

Trovogene, Inc.
Form 10-K
March 17, 2014
[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 000-54556

TROVAGENE INC.

(Name of small business issuer in its charter)

Edgar Filing: Trovagene, Inc. - Form 10-K

Delaware
(State or other jurisdiction of
incorporation or organization)

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

11055 Flintkote Avenue, Suite A, San Diego, California 92121

(Address of principal executive offices) (Zip Code)

Issuer's telephone Number: **(858) 952-7570**

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Units, each consisting of two shares of Common Stock and one Warrant to purchase one share of Common Stock	The NASDAQ Capital Market
Common Stock, \$0.0001 par value	The NASDAQ Capital Market
Warrants to purchase Common Stock	The NASDAQ Capital Market

Securities registered under Section 12(g) of the Exchange Act: **None.**

Indicate by check mark if the issuer is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes No

Indicate by check if the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if no disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Edgar Filing: Trovogene, Inc. - Form 10-K

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates (based on a closing sale price of \$6.99 per share which was the last sale price of the common stock as of June 28, 2013) was \$100,377,714.

As of March 13, 2014, the issuer had 18,902,991 outstanding shares of Common Stock.

Table of Contents

TABLE OF CONTENTS

		Page
	<u>PART I</u>	
<u>Item 1.</u>	<u>Business</u>	3
<u>Item 1A.</u>	<u>Risk Factors</u>	3
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	24
<u>Item 2.</u>	<u>Properties</u>	38
<u>Item 3.</u>	<u>Legal Proceedings</u>	38
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	39
	<u>PART II</u>	
<u>Item 5.</u>	<u>Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	40
<u>Item 6.</u>	<u>Selected Financial Data</u>	40
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	42
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	42
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	52
<u>Item 9.</u>	<u>Changes In and Disagreements with Accountants on Accounting and Financial Disclosure</u>	53
<u>Item 9A.</u>	<u>Controls and Procedures</u>	53
<u>Item 9B.</u>	<u>Other Information</u>	55
	<u>PART III</u>	
<u>Item 10.</u>	<u>Directors, Executive Officers, and Corporate Governance</u>	55
<u>Item 11.</u>	<u>Executive Compensation</u>	59
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	66
<u>Item 13.</u>	<u>Certain Relationship and Related Transactions, and Director Independence</u>	67
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	67
<u>Item 15.</u>	<u>Exhibits</u>	67
<u>SIGNATURES</u>		70

Table of Contents

PART I

ITEM 1. BUSINESS

We are a development stage molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based 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 license agreements or collaborations to develop our technology in areas such as infectious disease, transplant medicine, and prenatal genetics.

We are leveraging our proprietary urine-based molecular diagnostic technology for the detection of cell-free DNA and RNA originating from diseased cell death that can be isolated from urine and detected 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 or RNA 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 the urine represent a systemic liquid biopsy and allow for a simple, non-invasive sample collection method.

Our fundamental urine-based molecular diagnostic 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 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 February 28, 2014, our property portfolio consists of over 130 issued patents and over 47 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 our proprietary urine-based molecular diagnostic technology is uniquely positioned to address a high unmet clinical need in field of oncology. Our molecular diagnostic platform is designed to offer better cancer monitoring by tracking and analyzing levels of cell-free DNA in urine 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 extensive research and development efforts were strengthened due to investments to expand our intellectual property portfolio and were made commercially feasible following improved polymerase chain reaction (PCR) and 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 urine-based molecular diagnostic technology 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 drivers of cancer at the molecular level, 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

Table of Contents

response to treatments 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. Imaging only provides a rough indication of tumor size, and is an important tool for surgeons, but provides little practical advice to oncologists regarding mutational status and appropriate treatment options, especially for 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 available, 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. In the case of circulating tumor cells, which are typically measured using blood tests, there is very low sensitivity, and such tests are technically difficult and can be expensive. Targeted therapies themselves are not without issues. Targeted therapies are typically very expensive and can have significant side effects. In order to measure effectiveness, repeated monitoring is needed and serial biopsies can be difficult to obtain. If resistance develops, fast and accurate detection of emerging or changing oncogene mutations is critical. Our molecular diagnostic platform provides a novel solution using urine, a non-invasive, plentiful sample source, and we are continuing to build a growing body of evidence supporting the clinical utility of our technology to monitor cancer using cell-free DNA.

Our goal is to improve treatment outcomes for cancer patients using our proprietary technology to detect and quantitatively monitor cell-free DNA in urine.

Developing a Market for Molecular Diagnostic Tests based on Cell-free DNA in Urine

We intend to develop and expand our urine-based molecular diagnostic technology into a pipeline of potentially groundbreaking commercial molecular detection and monitoring products. Our Clinical Laboratory Improvement Amendments (CLIA)-certified, College of American Pathologists (CAP)-accredited laboratory in San Diego will enable us to initially commercialize our testing services and launch our platform technology and associated innovative molecular monitoring tests. Urine-based cell-free molecular diagnostics can provide relevant information across multiple therapeutic and clinical areas, and may lead to improvements in patient management. We are focused on the oncology treatment market, and the opportunity to enable clinicians to track oncogene mutational status in cancer patients. Repeat testing is expected with most cancer patients, and there also exists a need to chronically monitor for the re-emergence of oncogenes in people that are cancer survivors.

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

Targeting cell-free nucleic acid markers will allow for the development of genetic tests that use non-invasive and easy-to-obtain urine samples, rather than other more traditional, more invasive methods. These methods include imaging, blood testing, and bone marrow and tissue biopsies. We are exploring a broad range of clinical utilities where cell-free nucleic acid technology holds the potential to replace more complex, less robust existing technologies, which are based on circulating cells and nucleic acids in blood. We are developing more effective, non-invasive diagnostics, which align with the current industry shift toward highly personalized medicine. Urine-based cell-free nucleic acid molecular tests can make it easier to address important health problems, and may lead to significant advancements in patient care.

Table of Contents

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

The material terms of clinical collaboration, research and development, and technology license agreements that we have entered into are as follows:

In December 2013, the Company entered into a Clinical Trial Agreement with US Oncology Research LLC (USOR), pursuant to which USOR will provide the principal investigator and conduct the clinical trial related to examining the utility of transrenal quantitative KRAS testing to monitor disease in patients with metastatic pancreatic cancer. Under the agreement, the Company is committed to pay USOR approximately \$270,000 for services provided. During the year ended December 31, 2013 the Company has incurred and recorded approximately \$29,000 of research and development expense related to this agreement.

In August 2013, we entered into a Clinical Trial Agreement with the University of Southern California (USC), pursuant to which USC will provide the principal investigator and conduct the clinical trial related to the genetic characterization of metastatic colorectal cancers. Under the agreement, we are committed to pay USC approximately \$232,000 for services provided. During the year ended December 31, 2013, we did not incur any expense related to this agreement.

In June 2013, we entered into a Research Agreement with Illumina, Inc. pursuant to which the parties will work together to evaluate the potential for integrating our transrenal technology for isolating, extracting, and analyzing of nucleic acids from urine with Illumina's genetic analysis sequencing technology. The parties have agreed to share all results and reagents from the Research Plan. The agreement will terminate upon the earlier of 30 days after completion of the Research Plan or the one year anniversary of the agreement unless extended by mutual written agreement.

In April 2013, we entered into a Research and Development Agreement with PerkinElmer Health Sciences, Inc. (PerkinElmer) pursuant to which we will design an assay, based on our urine-based cell-free molecular diagnostic technology, to determine the risk for developing hepatocellular carcinoma. In addition, we have granted PerkinElmer an exclusive option (the HCC Option) to obtain an exclusive royalty-bearing license to use our technology within the hepatocellular carcinoma field (the HCC Field) as well as other fields. Together with Perkin Elmer we will jointly validate the assay and evaluate the potential of combining our urine-based cell-free molecular diagnostic technology with PerkinElmer's technology for automation of nucleic acid isolation. PerkinElmer will pay us milestone payments. We recognize milestone payments received from PerkinElmer as a reduction in research and development costs as the services are performed. Amounts received in advance of services performed are recorded as accrued liabilities until the services for which the payment has been received have been performed. We have received milestone payments related to this agreement of approximately \$90,000 and incurred approximately \$63,000 of research and development costs during the year ended December 31, 2013.

During 2012, we entered into research agreements with University of Texas MD Anderson Cancer Center (MDACC) to provide samples and evaluate methods used by us to identify pancreatic cancer mutations, as well as to measure the degree of concordance between the results of cell-free DNA mutation analysis from urine samples and tumor tissue. An amendment in 2013 increased the scope of the research agreements. We have committed to pay approximately \$266,000 for the services performed by MDACC. As of December 31, 2013 we have incurred and

Edgar Filing: Trovogene, Inc. - Form 10-K

recorded approximately \$142,000 of research and development expenses related to this agreement. There were no expenses incurred during the year ended December 31, 2012.

Table of Contents

In December 2012, we entered into a sublicense agreement with Genoptix, Inc. for non-exclusive worldwide rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, we have granted a license to certain NPM1 patents in exchange for a one time license fee of \$100,000 due upon execution of the agreement and royalty payments on net revenues. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, we have recorded royalty and license fee revenues of approximately \$10,000, \$100,000, and \$110,000 respectively.

In November 2012, we entered into a sublicense agreement with Duke University and Duke University Health Systems for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, we have granted a license to certain NPM1 patents in exchange for a one time license fee of \$5,000 due upon execution of the agreement and royalty payments on net revenues. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, we have recorded \$0, \$5,000, and \$5,000, respectively, of royalty and license fee revenues related to this agreement.

In September 2012, we entered into a collaboration and license agreement with Strand Life Sciences related to the validation and commercial launch of a urine-based DNA test for Human Papillomavirus (HPV). Under this agreement, we have granted a license for use of our tests to Strand in exchange for royalty payments on net sales earned in the territory specified in the agreement. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, no royalties or license fees had been received under this agreement.

