration with Memorial Sloan Kettering Cancer Center to monitor response to immunotherapy in melanoma patients using our PCM platform.

- We launched our Yellow Is The New Red marketing campaign for our PCM service at the 2015 American Society of Clinical Oncology Annual Meeting. The campaign is centered on our Clinical Experience Program, in which qualified oncologists can gain hands on clinical experience with the Company s proprietary urinary liquid biopsy tests.

- We completed an underwritten public offering of 5,111,110 shares of common stock with net proceeds of approximately $21.3 million in February 2015.

- We recruited Matthew Posard to our Executive Management Team as Chief Commercial Officer to lead our commercial operations.

- We entered into a clinical collaboration with University of California, San Diego Moores Cancer Center to determine the utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.

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- We entered into a clinical collaboration with City of Hope to conduct studies to determine the clinical utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.

- Two sets of clinical study results were presented at the 2015 Gastrointestinal Cancer Symposium supporting the potential utility of our PCM platform in colorectal and pancreatic cancer patients. Results demonstrated the ability of our PCM platform to detect and quantitate *KRAS* mutations at diagnosis and longitudinally in ctDNA obtained from colorectal and pancreatic cancer patients. We also showed data demonstrating that our proprietary *KRAS* assay may allow physicians to determine mutational status, monitor treatment response, and use genomics to aid in predicting patient prognosis.

- Two sets of clinical study results and one set of analytical data were presented at the 2015 American Association for Cancer Research (AACR) Annual Meeting that demonstrated potential clinical utilities and advantages of our PCM platform. Our liquid biopsy technology features single molecule sensitivity and the ability to obtain significantly more ctDNA from urine samples vs. plasma.

- Clinical results from the PREDICTORS 4 trial were presented by Jack Cuzick, Ph.D., Director, Wolfson Institute of Preventive Medicine and Head, Centre for Cancer Prevention at Queen Mary University of London at the European Research Organization on Genital Infection and Neoplasia 2015 Congress. Based on our analysis of more than 500 samples, the results showed high sensitivity (>90%) for our non-invasive, urine-based HPV assay for the detection of high-risk human papillomavirus (HPV) types and cervical intraepithelial neoplasia (CIN) Grade 2 or higher lesions.

- Clinical data from four studies utilizing our PCM platform were presented at the 2015 American Society of Clinical Oncology Annual Meeting in Chicago, IL. Results demonstrated that our PCM technology offers advantages over tissue biopsy and demonstrates the ability to monitor tumor dynamics in lung, pancreatic, and colon cancers.

Our product development and commercialization efforts are in their early stages, and we cannot make estimates of the costs or the time our development efforts will take to complete, or the timing and amount of revenues related to the sale of our tests and revenues related to our license agreements. The risk of completion of any program is high because of the many uncertainties involved in bringing new diagnostic products to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols and/or CLIA requirements, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses, and competing technologies being developed by organizations with significantly greater resources..

Corporate Information

On April 26, 2002, we were incorporated in the State of Florida. On July 2, 2004, we acquired Xenomics, a California corporation, which was in business to develop and commercialize urine-based molecular diagnostics technology. In 2007, we changed our fiscal year end from January 31 to December 31 and in January 2010, we re-domesticated our state of incorporation from Florida to Delaware and our name was changed to Trovagene, Inc. Our principal executive offices are located at 11055 Flintkote Avenue, Suite B, San Diego, CA 92121, and our telephone number is 858-952-7570. Our website address is www.trovagene.com. The information on our website is not part of this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website.

RISK FACTORS

You should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this prospectus, including our financial statements and related notes.

