Trovagene, Inc.
Form S-8
July 01, 2015
Table of Contents

As filed with the Securities and Exchange Commission on July 1, 2015

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Trovagene, Inc.

(Exact name of registrant as specified in its charter)

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

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

(Address of principal executive offices) (Zip Code)

2014 Equity Incentive Plan, as amended

(Full title of the plans)

Antonius Schuh

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

(Name and Address of agent for service)

(858) 952-7570

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

With a copy to:

Jeffrey Fessler, Esq.

Sichenzia Ross Friedman Ference LLP

61 Broadway, 32 nd Floor

New York, NY 10006

Phone (212) 930-9700

Fax (212) 930-9725

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

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o
	Smaller Reporting Company o	

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee

Common Stock, $.0001 par value	5,000,000(1)	$ 10.15(2)	$ 50,750,000	$ 5,897.15

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended (the Securities Act), this Registration Statement shall also cover any additional shares of the Registrant s common stock that become issuable under the Company s 2014 Equity Incentive Plan, as amended, by reason of any stock dividend, stock split, recapitalization or other similar transaction that increases the number of the outstanding shares of the Registrant s common stock.

(2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) of the Securities Act, using the last sale price reported on The NASDAQ Capital Market on June 30, 2015.

Table of Contents

EXPLANATORY NOTE

This registration statement on Form S-8 (the Registration Statement) relates to 5,000,000 shares of the common stock of Trovagene, Inc., a Delaware corporation (the Registrant, the Company, we, us or our), $0.0001 par value per share, which are issuable pursuant to, or upon exe of, options that may be granted under the Trovagene, Inc. 2014 Equity Incentive Plan, as amended (the Plan). Under the Plan, a total of 5,000,000 shares of common stock have been reserved for issuance.

This Registration Statement also includes a reoffer prospectus prepared in accordance with General Instruction C of Form S-8 and in accordance with the requirements of Part I of Form S-3, which may be utilized for reofferings and resales on a continuous or a delayed basis in the future related to the following:

- 447,668 shares of common stock (the Shares) which are issuable upon exercise of options that have been granted under the Plan, with respect to which the reoffer prospectus relates are being registered for reoffers and resales by certain stockholders listed (the Selling Stockholders), who are our officers and directors and may be deemed to be our affiliates , as defined in Rule 405 of the Securities Act. The Selling Stockholders may acquire the Shares upon exercise of options granted under the Plan. We do not know whether any of such Selling Stockholders will use this reoffer prospectus in connection with the offer or sale of the Shares, or, if this reoffer prospectus is so used, how many shares of common stock will be offered or sold. Such Selling Stockholders may resell all, a portion, or none of the shares that they may acquire pursuant to the Plan.

The reoffer prospectus does not contain all of the information included in the Registration Statement, certain items of which are contained in schedules and exhibits to the Registration Statement, as permitted by the rules and regulations of the Securities and Exchange Commission (the SEC or the Commission). Statements contained in this reoffer prospectus as to the contents of any agreement, instrument or other document referred to herein are not necessarily complete. With respect to each such agreement, instrument or other document filed as an exhibit to the Registration Statement, we refer you to the exhibit for a more complete description of the matter involved, and each such statement shall be deemed qualified in its entirety by this reference.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.

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

with Rule 428(b)(1) under the Securities Act.

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

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

Antonius Schuh

Trovagene, Inc.

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

Table of Contents

REOFFER PROSPECTUS

Trovagene, Inc.

447,668

Shares of

Common Stock

This reoffer prospectus relates to the sale of up to 447,668 shares of our common stock, $.0001 par value per share that may be offered and resold from time to time by existing selling stockholders identified in this prospectus for their own account issuable pursuant to the Trovagene, Inc. 2014 Equity Incentive Plan, as amended (the Plan). It is anticipated that the selling stockholders will offer common shares for sale from time to time in one or more transactions on The NASDAQ Capital Market, or such other stock market or exchange on which our common stock may be listed or quoted, in negotiated transactions or otherwise, at market prices prevailing at the time of the sale or at prices otherwise negotiated (see Plan of Distribution starting on page [ ] of this prospectus). We will receive no part of the proceeds from sales made under this reoffer prospectus. The selling stockholders will bear all sales commissions and similar expenses. Any other expenses incurred by us in connection with the registration and offering and not borne by the selling stockholders will be borne by us.

The shares of common stock are issuable upon the exercise of outstanding options that have been issued pursuant to the Plan.

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

Investing in our common stock involves risks. See Risk Factors beginning on page 7 of this reoffer prospectus. These are speculative securities.

Our common stock is quoted on The NASDAQ Capital Market under the symbol TROV and the last reported sale price of our common stock on June 30, 2015 was $10.15 share.

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

The date of this prospectus is July 1, 2015

Table of Contents

TROVAGENE, INC.

TABLE OF CONTENTS

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

Table of Contents

PROSPECTUS SUMMARY

We are a 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 MonitoringSM 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 March 31, 2015, our intellectual property portfolio consists of over 50 issued patents and over 60 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 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.

Table of Contents

Our accumulated deficit through March 31, 2015 is $88,572,351. 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 closed an underwritten public offering of 5,111,110 shares of common stock with net proceeds of approximately $21.3 million.

- 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.

- 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 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 can enable physicians to determine mutational status, monitor treatment response, and use genomics to aid in predicting patient prognosis.

- 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. Results demonstrated that our urinary ctDNA assay outperformed tissue biopsy in a clinical study for the detection of *EGFR T790M* mutations in metastatic lung cancer patients. In addition, the study demonstrated that our non-invasive liquid biopsy enables detection of emerging *T790M* mutations with greater sensitivity than tissue biopsy and months before detection of cancer progression with imaging. We also showed that tracking ctDNA in urine enables determination of response to novel *EGFR T790M* inhibitors within days of initial treatment.

- 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 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 dor Cancer Prevention at Queen Mary University of London at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) 2015 Contress. Results demonstrated high sensitivity for our non-invasive, urine-based HPV assay when determining high-risk human papillomavirus (HPV) types and cervical lesions or cervical intraepithelial neoplasia (CIN) Grade 2/3.

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.

Table of Contents

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 March 31, 2015 and December 31, 2014, we have an accumulated total deficit of approximately $88.6 million and $81.4 million, respectively. For the three months ended March 31, 2015 and the fiscal year ended December 31, 2014, we had a net loss and comprehensive loss attributable to common stockholders of approximately $7.2 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 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 March 31, 2015, our cash balance was approximately $44.0 million and our working capital was approximately $39.2 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;

Table of Contents

- 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.

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.

Table of Contents

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;
- 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 tests for 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.

Table of Contents

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 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.

Table of Contents

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

Our success is largely dependent upon the continued contributions of our officers such as 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 47 full-time employees as of June 16, 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 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.

Table of Contents

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, insura