Also in September 2012, we entered into a sublicense agreement with Quest Diagnostics for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, we have granted a license to certain NPM1 patents in exchange for a one time license fee of \$20,000 due upon execution of the agreement and royalty payments on net sales of Quest Diagnostics and its affiliates. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license revenues of approximately \$14,000, \$20,000 and \$34,000, respectively.

In December 2011, we entered into an exclusive license agreement with Columbia University to license the patent rights to hairy cell leukemia biomarkers. In consideration of the license we paid \$1,000 as an upfront license fee and agreed to make royalty payments as a single digit percentage of net sales if sales are made by us or a single digit royalty rate as a percentage on sublicense income received by us if sales are made by sublicensees. The license agreement shall continue until May 10, 2021, which is the date of the last to expire of the licensed patent rights covering the license product. The license agreement may also be terminated upon a material breach by any party or by us if we determine that it is not commercially or scientifically appropriate to further develop the license product rights. For the years ended December 31, 2013, 2012 and 2011, and from inception (August 4, 1999) to December 31, 2013, there has been no royalty expense recorded related to this agreement.

In October 2011, we entered into an exclusive license agreement with Gianluca Gaidano, Robert Foa and Davide Rossi for the patent rights to a specific gene mutation with respect to chronic lymphoblastic leukemia (CLL). In consideration of the license, we paid \$1,000 as an upfront license fee and agreed to make royalty payments as a single digit percentage of net sales if sales are made by us or a single digit royalty rate as a percentage of sublicense income received by us if sales are made by sublicensees. We have an option to purchase the licensed patent rights in the event the licensor decides to sell such licensed patent rights. The

Table of Contents

license agreement shall continue until September 29, 2031, which is the date of the last to expire of the licensed patent rights covering the license product. The license agreement may also be terminated upon a material breach by any party or by us if it is determined that it is not commercially or scientifically appropriate to further develop the license product rights. For the years ended December 31, 2013, 2012 and 2011, and from inception (August 4, 1999) to December 31, 2013, there has been no royalty expense recorded related to this agreement.

In July 2011, we entered into a sublicense agreement with Fairview Health Services (Fairview) for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Fairview paid an initial license fee of \$10,000 upon execution of the agreement and will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. Fairview is obligated to pay a royalty with annual minimums of \$1,000 each year. During the years ended December 31, 2013, 2012 and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license fee revenues of approximately \$1,000, \$2,000, \$10,000 and \$13,000, respectively.

In February 2011, we entered into a sublicense agreement with MLL Münchner Leukämielabor (MLL) for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. MLL paid an initial license fee of \$20,000 upon execution of the agreement and will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. MLL is obligated to pay a royalty with annual minimums of \$15,000 for the first year and \$20,000 thereafter. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license fee revenues of approximately \$85,000, \$71,000, \$35,000 and \$191,000, respectively.

In January 2011, we entered into an asset purchase agreement with TTFactor S.r.l. for a hybridoma able to produce a monoclonal antibody targeting the NPM1 biomarker for \$10,000. In addition we agreed to pay the seller of the hybridoma for a period of seven years commencing with the first sale of the antibody, annual royalties on a country by country basis. In addition, we agreed to pay a percentage of all cash consideration received from licensees as an upfront license fee pursuant to any licenses of the product and a percentage of all cash consideration received from licensees as milestone payments. This agreement was terminated in 2013. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, there were no royalty expense, license fee or milestone payments recorded related to this agreement.

In June 2010, we signed a sublicensing agreement with Skyline Diagnostics BV for the non-exclusive rights to develop, commercialize and market, research and diagnostic laboratory services for the stratification and monitoring of patients with AML. Skyline Diagnostics BV paid an initial licensing fee of \$10,000 upon execution of the agreement and may make future payments to us upon the attainment of certain regulatory and commercial milestones. Skyline Diagnostics BV will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license revenues of approximately \$0, \$0, \$20,000 and \$40,000, respectively. During those same periods, we did not record any license fee expenses.

In December 2008, we signed a sublicensing agreement with InVivoScribe Technologies, Inc. for the non-exclusive rights to develop and market lab testing services for NPM1 for the diagnosis and monitoring of patients with AML. InVivoScribe Technologies paid an initial licensing fee of \$10,000 upon execution of the agreement. InVivoScribe Technologies will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of

Table of Contents

expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty revenues of approximately \$25,000, \$27,000, \$20,000 and \$100,000, respectively. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we did not record any license fee expenses.

In October 2008, we signed a licensing agreement with Sequenom, Inc. for the rights to three patents for the methods for detection of nucleic acid sequences in urine. Sequenom paid an initial licensing fee of \$1 million upon execution of the agreement. Sequenom also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. As the agreement was terminated in March 2011, there were no revenues related to the agreement for the year ended December 31, 2013 and 2012. During the year ended December 31, 2011, we recorded royalty revenues of approximately \$40,000. From inception (August 4, 1999) to December 31, 2013, we recorded royalty and license fee revenues of approximately \$1,179,000. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we have not recorded any license fee expenses.

In August 2008, we signed a sublicensing agreement with LabCorp for the non-exclusive rights to develop and market lab testing services for NPM1, for the diagnosis and monitoring of patients with AML. LabCorp paid an initial licensing fee of \$20,000 upon execution of the agreement. LabCorp will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends August 25, 2018. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license fee revenues of approximately \$20,000, \$5,000, and \$20,000, and \$92,000, respectively. During the years ended December 31, 2013, 2012 and 2011, and from inception (August 4, 1999) to December 31, 2013, we did not record any license fee expenses.

In January 2008, we signed a sublicensing agreement with Warnex Medical Laboratories for the non-exclusive rights to develop and market lab testing services for nucleophosmin protein (NPM1), for the diagnosis and monitoring of patients with AML. Warnex Medical Laboratories will pay us a royalty on any net revenues during the term of the agreement. We did not receive any royalty and license fee revenues nor record any license fee expenses in connection with this license agreement. Warnex Medical Laboratories sold off its laboratory business in 2013 and this agreement has been cancelled.

In October 2007, we signed a sublicensing agreement with ASURAGEN, Inc. for the co-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification and monitoring of patients with AML. ASURAGEN paid an initial licensing fee of \$120,000 upon execution of the agreement and may make future payments to us upon the attainment of certain regulatory and commercial milestones. ASURAGEN will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012 and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty and license fee revenues of approximately \$50,000, \$50,000, and \$50,000, and \$455,000, respectively. During the years ended December 31, 2013, 2012, and 2011 we had no license fee expenses related to this agreement, and from inception (August 4, 1999) to December 31, 2013, we recorded license fee expenses of approximately \$16,000. In March 2007, we signed amendment No. 2 to the co-exclusive sublicense agreement with ASURAGEN. The amendment limited the field of use to research use only (RUO) kits. ASURAGEN was also granted a non-exclusive sublicense for NPM1 laboratory testing services.

During August 2007, we signed a sublicensing agreement with IPSOGEN SAS, a leading molecular diagnostics company with operations in France and the United States for the co-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification and monitoring of patients with AML. Upon execution of this agreement, IPSOGEN paid an initial licensing fee of \$120,000 and may make

Table of Contents

milestone payments upon the attainment of certain regulatory and commercial milestones. IPSOGEN will also pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty, milestone and license fee revenues of approximately \$60,000, \$180,000, and \$50,000, and \$487,000, respectively. We had no license fee expense during the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded license fee expenses of approximately \$4,000.

In May 2006, we entered into a license agreement with Drs. Falini and Mecucci, wherein we obtained the exclusive rights for the genetic marker for AML, and the intention to utilize these rights for the development of new diagnostic tools. In connection with this agreement, we paid \$70,000 to Drs. Falini and Mecucci and are obligated to pay royalties of 6% on royalty revenues and/or 10% of any sublicense income. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, we recorded royalty expenses of approximately \$30,000, \$24,000, \$15,000, and \$87,000 respectively.

Additionally, we paid \$100,000 and issued warrants for the purchase of 16,667 shares of common stock at \$10.80 per share as a finder's fee to an independent third party. These warrants had a value of \$101,131 on the date of issuance utilizing the Black-Scholes model and they expire June 29, 2014. All such payments and the value of the warrants were immediately expensed as research and development expenses.

History

On April 26, 2002, we were incorporated in the State of Florida as Used Kar Parts, Inc. On July 2, 2004, we acquired Xenomics, a California corporation, which was in business to develop and commercialize urine-based molecular diagnostics technology. As part of the acquisition, our corporate name was changed to Xenomics, Inc. (Xenomics). In 2007, we changed our fiscal year end from January 31 to December 31. In January 2010, we re-domesticated our state of incorporation from Florida to Delaware and our name was changed to Trovogene, Inc. In June 2012, our common stock was listed on The NASDAQ Capital Market under the ticker symbol TROV.

The Basis for Our Urine-based Molecular Diagnostic Technology

Cell-free nucleic acids have been found in a variety of human bodily fluids, with the nucleic acids isolated from urine having been extensively characterized. Cell-free nucleic acids in urine have been proven to contain mutated DNA and other markers of disease, including microRNA. In contrast to other bodily fluids (e.g. blood plasma), urine allows for truly non-invasive collection of the sample, provides a larger sample size, and allows for frequent collection. Importantly, urine enables the collection of nucleic acid material from the systemic circulation over a period of time, and those DNA and RNA fragments remain stable in urine. These factors, combined with recently developed technologies to sequence, count, and track nucleic acids with low relative abundance, make the development of these non-invasive diagnostics commercially practical and scalable.