Risks Related to Our Business

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

We are a development stage company and have incurred losses since we were formed. As of September 30, 2015 and December 31, 2014, we have an accumulated total deficit of approximately $101.5 million and $81.4 million, respectively. For the nine months ended September 30, 2015 and the fiscal year ended December 31, 2014, we had a net loss and comprehensive loss attributable to common stockholders of approximately $20.1 million and $14.3 million, respectively. To date, we have experienced negative cash flow from development of our cell-free molecular diagnostic technology. We have not generated any revenue from operations except for

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licensing, milestone and royalty income and expect to incur substantial net losses for the foreseeable future to further develop and commercialize the cell-free molecular diagnostic technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from the cell-free molecular diagnostic technology or attain profitability, we will not be able to sustain operations.

Because of the numerous risks and uncertainties associated with developing and commercializing our cell-free molecular diagnostic 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 cell-free molecular diagnostic technology or any future tests, and our business may fail.

We will need to raise substantial additional capital to commercialize our cell-free molecular diagnostic 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 September 30, 2015, our cash balance was approximately $74.2 million and our working capital was approximately $67.8 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. This amount will be sufficient to launch our products in the marketplace currently under development as LDTs. We have historically relied upon private and public sales of our equity to fund our operations. We currently have a $15.0 million loan payable. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms.

Our Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

We have entered into a Loan and Security Agreement with Oxford and SVB for a term loan of $15 million. The term loan is secured by all of our assets, other than intellectual property. The Loan and Security Agreement contains affirmative and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness or guarantees;
- incur liens;

- make investments, loans and acquisitions;
- consolidate or merge;
- sell or assign any part of our business or property;
- engage in transactions with affiliates; and
- pay dividends.

The Loan and Security Agreement also includes events of default, including, among other things, payment defaults; breaches of representations, warranties or covenants; certain insolvency events; and the occurrence of certain material adverse changes. Upon the occurrence of an event of default and following any cure periods (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan and Security Agreement.

These terms of the Loan and Security Agreement could prevent us from taking certain actions without the consent of our lenders and, if an event of default should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Loan and Security Agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

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

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

Our business could be adversely impacted by adoption of new coding for molecular genetic tests.

If our technology were commercially available today, reimbursement would be available under the current procedural terminology, or CPT codes, for molecular-based testing. The American Medical Association CPT® Editorial Panel is continuing its process of establishing analyte specific billing codes to replace codes that describe procedures used in performing molecular testing. The adoption of analyte specific codes will allow payers to better determine tests being performed. This could lead to limited coverage decisions or payment denials.

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 and on our ability to successfully market our product candidates.

The use of the cell-free molecular diagnostic 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 cell-free molecular diagnostic technology, in which event we may be unable to generate significant revenue or become profitable. Acceptance of the cell-free molecular diagnostic technology will depend on a number of factors including:

- acceptance of products based upon the cell-free molecular diagnostic technology by physicians and patients;
- successful integration into clinical practice;
- adequate reimbursement by third parties;

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- cost effectiveness;
- potential advantages over alternative treatments; and
- relative convenience and ease of administration.

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

We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have limited experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other molecular diagnostic companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products, however, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

If our potential medical diagnostic tests are unable to compete effectively with current and future medical diagnostic tests targeting similar markets as our product candidates, 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 cell-free molecular diagnostic technology is under development, we cannot predict the relative competitive position of any product based upon the cell-free molecular diagnostic 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 cell-free 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 product candidates.

Our failure to obtain human urine samples from medical institutions for our clinical studies will adversely impact the development of our cell-free molecular diagnostic 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.

Cell-free nucleic acids in urine are stable at room temperature for extended periods of time with the addition of a simple preservative. Successful implementation of our cell-free nucleic acid technology in molecular testing is closely linked to the

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availability of techniques and procedures for cell-free nucleic acid preservation, purification, and analysis. In the event urine specimens are not adequately preserved, improperly stored, or contaminated, we may be delayed in pursuing our clinical studies, and we may incur additional costs associated with procuring new human urine samples.

If our clinical studies do not prove the superiority of our technologies and demonstrate clinical utility of our technology, we may never sell our product candidates and services.

The results of our clinical studies may not show that tests using our cell-free molecular diagnostic technology are superior to existing testing methods and demonstrate clinical utility. 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.

