

Trovogene, Inc.
Form S-8
August 06, 2013
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As filed with the Securities and Exchange Commission on August 6, 2013

Registration No.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-8

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Trovogene, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

(Address of principal executive offices) (Zip Code)

2004 Stock Option Plan

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(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

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

CALCULATION OF REGISTRATION FEE

Title 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, \$.0001 par value	6,000,000(2) \$	9.84(3) \$	59,040,000 \$	8,053.06

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

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

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

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS

Item 1. Plan Information.

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

Item 2. Registrant Information and Employee Plan Annual Information.

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

Antonius Schuh

1055 Flintkote Avenue, Suite B

San Diego, CA 92121

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REOFFER PROSPECTUS

Trovogene, Inc.

3,769,045 Shares of

Common Stock

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

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

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

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

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

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

The date of this prospectus is August 6, 2013

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TROVAGENE, INC.

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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.

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PROSPECTUS SUMMARY

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

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

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

Corporate Information

We were incorporated in the State of Florida on April 26, 2002 under the name Used Kar Parts, Inc. Our name was changed to Trovogene, Inc. and we redomesticated our state of incorporation from Florida to Delaware in January 2010. Our principal executive offices are located at 11055 Flintkote Avenue, Suite B, San Diego, CA 92121, and our telephone number is 858-952-7570. Our website address is www.trovogene.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.

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RISK FACTORS

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

Risks Related to Our Business

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

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

Because of the numerous risks and uncertainties associated with developing and commercializing our transrenal molecular technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our common stock. An investor in our common stock must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize transrenal molecular technology or any future tests, and our business may fail.

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

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

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

As of December 31, 2012 and March 31, 2013 our cash balance was approximately \$10.8 million and \$9.1 million, respectively, and our working capital was approximately \$10.3 million and \$8.2 million, respectively. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. We have historically relied upon private sales of our equity and issuances of notes to fund our operations. We currently have no credit facility or committed sources of capital. During the next 12 months, we will have to raise additional funds to continue the development and commercialization of our transrenal molecular technology. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms.

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

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

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Reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that our product candidates are:

- not experimental or investigational;
- effective;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our success is largely dependent upon the continued contributions of our officers such as our current key employee, Dr. Antonius Schuh, Chief Executive Officer. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire, or engage as consultants, additional personnel with specialized experience in a number of disciplines, including assay development, bioinformatics and statistics, laboratory and clinical operations, clinical affairs and studies, government regulation, sales and marketing, billing and reimbursement and information systems. There is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any future tests could be delayed or negatively impacted.

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

We are a small company with 13 full-time employees as of August 5, 2013. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of transrenal molecular technology. Our future financial performance and our ability to commercialize TrDNA and TrRNA assays and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical studies effectively;
- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

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

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

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

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

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

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

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

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

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

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new

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

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

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition to our patents, we rely on contractual restrictions to protect our proprietary technology. We require our employees and third parties to sign confidentiality agreements and employees to also sign agreements assigning to us all intellectual property arising from their work for us. Nevertheless, we cannot guarantee that these measures will be effective in protecting our intellectual property rights.

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

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

We cannot rely solely on our current patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent offices use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same and are not always applied predictably or uniformly and can change, particularly as new technologies develop. As such, the degree of patent protection obtained in the

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U.S. may differ substantially from that obtained in various foreign countries. In some instances, patents have been issued in the U.S. while substantially less or no protection has been obtained in Europe or other countries.

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

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

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in