In the human body, about 10¹¹ - 10¹² cells die each day primarily as a consequence of natural physiological processes for tissue and organ maintenance, but also as a result of disease. Together, these dead and dying cells contain more than 1 gram of DNA, which is mostly degraded into short fragments by specific enzymes. A small proportion of these cell-free nucleic acids escapes complete degradation and appear in the bloodstream. Our scientists were the first to discover that circulating cell-free nucleic acids cross the kidney barrier and can be found in the urine

as transrenal nucleic acids (TrNA). This simple yet remarkable

Table of Contents

discovery that genetic information from various cells throughout the body is present in urine enabled the development of new, non-invasive techniques for molecular diagnostics and genetic testing.

To unlock the full potential of cell-free nucleic acids, we have developed a proprietary method for the isolation of the short fragmented nucleic acids that pass through the kidneys, and proprietary ultra-short amplicon assays necessary for the efficient detection of cell-free nucleic acids, which can be analyzed at our San Diego-based CLIA laboratory.

Because of the small size of cell-free nucleic acids in urine, having an isolation method that efficiently captures short nucleic acids is critical. We have multiple methods (patents pending) for the isolation of nucleic acids from bodily fluids, including urine. Many nucleic acid isolation methods are not suited for isolation of cell-free nucleic acids in urine. For example, many DNA isolation kits only capture DNA greater than 200 base-pairs (bp) in length, with a few claiming 100 bp or longer. No manufacturer states that their product is suitable to capture DNA shorter than 80 bp in length.

When compared to leading kits for the isolation of DNA from bodily fluids, we have observed by conducting internal studies that our method is three to twenty times more efficient in isolating a 50 bp target. Our method is also suitable for the isolation of RNA, including miRNAs.

Paired with our cell-free nucleic acid isolation method, is our technology for detecting ultra-short amplicons (patents pending). By combining our proprietary nucleic acid isolation method with our ultra-short amplicon assays, we are able to detect at least six times more mutations in a urine-based cell-free DNA sample than any other PCR-based assay, according to our internal test data. We believe that these methods are also applicable to other small or fragmented nucleic acids, including cell-free DNA from blood and formalin-fixed, paraffin-embedded (FFPE) samples.

Determining DNA and RNA signatures using urine as a systemic biopsy may provide a more powerful and effective tool for following and uncovering both pre-clinical and clinical changes, which may include: monitoring cancer patients to determine therapeutic response or non-response and disease recurrence; following organ transplant status to watch for rejection; non-invasively securing samples for the clinical diagnosis of infectious diseases; and screening and testing expectant mothers, who's fetus may be at risk for certain genetic abnormalities. Currently, these clinical needs are addressed by the use of invasive blood and bone marrow tests, tissue biopsies, amniocentesis, as well as costly CT, MRI, and PET scans.

Urine is a relatively simple aqueous solution and, unlike plasma, contains few components that can attack and break down cell-free nucleic acid fragments. Since urine does not contain many cells, proteins and other contaminants, cell-free nucleic acid isolation is a procedure which can be easily automated for high throughput screening applications. Cell-free nucleic acid fragments can be accurately analyzed using conventional methods that are either in use or in development within many molecular genomics laboratories.

Our urine-based cell-free nucleic acid tests are based upon a proprietary method of nucleic acid isolation, followed by detection of specific genetic markers. These proven and well-established detection methods can be used to detect nucleic acids in blood, stool, and other specimen types. Using enhancements of these techniques, cell-free nucleic acid markers can be isolated from easily obtained urine specimens.

Edgar Filing: Trovogene, Inc. - Form 10-K

Our urine-based cell-free nucleic acid technology may be applied to the detection and monitoring of an extremely broad spectrum of medical conditions.

Table of Contents

Characteristics of Urine-based Cell-free Nucleic Acid Testing

- The kidney acts as a filter, passing cell-free nucleic acids from complex, multicellular, multicomponent blood into urine, a much less complex aqueous environment.
- The collection procedure is non-invasive and does not require the involvement of trained medical staff.
- Urine as a sample type supports repeated testing when required and poses no discomfort for the patient.
- Cell-free nucleic acids in urine are stable at room temperature for extended periods of time with the addition of a simple preservative. Nucleic acids in blood and many other traditional samples are not.
- Sample processing and tests can often be easily automated.
- Isolation of cell-free markers from large sample volumes increases the sensitivity of the tests. This cannot be done as easily using blood or tissue specimens, which have inherent volume limitations.
- Blood or sputum samples for detection of infectious diseases may not be easily obtained from certain patients, including small children and the elderly. Urine specimens typically present minimal acquisition concerns.
- Blood and other bodily fluids are highly infectious by nature, urine is not.
- Blood and other bodily fluids are legally considered biohazardous, urine is not.

Clinical Applications

Edgar Filing: Trovogene, Inc. - Form 10-K

We believe that our urine-based cell-free molecular diagnostic test will make it easier to address important health problems worldwide, and will lead to significant advances in personalized medicine for improved patient care. We intend to develop clinical evidence for our cancer monitoring tests in three distinct and potentially overlapping stages. Stage 1 studies are qualitative in nature and are designed to determine the mutational status of actionable biomarkers in urine especially when biopsy is not an option. These studies demonstrate concordance (agreement) of the oncogene mutation status between a urine sample and a tumor tissue sample. These studies are considered to have diagnostic value, and would prove that urine-based molecular test results match the tissue biopsy closely. The clinical utility of such a study would validate that mutational status of actionable biomarkers can be determined in urine when a biopsy is not an option. Stage 2 studies are quantitative in nature, and are designed to assess patient mutational status in urine longitudinally (over time) as an indicator of responsiveness to therapy and disease status of the patient. Demonstrated clinical utility includes quantitatively assessing mutation status in urine longitudinally as an indicator of responsiveness to therapy and disease status of the patient. Stage 3 studies are conducted with the goal to demonstrate improved patient outcomes and eventually could lead to changing medical guidelines and the clinical standard of care for managing certain cancers. Demonstrated clinical utility includes quantitatively assessing patient mutational status in urine longitudinally for mutational status as well as early detection of resistance to therapy as a decision tool for therapy selection. Generating data with our technology that supports better patient outcomes and more efficient use of healthcare resources is a key component of Stage 3.

Table of Contents

Oncology

Urine may offer an alternative to blood-based tests such as circulating tumor cells, biopsy and imaging. By tracking mutations we can inform medical practice. Our initial pilot study is focused on the BRAF mutation because of its link to discreet cancers and associated treatments, as well as the KRAS mutation because of its broad applicability in many cancers. We are now developing both single mutation tracking tests using droplet digital PCR (ddPCR) and panel monitoring for multiple mutations using NGS for a variety of mutations seen in many cancer types. We believe the potential exists to expand the use of this latter technique across many cancer types.

During 2013, we had six ongoing clinical studies with leading cancer centers and pharmaceutical companies to demonstrate the qualitative and quantitative clinical utility of our tests. Clinical study sites include MD Anderson Cancer Center, USC Norris Cancer Center, US Oncology, pharmaceutical collaborators and other top cancer centers.

The MD Anderson Cancer Center clinical study is focused on detecting and monitoring BRAF and KRAS tumor mutations in cell-free DNA from urine in metastatic cancer patients. BRAF mutations are common in melanoma, thyroid, and other cancers. Within the U.S., it is estimated that nearly 730,000 patients have tumors with BRAF mutations. Several targeted therapies are either on the market or in development for BRAF-mutation positive cancers. Pancreatic cancer represents an additional diagnostic and treatment challenge. Each year, more than 43,000 new cases of pancreatic cancer are diagnosed, and 37,000 patients succumb to this disease. It is estimated that KRAS mutations occur in >90% of pancreatic cancers and 11%-17% of these patients do not express the CA19-9 marker, which makes their disease more difficult to track.

Initial results from the MD Anderson Cancer Center clinical study were published at the AACR-NCI-EROTC International Conference in October 2013. During the study, urine samples from metastatic cancer patients known to have BRAF V600E, KRAS G12D or KRAS G12V mutations were assessed. Our researchers analyzed the urine samples using our urine-based cell-free DNA mutation assays. Results demonstrated high concordance between urine and tissue mutational status. In addition, preliminary results indicate that cell-free BRAF V600E mutation monitoring in urine correlates with clinical response to therapy.

The clinical study demonstrated that BRAF V600E mutations were detected in urine irrespective of the cancer type, and a multitude of different cancer types, including brain cancer (glioblastoma), were included in the initial study results. The BRAF V600E assay demonstrated 95% concordance vs. tissue biopsy (both detected and borderline), and also demonstrated that urine DNA can be used to detect DNA fragments from circulation that harbor tumor mutations. The following cancers were detected: non-small cell lung cancer, papillary thyroid carcinoma, melanoma, colorectal cancer, glioblastoma, adenocarcinoma of unknown primary, ovarian cancer, and appendiceal cancer. In addition, preliminary results indicate that cell-free BRAF V600E mutation monitoring in urine longitudinally correlates with clinical response to therapy.

The study also evaluated the feasibility of using massively parallel deep sequencing (i.e. NGS) to identify DNA mutations in the urine of metastatic cancer patients harboring known KRAS mutations. Leveraging proprietary enrichment methods, our researchers were able to detect mutant cell-free DNA in the urine of cancer patients with verified KRAS mutations.

In October 2013, our first urine test for cancer mutation monitoring was made available to clinicians through the company's CLIA laboratory. The robustness of our ultra-sensitive assay procedure has been demonstrated for the detection of the BRAF V600E mutation from cell-free DNA in urine. This mutation commonly occurs in melanoma. Of the more than 70,000 cases of melanoma diagnosed each year in the United States,

up to 70 percent harbor a BRAF-type mutation and of those, 80 percent may be positive specifically for

Table of Contents

BRAF V600E. There are several FDA-approved targeted therapies for the treatment of BRAF-positive melanoma, making mutational status monitoring an area of clinical interest among treating physicians.