We have limited experience in establishing strong business relationships with leading clinical reference laboratories to perform cell-free molecular diagnostic tests using our technologies which could 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 cell-free molecular diagnostic tests. We have limited experience in establishing these business relationships. If we are unable to establish and maintain these business relationships, we will have limited ability to obtain revenues beyond the revenue we can generate from our limited in-house capacity to process tests.

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

Our success is largely dependent upon the continued contributions of our officers such as 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 56 full-time employees as of September 30, 2015. 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 cell-free molecular diagnostic technology. Our future financial performance and our ability to commercialize cell-free molecular diagnostic testsand 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 cell-free molecular diagnostic technology.

We may need FDA approval to market products based on the cell-free molecular diagnostic technology for diagnostic uses in the United States and approvals from foreign regulatory authorities to market products on the cell-free molecular diagnostic 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 cell-free molecular diagnostic technology, we will be unable to sell such product candidates 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 HR Detection test in Europe, we need to receive a

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CE Mark. If we do not obtain a CE Mark for our urine-based HPV HR Detection 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 studies of product candidates based on the cell-free molecular diagnostic 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 cell-free molecular diagnostic technology may require the submission of extensive preclinical and clinical data and supporting information to regulatory authorities to establish such product candidates 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 cell-free molecular diagnostic 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.

If we do not comply with governmental regulations applicable to our CLIA-certified laboratory, we may not be able to continue our operations.

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

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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (PPACA) has substantially changed the way health care is financed by both government health plans and private insurers. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our 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 studies, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA s exercise of this authority could result in delays or increased costs during product development, clinical studies and regulatory review, increased costs

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to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

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

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

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

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

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

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

Clinical laboratory tests like our current product offerings are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We expect that, upon the

commencement of commercialization, our product candidates will be an LDT and not a diagnostic kit. As a result, we believe that our product candidates should not be subject to regulation under current FDA policies, however there is no assurance that it will not be subject to such regulation in the future. Further, if we decide to market our products as a diagnostic kit rather than a LDT, our products would be subject to FDA regulation as a medical device. The container we expect to provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA regulation and while we expect that it will be exempt from pre-market review by FDA, there is no certainty in that respect.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our LDT product candidates, either through new policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law and may result in increased regulatory burdens for us to offer or continue to offer our product as a clinical laboratory service.

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

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We may be required to conduct clinical studies and we may find it difficult to enroll patients in such clinical studies, which could delay or prevent clinical studies of our product candidates.

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 and completion of clinical trials may be delayed by factors such as unforeseen safety issues, lack of effectiveness during clinical trials, inability to monitor patients adequately during or after testing, and slower than expected rates of patient recruitment.

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

In addition, in the event we are required to conduct clinical trials, it may be very expensive and difficult to design and implement due to the rigorous regulatory requirements to which clinical trials are subjected. Clinical trials are also time consuming, and we would be unable to provide certainty regarding when we might complete the clinical trial process.

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

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

Our currently pending or future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated or held unenforceable. We may not 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.

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

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

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

We cannot be certain of the level of protection, if any, which 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

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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 cell-free molecular diagnostic technology.

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

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

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

The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability and personal injury claims.

To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, our existing insurance may not be renewed by us at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our cash flow and thus potentially a materially adverse effect on

our business, financial condition and results of operations.

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

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

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

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

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Risks Related to Ownership of our Common Stock

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

If we fail to comply with the rules under the Sarbanes-Oxley Act 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.

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

Our certificate of incorporation gives our board of directors the right to create new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be utilized as a method of discouraging, delaying or preventing a change of control. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to issue any additional shares of preferred stock or to create any new series of preferred stock and the certificate of designation relating to the Series A Convertible Preferred Stock restricts our ability to issue additional series of preferred stock, we may issue such shares in the future. Without the consent of the holders of the outstanding shares of Series A Convertible Preferred Stock we may not alter or change adversely the rights of the holders of the Series A Convertible Preferred Stock or increase the number of authorized shares of Series A Convertible Preferred Stock, create a class of stock which is senior to or on a parity with the Series A Convertible Preferred Stock, amend our certificate of incorporation in breach of these provisions or agree to any of the foregoing.

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 ordinary shares historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. These fluctuations may be due 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;

- announcements or press releases relating to the industry or to our own business or prospects;

- coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;

- regulation and oversight of our product candidates and services, including by the FDA, CMS and comparable ex-U.S. agency;

- FDA, CMS and comparable ex-U.S. agency regulation and oversight of our products and services;

- the establishment of partnerships with clinical reference laboratories;

- health care legislation;

- intellectual property disputes;

- 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;

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- loss of any strategic relationship;
- industry developments;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

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

We may become subject to federal and state tax assessments, penalties and interest related to issues with respect to certain executive compensation.

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

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

As of September 30, 2015, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 20% 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. In addition, under the terms of our Loan and Security Agreement, we are precluded from paying cash dividends without the prior written consent of the lenders, and the terms of the Series A Convertible Preferred Stock prohibit us from paying dividends to the holders of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid. Investors in our common stock should not rely on an investment in our company if they require dividend income.

If securities or industry analysts do not publish research or reports about our business, or if they 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

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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 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.

We may be subject to stockholder litigation, thereby diverting our resources that may have a material effect on our profitability and results of operations.

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

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 6 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

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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

The net proceeds from any disposition of the shares covered hereby would be received by the selling stockholders. We will not receive any of the proceeds from any such sale of the common stock offered by this prospectus other than the net proceeds of any warrants exercised for cash.

SELLING STOCKHOLDERS

We have prepared this prospectus to allow the selling stockholders, to sell, from time to time, of 100,000 shares of common stock and up to 588,650 shares of our common stock underlying warrants. All of the common stock offered by this prospectus may be offered by the selling stockholders for their own account. We will receive no proceeds from any such sale of these shares by the selling stockholders. We will, however, receive the net proceeds of any warrants exercised for cash.

In the fourth quarter of 2012, we issued 1,105,000 units in a private placement with each unit consisting of one share of common stock and one warrant to purchase one share of common stock. The gross proceeds to us from the sale of the securities was approximately $4.4 million. The warrants expire five years from the date of issuance and are exercisable at $5.32 per share. We are registering for resale in this registration statement 648,650 shares of common stock issuable upon exercise of the warrants, which includes 183,650 shares of common stock are issuable upon exercise of warrants issued to selling agents in connection with the private placement.

Selling Stockholder Table

The following table sets forth information with respect to our common stock known to us to be beneficially owned by the selling stockholders as of September 30, 2015. To our knowledge, each of the selling stockholders have sole voting and investment power over the common stock listed in the table below. Except as otherwise disclosed herein, each selling stockholder, to our knowledge, has not had a material relationship with us during the three years immediately preceding the consummation of the private placement.

	Beneficial Ownership of Common Stock Prior to the Offering		Common Stock Saleable Pursuant	Beneficial Ownership of Common Stock After the Offering (1)	
Name of Selling Stockholder	**Number of Shares**	**Percent of Class (2)**	**to This Prospectus**	**Number of Shares**	**Percent of Class (2)**

Morris Silverman	100,000	*	100,000		
Corinne Levy-Laurent	40,000	*	40,000		
Howard I. Freedberg Revocable Trust (3)	408,333(4)	1.4	75,000	333,333	1.1
Alison Deighton	87,500	*	87,500		
Francesco Sidoli	125,000	*	125,000		
Salinas Strategic Healthcare SA (5)	480,167(6)	1.6	143,650	336,517	1.1
Forest Nominees Limited (7)	60,000(8)	*	30,000	30,000-	*
Mauro Moretti	7,500	*	7,500		
Mike Wilkins	40,000	*	40,000		
Panetta Partners Ltd. (9)	1,467,060(10)	4.9	40,000	1,427,060	4.7

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* Less than 1%

(1) Assumes that all of the shares held by the selling stockholder covered by this prospectus are sold and that the selling stockholder acquires no additional shares of common stock before the completion of this offering. However, as the selling stockholder can offer all, some, or none of its common stock, no definitive estimate can be given as to the number of shares that the selling stockholder will ultimately offer or sell under this prospectus.