Our cell-free BRAF test is a LDT, designed to detect and monitor this mutation in metastatic cancer patients with biopsy-proven V600E BRAF mutation in their tumor. It is the first commercial assay within our cancer monitoring portfolio performed using a ddPCR platform. Using urine as a non-invasive, systemic sample, the cell-free BRAF test could help physicians monitor changes in mutation status for patients requiring therapy for cancers that have this mutation. For patients with difficult-to-biopsy metastatic tumors, urine-based mutation testing may also provide a viable alternative to gauge mutation status as part of the initial treatment workup.

The clinical study being conducted at the USC Norris Cancer Center is focused on mutation monitoring and the emergence of KRAS resistant mutations in colorectal cancer. With multiple targeted therapies for colorectal cancer on the market, detection of KRAS mutations in tissue has a direct impact on the initial treatment selection for these patients. In the U.S. alone, there are more than 140,000 new cases of colorectal cancer and 52,000 deaths annually. It is estimated that KRAS mutations occur in 35%-50% of all colorectal cancers. Metastatic pancreatic cancer is frequently associated with KRAS gene mutations. The primary purpose of the collaborative study is to determine whether KRAS mutations can be evaluated in urine to monitor treatment response in patients that test either positive or negative for the tumor marker CA19-9. CT scans and CA19-9 blood levels are currently the only two methods available to clinicians to monitor metastatic pancreatic cancer tumor burden and response to therapy. However, approximately 11%-17% of patients will not display elevated CA 19-9, even with high tumor load. For patients that test negative for CA19-9, our method to follow disease status could be distinctly beneficial. Patient enrollment is expected to begin in the first quarter of 2014, and up to 45 patients are expected to participate in the collaborative study.

The US Oncology clinical study is our first multi-site, multi-center study and will test detection and monitoring of KRAS mutations in pancreatic cancer patients. In addition to the 11 US Oncology Research affiliated community cancer care sites participating in this study, additional academic research institutions that specialize in oncology have also elected to participate.

We have a pharmaceutical collaboration to detect and monitor EGFR T790 resistant mutations in lung cancer.

We also have a multi-institutional clinical study underway to detect BRAF mutations in histocytic diseases.

PIK3CA mutations are common in breast, colon and endometrial cancers. Within the U.S., nearly one million cancer patients are positive for these mutations. Among our platform applications in development, we are working on an assay for the detection and monitoring of PIK3CA oncogene mutations. Other mutation marker assays in development include: EGFR, c-met amp, HER-2, and NRAS.

Transplant

Patients who receive solid organ or bone marrow transplants are at risk of rejection, particularly during the first few months following surgery. Non-invasive monitoring of transplant status could replace repeated biopsies and blood tests, while keeping both the patient and the physician informed about potential problems.

Table of Contents

Infectious Disease

HPV-HR DNA Assay

Following the completion of a pilot clinical study with a urine-based DNA test for high-risk HPV, our first HPV-HR DNA assay became commercially available in March 2013. Initial data from the pilot study showed that our assay provided superior performance to the current leading HPV assay. Our HPV-HR DNA assay showed a sensitivity of 93.0% and specificity of 96.0% for the detection of HPV virus in a comparative study of 320 high-risk individuals.

Urine-based HPV testing offers a significant advantage over the traditional cervical swab sample, which can present a logistic, invasive, or privacy concern. A urine-based assay also makes both female and male carrier screening feasible.

Through licensing agreements, we are pursuing commercialization of our HPV-HR DNA test, particularly in those geographies where compliance with cervical cell sampling is problematic.

Prenatal Genetics

The combination of NGS or ddPCR with our proprietary transrenal nucleic acid technology would allow for truly non-invasive prenatal screening of aneuploidies and monogenic disorders. We may pursue the development of our technology for use in prenatal genetics through licensing agreements.

Changing the Molecular Diagnostic Paradigm

Diagnosis and detection of severe and life-threatening diseases are among the most important outcomes of the Human Genome Project (HGP). There are four requirements to realize the full benefit of the HGP in relation to cancer diagnostics; large catalogues of cancer mutations; affordable sequencing of patient samples; detection technologies capable of identifying and quantifying rare instances of mutations at affordable costs; and large, systemic samples that can be collected easily and frequently in order to monitor an individual's cancer.

The first requirement has been met through the Sanger Centre's Catalogue of Somatic Mutations in Cancer (COSMIC) database, which has catalogued more than 233,000 mutations in more than 20,948 genes; and by the National Institutes of Health's (NIH) The Cancer Genome Atlas, which has data on more than 20 cancer types and provides a host of tools for their analysis. The second requirement has been met through the dramatic and continuing decrease in the cost of both conventional sequencing and NGS. ddPCR, capable of detecting rare mutations among thousands of wild type molecules at a reasonable cost, fulfills the third requirement.

Edgar Filing: Trovogene, Inc. - Form 10-K

Our proprietary methods provide the fourth and final requirement, the provision of a large, systemic sample that allows the purification of transrenal nucleic acids in amounts necessary to detect rare mutations. Furthermore, the liquid biopsy provided by urine can be collected frequently, is truly non-invasive, and requires no specialized personnel to collect it.

Taken together, these developments will increase the effectiveness of cancer diagnostics, improve healthcare spending efficiency, and overall, enable better patient care. These developments have made the era of personalized precision medicine in cancer possible.

Table of Contents

The Market

Estimates of the size of the global molecular diagnostics market vary, but are projected to approach \$15.0 billion by 2017. The market is poised to deliver strong double-digit annual growth during the next 5 years, with one industry source quoting a compound annual growth rate (CAGR) of nearly 15%. The molecular diagnostics market has emerged as the fastest growing segment of the in-vitro diagnostics (IVD) market. Geographically, the United States and Europe are the most advanced in terms of adoption of molecular diagnostics and make up the majority of the existing global market (greater than 75% share). Infectious disease is the largest and fastest growing segment of the molecular diagnostics market, followed by oncology testing. Key drivers of the market growth include the ability to quickly and accurately detect the primary cause of disease, the need for automated and easier techniques, and the increased availability of tests to monitor the efficacy of expensive drugs.

Cell-free transrenal molecular diagnostics from urine and plasma provide relevant information that can lead to improvements in personalized patient management. Beyond cancer care and infectious diseases, new products that facilitate personalized care are also emerging in the areas of central nervous system (CNS) diseases, diabetes, and autism. Most major pharmaceutical companies have active pharmacogenomic programs included in their clinical studies, anticipating the need to utilize diagnostic testing to stratify patients for clinical response. We believe that our broad intellectual property (IP) portfolio positions us to work within each of these markets, either alone or in partnership with other companies, to develop and market cell-free transrenal molecular diagnostic products, all of which we expect would address the large unmet market needs of simplicity, patient convenience and privacy, accuracy, and cost effectiveness. Such products could play key roles in their applications to improve testing compliance and as such, reduce morbidity and mortality. The use of urine as a sample should provide a paradigm shift in screening and monitoring practices as it provides an easier sample to acquire in a truly non-invasive fashion, with more nucleic acid targets present in the sample leading to greater sensitivity. We believe these modified screening practices will most likely meet with wide physician and patient acceptance in oncology, infectious disease, transplantation, and potentially, prenatal diagnostics.

Commercial Markets Internal Focus

Oncology

Cancer mutation testing and monitoring is the priority area for our scientists and commercial personnel. Early data from ongoing clinical studies have shown that cell-free nucleic acid analysis may be useful for determining the presence or absence of actionable mutations, and for monitoring therapeutic response and recurrent in metastatic cancers. Such testing could serve to help physicians monitor ongoing response to therapy, identify signs of early progression, or see markers of resistance emerge prior to clinical presentation. Once therapy is completed, a simple urine test could be used to monitor for early signs of disease recurrence over time. The market for these tests diagnosed cancer patients possessing mutations known to have clinical or therapeutic importance is already established. Use of urine-based testing could be disruptive, and change the pattern of use of other cancer monitoring tools, including expensive imaging technologies, such as PET, CT and MRI scans.

According to the American Cancer Society s (ACS) 2013 report, there are approximately 525,000 patients that die every year from cancer, not including cancers of the blood, bone marrow, or lymphatic system. Using this number as a proxy for metastatic cancers, it can be assumed that all of these patients are being treated within 12 months of death for their disease. Testing and monitoring these patients for response to therapy, progression while on therapy, or for markers of resistance to therapy (like T790M for lung cancer) would be a natural extension of our technology. The average lung, breast, or colon cancer patient receives between 18-21 radiographic imaging procedures (PET, CT, MRI, etc.) during the two years following their diagnosis. This

Table of Contents

averages to about 9-10 scans per patient per year. Use of a urine-based monitoring test at the start of therapy, at several time points during therapy, and at the completion of therapy would represent approximately six separate testing events that could occur within a 12 month period. At a reimbursed price of approximately \$1,000 per test, the total available market (TAM) for treatment response monitoring in the U.S. could be worth more than \$3.2 billion.

Once patients with cancer, primary or metastatic, have completed therapy, they will require monitoring for possible progression, and for the appearance of resistance markers, since many metastatic patients may remain on lower-dose maintenance therapy during the remainder of their lives, or until treatment is no longer considered an option. According to the ACS, as of 2012, there were over 11 million patients alive in the U.S. who have been treated for cancers that have metastatic potential, not including cancers of the blood, bone marrow, or lymphatic system. Use of a urine-based mutation monitoring test once a year at \$1000 per test would equate to a TAM for recurrence monitoring in the U.S. at approximately \$11 billion annually.

Both of these markets, treatment response and recurrence monitoring, are sizeable economic opportunities. Capturing 10% of the response monitoring market would produce revenues of ~\$320 million, and 5% of the recurrence monitoring market would yield annual revenues of ~\$550 million.

Beyond cancer patients being actively treated or monitored over time, cell-free nucleic acid testing may eventually emerge as a viable option for pre-cancerous screening. This was recently evaluated in a cancer clinical study at Thomas Jefferson University, funded jointly by the NIH and the National Cancer Institute (NCI). The study demonstrated that DNA fragments carrying a specific mutation (KRAS), and released from pre-cancerous colon polyps, can be detected in the urine of patients.