(2) Calculated based on 29,722,810 shares of common stock outstanding as of September 30, 2015.

(3) Howard Freedberg is the trustee of the Howard I. Freedburg Revocable Trust and in such capacity holds voting and dispositive power over securities of the company held by such entity.

(4) Consists of 183,333 shares of common stock issuable upon exercise of warrants held by Mr. Freedberg and 225,000 shares of common stock issuable upon exercise of warrants held by the Howard I. Freedberg Revocable Trust

(5) Christo Mathys Britz is a director of Salinas Strategic Healthcare SA and in such capacity holds voting and dispositive power over securities of the company held by such entity.

(6) Consists of shares of common stock issuable upon exercise of warrants.

(7) Dennis Lavin is affiliated with Forest Nominees Limited and in such capacity holds voting and dispositive power over securities of the company held by such entity.

(8) Includes 30,000 shares of common stock

(9) Gabriele Cerrone is a member of the board of directors of Panetta Partners Ltd. and in such capacity holds voting and dispositive power over securities of the company held by such entity. Mr. Cerrone was a director of Trovagene, Inc. from February 2010 to July 2013.

(10) Consists of 287,416 shares of common stock issuable upon exercise of warrants and 1,179,644 shares of common stock held by Panetta Partners Ltd.

DESCRIPTION OF CAPITAL STOCK

General

As of September 30, 2015, 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 September 30, 2015, there are 29,722,810 shares of our common stock issued and outstanding and 60,600 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.

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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:

•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.

Warrants

In the fourth quarter of 2012, we sold 1,105,000 units of our securities to certain accredited investors at a per unit price of $4.00 with gross proceeds to us of approximately $4.4 million. Each unit sold consisted of (i) one share of our common stock and (ii) a five year warrant to purchase one share of common stock at a per share price of $5.32. The warrants are exercisable only on a cash basis. The exercise price of the

warrants is subject to adjustment to account for any stock splits, recapitalizations, mergers, combinations and asset sales, stock dividends, and similar events. .

Transfer Agent and Registrar

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

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 662/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

•any merger or consolidation involving the corporation and the interested stockholder;

•any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

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•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.

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

Disclosure of SEC Position on Indemnification for Securities Act Liabilities

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, officers and persons controlling our company, we understand that it is the SEC s opinion that such indemnification is against public policy as expressed in the Securities Act and may therefore be unenforceable.

PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell, transfer, or otherwise dispose of any or all of its shares of common stock on any stock exchange, market, or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;

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

- a combination of any such methods of sale.

The aggregate proceeds to the selling stockholders from any sale of the common stock offered by it will be the purchase price of the common stock less discounts or commissions, if any. The selling stockholders reserve the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We would not receive any of the proceeds from any such sale.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 promulgated under the Securities Act, provided that it meets the criteria and conform to the requirements of that rule.

The selling stockholders and any broker-dealers or agents that participate in the sale of the common stock may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. The selling stockholders are subject to the prospectus delivery requirements of the Securities Act.

LEGAL MATTERS

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

EXPERTS

The financial statements of Trovagene, Inc. as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014 and management s assessment of the effectiveness of internal control over financial reporting as of December 31, 2014 incorporated by reference in this Prospectus have been so incorporated in reliance upon the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in accounting and auditing.

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, which forms a part of the registration statement, does 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 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, or in New York, New York and Chicago, Illinois. 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.