Studies have shown that cancer patients who have KRAS mutations do not respond successfully to treatment with anti-EGFR (epidermal growth factor receptor) drugs such as Erbitux, Iressa, Tarceva, Tykerb and Vectibix.

These anti-EGFR agents, particularly Erbitux and Vectibix, are a mainstay of treatment for colorectal cancer. It has been estimated that 17-25% of all human cancers have been found to harbor KRAS mutations, with mutation rates as high as 59%-90% in pancreatic cancers and 35%-40% in colorectal cancers. These tumors have a low probability of responding to anti-EGFR drugs. By first testing for KRAS mutations, physicians will be able to better manage their patients and avoid costly treatments that are unlikely to have a positive clinical response.

Screening and monitoring for KRAS and other key biomarker mutations (i.e. BRAF, PIK3CA, EGFR, etc.) using urine-based tests would provide a simple, non-invasive, cost effective, and convenient testing alternative for physicians and patients. Specimens may even be collected in the patients' home as required, or as requested by the physician.

Simple urine-based assays would likely lead to much improved personalized medicine for patients, resulting in the right drug being prescribed for the right disease at the right time. We believe this technology will lead to an improved quality of life for patients.

Drug Development and Monitoring of Therapeutic Outcomes

Cell-free nucleic acid technology has significant potential as a very simple, quick, non-invasive way of monitoring clinical responses to drugs in clinical development and evaluating patient-specific responses to already approved and marketed therapies. Specific target applications include, but are not limited to; the

Table of Contents

detection of metastasis following tumor surgery, monitoring of response and tumor progression during chemotherapy and/or radiation therapy, development of optimal hormonal and chemotherapeutic treatment protocols, and monitoring of transplantation patients on immunosuppressive drugs.

With cancer treatment today, it is often difficult to determine if a particular patient is responding to their current therapeutic regimen. Generally, patients are re-examined periodically to determine if a tumor has grown in size, reduced in size (i.e. partial response), disappeared (i.e. no sign of disease – complete response) or remained the same (stable disease). If the tumor has grown in size or remained the same, treatment may be adjusted. By measuring and monitoring tumor specific genetic markers in a patient's urine pre-, peri- and post-chemotherapy, it may be possible to more quickly determine whether a patient is responding to therapy. Use of cell-free DNA diagnostics may permit more rapid and real-time therapeutic decisions on a patient-specific basis. About 1.6 million new cancer cases are diagnosed annually, and there are several hundred companies developing therapeutic agents in the United States alone. We believe this indicates a large potential application to use cell-free nucleic acid technology for both drug development and the monitoring of therapeutic outcomes.

One of the largest costs associated with development of a new therapy is the size of human clinical studies required to identify the cohort of responders, and the resulting statistical power required. By measuring specific genetic markers, it may be possible to pre-identify, and subsequently screen, for the most likely responders to the therapy, and to limit patient recruitment to this subset. This strategy could significantly reduce the cost to develop a drug, and can improve development timelines as well. We believe that there is significant commercial potential for our urine-based cell-free nucleic acid tests to be incorporated into these clinical trial protocols, and ultimately post-approval patient identification protocols.

Commercial Markets External Focus

We will seek to license and/or partner with other companies who have vested interests or commercial strengths in the following areas in order to develop applicable diagnostic and/or monitoring tests using our cell-free nucleic acid technology.

***Infectious Diseases* Human Papilloma Virus (HPV)**

The rationale for screening HPV is that high-risk subtypes cause virtually all cases of cervical cancer. We have developed a urine-based HPV test capable of screening for known high-risk HPV types that are associated with the development of cervical cancer. Cervical cancer is the third most commonly diagnosed cancer, and the fourth leading cause of cancer deaths in females, worldwide. Deaths due to cervical cancer are a significant global problem, especially in the developing world where screening practices are far from adequate.

According to the American Cancer Society, India alone accounts for 27% (77,100) of total worldwide cervical cancer deaths. A recent clinical trial conducted in rural India found that a single round of HPV DNA testing was associated with about a 50% reduction in the risk of developing advanced cervical cancer and associated deaths. This compares with the United States, where better patient compliance and screening guidelines have reduced cervical cancer death rates to only 4,290 cases in 2011. The major drivers of poor screening in these developing regions are cultural acceptance, limited screening resources and funding, and poor cytology proficiency. Further exacerbating the compliance hurdles, is that the primary screening mechanism involves an invasive cervical scraping procedure (e.g. Pap smear). It is generally agreed that the early detection of cervical cancer leads to much higher cure rates, and lower rates of invasive disease.

Table of Contents

Beyond women's health and cervical cancer, HPV infection impacts the men who carry and help spread the virus. While not at risk for cervical cancer, men can experience clinical manifestations in the form of genital warts, as well as penile, anal, and oropharyngeal cancers. Determining male carrier status is an unmet medical need within the sexually-transmitted disease (STD) community. We intend to explore the viability of our urine-based HPV assay to be a potential screening test for both low-risk HPV types 6 and 11 (which cause up to 90% of all genital warts), as well as known high-risk HPV types that cause the development of cervical and other cancers. Knowing HPV carrier status may contribute to more stringent use of safe sex practices, and can prevent further spread of the disease during active infection periods. In addition to carrier screening, our test may also prove useful in monitoring patients with active HPV infection until resolution of the disease.

There is a tremendous unmet need for a new non-invasive, simple, private, and cost effective test to simplify the HPV screening process for patients, both male and female, and in turn improve compliance. We believe our urine-based HPV test can address these market needs.

Other areas beyond HPV detection and monitoring include those infectious diseases caused by viruses, bacteria, fungi, and parasites. Cell-free nucleic acid assays that detect molecular targets in such organisms can provide a quick, accurate, simple, and cost effective method for screening and monitoring disease. Specific areas of interest include testing for molecular targets from organisms that cause Lyme disease, JC Virus, valley fever, and various fungal infections. These organisms all tend to be difficult to identify with current technology, making differential diagnosis especially challenging, thus delaying the start of potentially curative anti-infective treatment.

Aspergillus is a genus of a few hundred mold species found worldwide throughout much of nature. Aspergillus infections can cause considerable problems in immune compromised patients such as patients with HIV, and patients who are undergoing cancer treatments, etc. A test for these infections that can identify cell-free nucleic acids specific to Aspergillus species in a urine sample could provide a much easier and faster way to diagnose and treat affected patients. With these patients, getting fast results is paramount, and can mean the difference between survival and death. We are actively pursuing partnerships with companies interested in developing our technology for infectious diseases, either in conjunction with our scientists, or by licensing our technology for their own development and use. Relevant diseases include Borrelia, which causes Lyme disease, and JC virus, which is associated with progressive multifocal leukoencephalopathy (PML) in patients being treated with certain drugs for multiple sclerosis and rheumatoid arthritis. JC Virus is also the primary cause of nephropathy (kidney disease) in people who have received a kidney transplant and are on immunosuppressive therapy.

Another area with a high unmet market need involves opportunistic infections in patients treated with immunosuppressive drugs such as tumor necrosis factor, or TNF, inhibitors. TNF inhibitors are used for the treatment of such conditions as rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and Crohn's disease. This class of drugs has a known risk of causing serious infections mediated by induced immunosuppression. Currently, there are hundreds of thousands of patients being treated with this drug class within the U.S., and the number is steadily growing, especially in patients with advanced arthritic symptoms. The ease of urine collection and urine-based testing and monitoring allows for very quick diagnosis, heightened turnaround time allowing for quick treatment decisions, and enhanced patient convenience (i.e. at-home collection). The goal of such a test will be to detect active infection prior to the onset of symptoms, and to allow for more proactive and informed intervention and treatment planning.

Table of Contents

Transplantation

According to government statistics, there are approximately 28,000 solid organ transplants performed in the U.S. annually. Post-transplant monitoring for organ rejection episodes requires a highly invasive tissue biopsy. Approximately 10 such biopsies are taken over a period of one year per patient. Because organ rejection is marked by the early death of cells, we believe that an early indication of rejection can be identified by measuring a unique series of genetic markers characteristic of the organ donor that can be easily detected in random urine specimens from the transplant recipient. Providing early evidence of tissue rejection is key to the administration and monitoring of immunosuppressive therapies used to fend off rejection. Given the annual number of transplants performed in the U.S. and the annual number of corresponding biopsies performed per patient, this would equate to a market opportunity in the U.S. of roughly 300,000 urine-based tests per year. Transplantation monitoring with our technology offers opportunities for partnering with companies developing drugs for controlling tissue rejection, developing cell transplantation, or developing novel transplantation technologies. This illustrates the breadth of commercial potential of our transrenal molecular testing platform technology, and we intend to leverage such potential applications to maximize shareholder value.

Ultra-sensitive Analytical and Detection System

As it relates to detection platforms, which are required for final assay analyses, we may be developing a new instrument that provides features that will be synergistic and complementary to our transrenal technology. In this regard, in August 2010 we acquired Etherogen, Inc. which owns the CMOS Sensor Detection Platform, and we may design a next generation version of this screening and detection device. The major differentiating features of this platform are simplicity, unsurpassed ultra-sensitive detection of nucleic acids and proteins without the need for target amplification or the resulting investments in amplification-related infrastructure or capital equipment, significantly heightened speed, and the ability to perform multi-analyte assays. We believe that such a platform would undoubtedly expand the user base for molecular diagnostics. Currently, the cost of adding these new testing modalities in hospitals can be daunting. These high costs include extensive capital equipment and infrastructure requirements (i.e. amplification technology, highly trained personnel, special facilities, etc.) that most hospitals cannot afford. Our platform may address cost efficiencies, and potentially could help overcome these adoption hurdles. Finalization of the system architecture, operating procedure, and software specifications for this platform are required, and system development will take place when resources are allocated to fund the project.

Technologies for the collection, shipment and storage of urine specimens, and transrenal nucleic acid extraction

Successful implementation of our cell-free nucleic acid technology in molecular testing is tightly linked to the availability of techniques and procedures for cell-free nucleic acid preservation, purification, and analysis. Our strategic plan includes the allocation of sufficient resources for the creation of robust, feasible, and inexpensive approaches to improve the efficiency of working with urine samples.

Instrumentation/System Platform

As part of our product offerings, we intend to provide various types of automation alternatives that will further enhance the acceptance and use of our urine-based assays incorporating our transrenal platform. In this regard, there are several alternatives that we will pursue. For example, in sample extraction, we will either develop applications for existing extraction systems that already exist in laboratories or recommend that they acquire instruments that can be used with our assays. An alternative will be to explore an OEM (original

Table of Contents

equipment manufacturer) arrangement with one of the instrument suppliers, which will allow us to private label the instrument thus supporting a complete system at the customer site.

Our Business Strategy

We plan to leverage our transrenal cell-free nucleic acid technology to develop and market, either independently or in conjunction with corporate partners, molecular diagnostic products in each of our four core markets – oncology, infectious disease, transplantation, and prenatal diagnostics. Our marketing strategy includes approaches across multiple fronts. In the U.S. market, we have acquired a Clinical Laboratory Improvement Amendments of 1988 (CLIA) laboratory. At the late stages of development for each product, while collecting clinical data for regulatory submissions, we intend to market the products as LDTs through our CLIA laboratory. CLIA laboratories can develop and offer their own in-house tests that receive reimbursement under the provisions of LDT rules.

Congress passed the Clinical Laboratory Improvement Amendments in 1988 to regulate development, evaluation, and use of LDTs. CLIA states that laboratories must demonstrate how well an LDT performs using certain performance standards. Laboratories that perform testing on human specimens for the diagnosis, prevention, or treatment of disease, or for the assessment of health, must comply with all applicable CLIA 88 regulations. These regulations, which were finalized in 2003, establish standards to help ensure the quality and accuracy of laboratory testing. While most common laboratory tests are commercial tests, manufactured and marketed to multiple laboratories, some new tests are developed, evaluated, and validated within one particular laboratory. These LDTs are used solely within that laboratory and are not distributed or sold to any other labs or health care facilities.

Because LDTs are not marketed to other labs or facilities, they do not require approval for marketing from the U.S. Food and Drug Administration (FDA) as do commercially developed and marketed tests. However, these types of tests must go through rigorous validation procedures and must meet several criteria before results can be used for decisions regarding patient care. These include demonstration of test accuracy, precision, sensitivity, and specificity.

We may pursue FDA review and approval for our products as clinical studies are completed. Assuming we receive FDA clearance or approval for our products, we plan to market such urine-based test kits through a U.S. commercial organization directly to national and regional CLIA medical testing laboratories. We also intend to complete business partnerships (out-license agreements) with diagnostic and pharmaceutical companies in the U.S., Europe, Asia Pacific and the rest of the world as appropriate given market conditions and opportunities. This strategy would provide both short term (license fees) and long term (royalty) revenue streams. Licensees of our technology will use our platform technology in the clinical development of their products, to monitor patients taking their marketed products (i.e. TNF inhibitors), and in certain situations to develop, market and sell our transrenal cell-free nucleic acid tests in predefined fields of use and geographic territories. We plan to become a fully vertically integrated business in which we develop, manufacture, register, market, and sell our products.

The major advantages of our cell-free nucleic acids tests, when commercially available, will be the ease of sample collection, anticipated higher levels of sensitivity and specificity, larger quantities of genetic material for analysis (allowing for the detection of oncogene mutations that are low in abundance), patient convenience, non-invasiveness, and the ability to provide more efficient and effective monitoring protocols. Our cell-free nucleic acid tests must be cost effective, and we believe the process to make, sell, and process our assays is relatively simple and suitable for automation.

Table of Contents

During the last decade, medical laboratory operating margins have declined in the face of Medicare fee schedule reductions, managed care contracts, competitive bidding, and other cost containment measures. If our technology were commercially available today, reimbursement would be available under the current procedural terminology, or CPT codes, for molecular-based testing. We expect to market our tests through our CLIA laboratory directly to physicians, and we will work with public and private payers for appropriate reimbursement. We believe this strategy, coupled with strong clinical results supporting the use of our transrenal cell-free nucleic acid tests, will lead to broad market adoption of our technology.

Research and Development

As of February 28, 2014, we have thirteen dedicated scientists who are located in our office in San Diego, CA. We plan to continue to grow our R&D organization to approximately 18 individuals that will represent a good mix of senior lead researchers and scientists (PhDs), laboratory associate scientists, and experts in clinical development and regulatory affairs of molecular diagnostics. We plan to rapidly introduce new products to the market that could be used as LDTs within our CLIA lab, and simultaneously continue funding and collaborating on the necessary clinical studies that can support the utility of our tests, and potentially support regulatory submissions for marketing approval or clearance depending upon the nature of the product. We currently have sufficient resources to complete these projects extending into 2015. We plan to seek additional funding as required to supplement current commercial and licensing revenue. Information and documentation systems infrastructure (e.g. design history files, firewalls, etc.) must be in place to support the confidentiality of multiple partnering programs, and the rigorous scientific and regulatory oversight needed for products in the in-vitro diagnostics markets. Research and development expenses for the year ended December 31, 2013 were approximately \$3.9 million, as compared to approximately \$1.9 million and \$911,000 for the years ended December 31, 2012 and 2011, respectively.

Intellectual Property

We consider the protection of our proprietary technologies and products to be a critical element in the success of our business. As of February 28, 2014, our wholly owned and licensed intellectual property includes over 130 issued patents and over 47 pending patent applications in the U.S. and abroad. The pending applications include multiple international applications filed under the Patent Cooperation Treaty (PCT applications) that will be used as the basis of multiple additional patent applications.

One group of patents and patent applications includes seven U.S. patents, with over 44 counterpart European patents that include a majority of European countries. These patents are directed to the detection of nucleic acid sequences in urine and nucleic acid modifications and alterations in urine. This patent family includes claims directed to prenatal analysis of fetal DNA and determining the sex of a fetus and detecting diseases such as Down Syndrome caused by genetic alterations. Other patented claims are directed to detecting and monitoring cancer through urine-based testing; nucleic acid screening, and monitoring in cases of transplantation and infectious diseases, including infection by viruses and pathogens; and other potential diagnostic and genetic testing applications. Additional pending claims are directed to the preparation of transrenal nucleic acids, as well as detection of transrenal microRNA and short transrenal nucleic acid molecules. Members of this patent group expire between 2018 and 2026.

A second group is directed to detection of specific gene mutations and indicators of disease. These include nucleophosmin (NPM1) protein gene mutations, BRAF mutations, SF3B1 mutations, HPV, acute myeloid leukemia (AML), and hairy cell leukemia (HCL). The detection includes analysis of transrenal nucleic acid molecules. The group includes U.S. patents 8,222,370 B1, 8,501,924 B1, and 8,642,261 B1, as well as six

Table of Contents

pending U.S. patent applications. There are also 14 pending non-U.S. patent applications, and four PCT applications. Members of this patent group expire between 2025 and 2033.

A third group is directed to our molecular detection platform utilizing proprietary probe chemistry on optical detectors such as CMOS (complementary metal-oxide semiconductor). This platform technology utilizes a conjugated probe and optical detection of analytes in medical diagnostics. The group includes one issued Japanese patent, with pending applications in the US, Canada, Europe, and Hong Kong. Members of this patent group expire beginning in 2022.

Wherever possible, we seek to protect our inventions by filing U.S. patents as well as foreign counterpart applications in selected other countries. Because patent applications in the U.S. are maintained in secrecy for at least eighteen months after the applications are filed, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications, or that we were the first to file for protection of inventions set forth in such patent applications. Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case continued development and marketing of the products would require a license. Required licenses may not be available to us on commercially acceptable terms, if at all. If we do not obtain these licenses, we could encounter delays in product introductions while we attempt to design around the patents, or could find that the development, manufacture or sale of products requiring such licenses are not possible.

We may rely on trade secrets to protect our technology. Trade secrets are difficult to protect. We seek to protect our proprietary technology and processes by entering into confidentiality agreements with our employees, certain consultants and contractors. These agreements may be breached, we may not have adequate remedies for any breach and our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees or our consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Manufacturing and Distribution

In 2014, we plan to continue introducing our laboratory-developed tests (LDTs) into the marketplace through our CLIA licensed and CAP accredited laboratory. We source all reagents and consumables needed for our LDTs from third party vendors, and we currently do not manufacture reagents kits for use in our own lab, or to distribute to 3rd party labs.

We have established a sales and marketing organization to directly market our LDTs for oncogene mutations to end users in the oncology market segment. As of December 31, 2013 we had two employees dedicated to the sales and marketing of our LDTs in the U.S. market. We intend to add additional employees as needed to support the introduction of new LDTs planned for 2014.

Reimbursement

Medicare and other third-party payers will independently evaluate our technologies by, among other things, a cost/benefit analysis, assessing other available options and reviewing the published literature with respect to the results obtained from our clinical studies. Currently, CPT codes

Edgar Filing: Trovogene, Inc. - Form 10-K

are available for molecular testing which we believe will allow our technologies to be billed following completion of a test which has been prescribed (ordered) by a physician for a patient. We believe that the existence of current CPT codes with

Table of Contents

applicability to our tests will help facilitate Medicare's reimbursement process, as well as that for third party insurance providers.