INCORPORATION OF DOCUMENTS BY REFERENCE

We have filed a registration statement on Form S-3 with the Securities and Exchange Commission under the Securities Act. 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, 2014 filed on March 12, 2015;

- Quarterly Reports on Form 10-Q for (i) the quarterly period ended March 31, 2015 filed on May 5, 2015; (ii) the quarterly

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period ended June 30, 2015 filed on August 10, 2015; and (iii) the quarterly period ended September 30, 2015 filed on November 9, 2015;

- Current Reports on Form 8-K or Form 8-K/A (excluding any reports or portions thereof that are deemed to be furnished and not filed) filed on January 6, 2015, January 7, 2015, January 8, 2015, January 12, 2015, January 20, 2015, January 21, 2015, January 26, 2015, February 5, 2015, February 6, 2015, February 9, 2015, February 11, 2015, March 18, 2015, April 20, 2015, April 23, 2015, April 28, 2015, May 4, 2015, May 13, 2015, May 19, 2015, May 28, 2015, June 8, 2015, June 10, 2015, June 29, 2015, July 6, 2015, July 7, 2015, July 8, 2015, July 16, 2015, July 17, 2015, July 22, 2015, August 18, 2015, September 9, 2015, September 10, 2015, September 21, 2015, September 24, 2015, October 27, 2015 and November 6, 2015.

- our definitive proxy statement on Schedule 14A relating to a special meeting of stockholders filed on October 16, 2015;

- our definitive proxy statement on Schedule 14A relating to our 2015 annual meeting of stockholders filed on April 20, 2015; and

- the description of our common stock contained in the Registrant s Registration Statement on Form 8-A filed with the Commission on May 23, 2012.

You may request and obtain a copy of any of the filings incorporated herein by reference, at no cost, by writing or telephoning us at the following address or phone number:

Trovagene Inc.

11055 Flintkote Avenue, Suite B
San Diego, CA 92121

Attn.: Corporate Secretary

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth an estimate of the fees and expenses relating to the issuance and distribution of the securities being registered hereby, other than underwriting discounts and commissions, all of which shall be borne by Trovagene, Inc. (the Registrant or the Company). All of such fees and expenses, except for the SEC Registration Fee, are estimated:

SEC registration fee	$	362
Transfer agent s fees and expenses	$	2,000*
Legal fees and expenses	$	20,000*
Printing fees and expenses	$	2,500*
Accounting fees and expenses	$	10,000*
Miscellaneous fees and expenses	$	1,138*
Total	$	36,000

* Estimated

Item 15. Indemnification of Officers and Directors.

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

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

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Item 16. Exhibits.

a) Exhibits.

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company s Form 10-12G filed on November 25, 2011)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to the Company s Proxy Statement on Schedule 14A filed March 20, 2012)
3.3	Bylaws of Trovagene, 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).

* Filed herewith.

Item 17. Undertakings.

(a) The undersigned Registrant hereby undertakes:

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

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

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price

represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

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

provided, however, That:

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

B. Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 or Form F-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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(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:

(i) If the Registrant is relying on Rule 430B:

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

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

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

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

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

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Form S-3 to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 13th day of November 2015.

TROVAGENE, INC.

By: /s/ ANTONIUS SCHUH
Antonius Schuh
Chief Executive Officer and Director

By: /s/ STEPHEN ZANIBONI
Stephen Zaniboni
Chief Financial Officer

POWER OF ATTORNEY

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

Signature	Title	Date
/s/ ANTONIUS SCHUH Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	November 13, 2015
/s/ STEPHEN ZANIBONI Stephen Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	November 13, 2015
Thomas H. Adams	Chairman of the Board	November , 2015
/s/ JOHN P. BRANCACCIO John P. Brancaccio	Director	November 13, 2015
/s/ GARY S. JACOB Gary S. Jacob	Director	November 13, 2015

/s/ STANLEY N. TENNANT Stanley N. Tennant	Director	November 13, 2015
/s/ PAUL BILLINGS Paul Billings	Director	November 13, 2015
/s/ RODNEY S. MARKIN Rodney S. Markin	Director	November 13, 2015

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/s/ CARL FELDBAUM Carl Feldbaum	Director	November 13, 2015