Reimbursement for our novel tests is a top priority, as physician and patient access to our technology is key to widespread adoption of our products. To gain initial reimbursement, our qualitative tests will be billed and reimbursed under established Tier I codes for their respective mutation (ie BRAF, KRAS, EGFR, etc.). These are CPT codes from the American Medical Association (MoPath system), which should enable us to bill and obtain reimbursement for our tests without much issue. As we develop our tests and demonstrate novel clinical utility in cancer monitoring, supported by our high analytical sensitivity, quantitative performance over a large dynamic range, and clinical experience, we will pursue a Not Otherwise Classified (NOC) code for billing and reimbursement. Under these conditions, premium pricing is expected. Over time, we intend to pursue permanent CPT codes unique to our cancer monitoring diagnostics once sufficient value is being assigned under the NOC code system. We will engage with 3rd party payors including integrated healthcare networks and Medicare for reimbursement of our tests, with the goals of obtaining strong adoption of our tests, positive coverage decisions, and appropriate valuation of our tests on a widespread basis over time. In 2014, we plan to continue developing clinical evidence around the utility and performance of our testing platform, and interacting with payors for the reimbursement of our commercially available urine-based cell-free nucleic acid diagnostics.

Government Regulation

Regulation by governmental authorities in the United States and other countries will be a significant factor in the development, production and marketing of any products that we may develop. The nature and extent to which such regulation may apply will vary depending on the nature of any such products and the policy of each country. Virtually all of our potential products will require regulatory allowance or approval by governmental agencies prior to commercialization, except for the LDTs as mentioned above. We may submit and obtain FDA approval or clearance for some or all of our diagnostic products. Pursuing and receiving FDA approval or clearance may be vital to maximizing our customer base and revenue potential for our numerous products.

FDA clearance for our products may be obtained through submission of a 510(k) statement of equivalency. Another regulatory option, albeit more complicated and expensive, is to pursue FDA approval by submitting a Pre-Market Approval (PMA) application. A 510(k) submission requires that we show equivalency of results in a clinical study with parallel comparison against an existing and FDA-recognized reference method (predicate device).

The FDA also regulates the sale of certain reagents, including our potential reagents, used by laboratories under the LDT rules to perform tests. The FDA refers to such a reagent as an Analyte-Specific Reagent (ASR). ASRs generally do not require FDA pre-market approval or clearance if they are (i) sold to clinical laboratories certified under the Clinical Laboratory Improvement Act to perform high complexity testing and (ii) are labeled in accordance with FDA requirements, including a statement that their analytical and performance characteristics have not been established. Prior to, or in lieu of FDA approval, we can sell our reagents to laboratories that meet the established criteria. The FDA also regulates all promotional materials and specifically prohibits medical and efficacy claims.

Assuming that FDA approval or clearance is received for our products, a number of other FDA requirements would apply to our manufacturing and distribution efforts. Medical device manufacturers must be registered and their products listed with the FDA, and certain adverse events, such as reagent failures, significant changes in quality control and other events requiring correction and/or replacement/removal of reagents must be documented and reported to the FDA. The FDA also regulates product labeling, promotion,

Table of Contents

and in some cases, advertising, of medical devices. As discussed above, we must comply with the FDA's Quality System Regulation that establishes extensive requirements for design control, quality control, validation, and manufacturing. Thus, even with FDA approval or clearance, we must continue to be diligent in maintaining compliance with these various regulations, as failure to do so can lead to enforcement action. The FDA periodically inspects facilities to determine compliance with these and other requirements.

Competition

The medical diagnostic industry is characterized by rapidly evolving technology and intense competition. Our competitors include medical diagnostic companies, most of which have financial, technical, and marketing resources significantly greater than our resources. In addition, there are a significant number of biotechnology companies working on evolving technologies that may supplant our technology, or make it obsolete. Academic institutions, government agencies, and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or through joint venture. We are aware of certain development projects for products to prevent or treat certain diseases targeted by us. The existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of our products or product candidates.

We believe that direct competition in the area of transrenal cell-free DNA or RNA detection and analysis is precluded by our growing patent estate. However, there are other companies working in the area of cell-free nucleic acids and circulating tumor cell (CTC) collection and analysis in blood plasma that could compete in similar clinical areas - including disease detection, therapeutic response monitoring, and minimal disease detection. These companies include Johnson & Johnson (Veridex), Qiagen, Quest, Labcorp, Biocept, Exact Sciences, Boreal Genomics, Sysmex-Inostics, and numerous other smaller companies both in the R&D and early commercial development phases. However, we believe that the advantages of urine as a specimen (large amounts of cell-free nucleic acid material, ease of collection, continuous collection over time, and virtually no limit on sample size and frequency) position us favorably even among such competing companies.

Employees

As of February 28, 2014 we had 21 full-time employees.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. An investor should carefully consider the risks described below as well as other information contained in this registration statement. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our securities could decline, and an investor may lose all or part of his or her investment.

Table of Contents

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 December 31, 2013, we have an accumulated total deficit of approximately \$67.0 million. For the fiscal year ended December 31, 2013, we had a net loss and comprehensive loss attributable to common stockholders of approximately \$11.8 million. To date, we have experienced negative cash flow from development of our transrenal molecular 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 transrenal molecular technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from the transrenal molecular technology or attain profitability, we will not be able to sustain operations.

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

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

In their report dated March 17, 2014 our independent registered public accountants stated that our financial statements for the year ended December 31, 2013 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, 2013 our cash balance was approximately \$25.8 million and our working capital was approximately \$24.1 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 in the next twelve to eighteen months 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 \$1.0 million equipment line of credit, of which approximately \$484,000 is available for additional borrowing. 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

Edgar Filing: Trovogene, Inc. - Form 10-K

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.

Table of Contents

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

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

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

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

Market acceptance, sales of products based upon the TrDNA or TrRNA technology, and our profitability may depend on reimbursement policies and health care reform measures. Several entities conduct technology assessments of medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payors and health care providers as grounds to deny coverage for a test or procedure. The levels at which government authorities and third-party payors, such as private health 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.

Table of Contents

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

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

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

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

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

Edgar Filing: Trovogene, Inc. - Form 10-K

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

Table of Contents

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.

We have limited experience in establishing strong business relationships with leading clinical reference laboratories to perform TrDNA/TrRNA 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 TrDNA or TrRNA tests. We have limited experience in establishing these business relationships. If we are unable to establish and maintain these business relationships, we will have limited ability to obtain revenues beyond the revenue we can generate from our limited in-house capacity to process tests.

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

Edgar Filing: Trovogene, Inc. - Form 10-K

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

Table of Contents

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 21 full-time employees as of February 28, 2014. 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

Edgar Filing: Trovogene, Inc. - Form 10-K

our urine-based HPV DNA test, we will be unable to sell this product in Europe and countries that recognize the CE Mark.

The regulatory review and approval process, which may include evaluation of preclinical studies and clinical studies 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.

Table of Contents

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 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 studies, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical studies and regulatory review, increased costs to assure compliance with

Table of Contents

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

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

Clinical laboratory tests like our current product offerings are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. Most LDTs currently are not subject to FDA regulation,

Edgar Filing: Trovogene, Inc. - Form 10-K

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

Table of Contents

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

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

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

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

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

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

Table of Contents

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

We cannot be certain of the level of protection, if any, which will be provided by our patents if we attempt to enforce them and they are challenged in court where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid 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.

Table of Contents

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

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

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

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

Risks Related to Ownership of our Common Stock

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

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business

Table of Contents

and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

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

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

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

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

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

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

- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to our tests or those of our competitors;
- commercial acceptance of our products, if approved or cleared;

Edgar Filing: Trovogene, Inc. - Form 10-K

- coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
- FDA, CMS and comparable ex-U.S. agency regulation and oversight of our products and services;
- the establishment of partnerships with clinical reference laboratories;

Table of Contents

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

Because we are a development stage company with no revenues to date, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the above.

Edgar Filing: Trovogene, Inc. - Form 10-K

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

As of March 13, 2014, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 32% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Table of Contents

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

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

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

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

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

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. For example, our board of directors have the authority to issue up to 20,000,000 shares of preferred stock in one or more series and to fix the powers, preferences and rights of each series without stockholder approval. The ability to issue preferred stock could discourage unsolicited acquisition proposals or make it more difficult for a third party to gain control of our company, or otherwise could adversely affect the market price of our common stock. Our bylaws require that any stockholder proposals or nominations for election to our board of directors must meet specific advance notice requirements and procedures, which make it more difficult for our stockholders to make proposals or director nominations.

Furthermore, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law. These provisions may prohibit or restrict large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. These provisions in our certificate of incorporation and bylaws and under Delaware law could discourage potential takeover attempts and could reduce the price that investors might be willing to pay for shares of our common stock in the future and result in our market price being lower than it would without these provisions.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline and may impair our ability to raise capital in the future.

Our common stock is traded on The NASDAQ Capital Market and, despite certain increases of trading volume from time to time, there have been periods when it could be considered thinly-traded, meaning that the number of persons interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our stock. In addition, the lack of a robust resale market may require a

Table of Contents

stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

If our stockholders sell, or the market perceives that our stockholders intend to sell for various reasons, including the ending of restriction on resale, substantial amounts of our common stock in the public market, including shares issued upon the exercise of outstanding options or warrants, the market price of our common stock could fall. Sales of a substantial number of shares of our common stock may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. We may become involved in securities class action litigation that could divert management's attention and harm our business.

Our common stock is subject to volatility.

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

- announcements or press releases relating to the industry or to our own business or prospects;
- regulatory, legislative, or other developments affecting us or the industry generally;
- sales by holders of restricted securities pursuant to effective registration statements or exemptions from registration; and
- market conditions specific to biopharmaceutical companies, the healthcare industry and the stock market generally.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES.

Edgar Filing: Trovogene, Inc. - Form 10-K

We lease approximately 8,300 square feet of laboratory and office space in our headquarters in San Diego, California under a lease that expires in December 2017. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in litigation relating to claims arising out of its operations in the normal course of business. We are not involved in any pending legal proceeding or litigation and, to the best of our knowledge, no governmental authority is contemplating any proceeding to which we are a party or to which any of our properties is subject, which would reasonably be likely to have a material adverse effect on us.

Table of Contents

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock has been traded on The NASDAQ Capital Market (NASDAQ) under the symbol TROV since May 29, 2012.

Our common stock was traded over the counter on the pink sheets under the symbol TROV.PK from June 15, 2007 until May 30, 2012. From July 27, 2004 until June 14, 2007, our common stock was quoted on the OTC Bulletin Board under the symbol XNOM.OB . Prior to July 27, 2004, our common stock was quoted on the OTC Bulletin Board under the symbol UKAR.OB but never traded. The following table shows the reported high and low bid quotations per share for our common stock based on information provided by NASDAQ and the OTC Bulletin Board. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly since our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market.

The closing price of our common stock on The NASDAQ Capital Market on March 13, 2014 was \$5.90 per share.

Fiscal 2013		High		Low
Fourth Quarter	\$	8.50	\$	4.81
Third Quarter	\$	10.27	\$	6.61
Second Quarter	\$	7.23	\$	5.27
First Quarter	\$	8.96	\$	5.09

Fiscal 2012		High		Low
Fourth Quarter	\$	7.75	\$	3.31
Third Quarter	\$	4.00	\$	2.09
Second Quarter	\$	6.66	\$	1.86
First Quarter	\$	5.58	\$	2.55

Number of Stockholders

As of March 13, 2014, we had 77 stockholders of record of our common stock.

Dividend Policy

Edgar Filing: Trovogene, Inc. - Form 10-K

Historically, we have not paid any dividends to the holders of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business. Pursuant to the terms of the Series A Convertible Preferred Stock, dividends cannot be paid to the holders of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid.

Table of Contents

Corporate Performance Graph

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN

Among the NASDAQ Stock Market (U.S.),

The NASDAQ Pharmaceutical Index, the Russell 3000 Index

and Trovogene, Inc.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2013.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted- Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	4,158,359	\$ 5.24	1,788,921
Equity Compensation Plans Not Approved by Stockholders	129,186	\$ 3.15	
Total	4,287,545		

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

The following table sets forth our selected consolidated financial data and has been derived from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2013 and 2012, as well as consolidated statements of operations for the years ended December 31, 2013, 2012 and 2011, and the reports thereon are included elsewhere in this Annual Report on Form 10-K. The information should be read in conjunction with our audited consolidated financial statements and the notes to such statements, included below in Item 8, and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7. Historical results are not necessarily indicative of the results to be expected in the future.

	Year ended December 31,				
	2013	2012	2011	2010	2009
	(in thousands, except for share and per share data)				
Consolidated Statement of Operations Data:					
Revenues	\$ 259	\$ 450	\$ 258	\$ 266	\$ 654
Costs and Expenses:					
Research and development	3,948	1,920	911	1,024	562
Purchased in-process research and development				2,667	
General and administrative	7,002	3,379	2,324	1,954	1,661
Loss from operations	(10,691)	(4,849)	(2,977)	(5,379)	(1,569)
(Loss) gain on disposal of equipment	(23)	4			
Net interest income (expense)	(13)		(56)	(116)	(161)
Change in fair value of derivative instruments-warrants	(1,084)	(6,721)	171	267	273
Amortization of deferred debt costs and original issue discount				(221)	(203)
Gain on extinguishment of debt			623		
Liquidated damages and other forbearance agreement settlement costs					(824)
Net loss and comprehensive loss	(11,811)	(11,566)	(2,239)	(5,449)	(2,484)
Preferred stock dividend	(30)	(38)	(38)	(38)	(38)
Net loss and comprehensive loss attributable to common stockholders	(11,841)	(11,604)	(2,277)	(5,487)	(2,522)
Net loss per common share, basic and diluted	\$ (0.70)	\$ (0.89)	\$ (0.23)	\$ (0.77)	\$ (0.49)
Weighted average common shares outstanding *	16,978,212	13,066,600*	9,711,519*	7,158,791*	5,196,385

(*) Weighted average share outstanding reflects retroactive change of a one for 6 (1:6) reverse stock split effective on May 29, 2012

	December 31,				
	2013	2012	2011	2010	2009
	(\$ in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 25,837	\$ 10,820	\$ 700	\$ 59	\$ 545
Working capital	24,060	10,318	(588)	(3,137)	(2,557)

Edgar Filing: Trovagene, Inc. - Form 10-K

Total assets		27,156		11,665		1,039		512		762
Total stockholders' equity (deficit)	\$	20,392	\$	2,169	\$	(4,231)	\$	(4,995)	\$	(3,787)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

The information in this report contains forward-looking statements. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These forward-looking statements can be identified by the use of words such as believes, estimates, could, possibly, probably, anticipates, projects, expects, may, will, or should or other variations or similar words. No assurances can be given that the future results anticipated by the forward-looking statements will be achieved. Forward-looking statements reflect management's current expectations and are inherently uncertain. Our actual results may differ significantly from management's expectations.

Table of Contents

The following discussion and analysis should be read in conjunction with our financial statements, included herewith. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any conclusion reached herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best present assessment of our management.

Overview

We are a development stage molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. Our primary focus is in the field of oncology, and the management of cancer treatment. Our goal is to improve treatment outcomes for cancer patients using our proprietary technology to detect and quantitatively monitor cell-free DNA in urine as a marker of disease.

From August 4, 1999 (inception) through December 31, 2013, we have sustained a cumulative total deficit of \$67,043,410. From inception through December 31, 2013, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities. During 2013, we advanced our business with the following activities:

- Made available the first urine-based cancer mutation monitoring test through our CLIA laboratory. The highly sensitive assay is designed to detect the BRAF V600E mutation from cell-free DNA in urine. This mutation commonly occurs in melanoma, as well as several other prevalent cancer types.
- Announced the commercial availability of our urine-based human papillomavirus (HPV) test, which we plan to license to marketing partners on a global basis.
- Continued to file and maintain our patent portfolio and issued new patents including a broad microRNA patent covering methods of detecting and quantitating cell-free microRNA in urine and blood.
- Expanded our clinical collaboration with the University of Texas MD Anderson Cancer Center to include the detection of transrenal BRAF mutations in the urine of patients with advanced or metastatic cancers.
- Entered into a collaboration with USC Norris Cancer Center to conduct a clinical study evaluating our oncogene mutation monitoring technology.

Edgar Filing: Trovogene, Inc. - Form 10-K

- Announced a collaboration with a pharmaceutical company to evaluate our proprietary urine-based cell-free DNA technology for the detection of certain epidermal growth factor receptor (EGFR) mutations associated with lung cancer. The collaboration focuses on detecting and monitoring oncogene mutations in patients in clinical studies for drug development.
- Released early data from a clinical study with MD Anderson Cancer Center demonstrating that our novel, non-invasive oncogene mutation detection technology can be a clinically useful cancer-monitoring tool. During the study, urine samples from metastatic cancer patients known to have BRAF V600E, KRAS G12D, or KRAS G12V mutations were assessed and researchers observed a high concordance between the urine and tissue mutational status. In addition, preliminary results indicated that cell-free BRAF V600E mutation monitoring in urine correlates to clinical response to therapy. This research suggests that our novel urine-based assays have potentially strong clinical utility and may prove to be useful tools for monitoring therapeutic response.
- Signed a Clinical Study Agreement with US Oncology Research, one of the largest community-based research programs in the United States, to examine the utility of quantitative urine-based KRAS mutation detection and monitoring in pancreatic cancer patients. In addition to the 11 US Oncology Research affiliated community cancer care sites participating in this study, academic research institutions that specialize in oncology have also elected to participate.
- On January 25, 2013 we filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for

Table of Contents

common stock or preferred stock or other securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, we entered into an agreement with Cantor Fitzgerald & Co. (Agent) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds. Under the agreement with the Agent, we have received approximately \$4.2 million from the sale of 488,476 shares of our common stock during 2013.

- In July 2013 we received gross proceeds of approximately \$15.0 million from the sale of 2,142,857 shares of our common stock through a registered direct offering.

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.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 8. Financial Statements *Note 2 Basis of Presentation and Summary of Significant Accounting Policies*. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. We believe that the following discussion represents our critical accounting policies.

Milestone, Royalty and License Revenues

We license and sublicense our patent rights to healthcare companies, medical laboratories and biotechnology partners. These agreements may involve multiple elements such as license fees, royalties and milestone payments. Revenue is recognized for each element when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

- Up-front nonrefundable license fees pursuant to agreements under which we have no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is reasonably assured.
- Minimum royalties are recognized as earned, and royalties in excess of minimum amounts are recognized upon receipt of payment when collection is assured.

- Milestone payments are recognized when both the milestone is achieved and the related payment is received.

Diagnostic Service Revenues

Revenue for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, bill third-party payors for testing.

Diagnostic services revenues earned by us will be recognized upon receipt of payment when collection is assured due to the lack of contractual reimbursement agreements with third-party payors for a significant portion of our services and limited collections experience.

We have not recognized any revenue for our clinical laboratory tests to date.

Table of Contents

Derivative Financial Instruments-Warrants

Our derivative liabilities are related to warrants issued in connection with financing transactions and are therefore not designated as hedging instruments. All derivatives are recorded on our balance sheet at fair value in accordance with current accounting guidelines for such complex financial instruments.

We have issued common stock warrants in connection with the execution of certain equity and debt financings. Such warrants are classified as derivative liabilities under the provisions of FASB ASC 815 *Derivatives and Hedging* (ASC 815), and are recorded at their fair market value as of each reporting period. Such warrants do not meet the exemption that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of derivative instruments."

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus use model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820. At December 31, 2013 and 2012, the fair value of such warrants was \$4,431,871 and \$6,252,760, respectively, which are included in the derivative financial instruments liability on our balance sheet.

We issued units that were price protected during the year ended December 31, 2012. Based upon our analysis of the criteria contained in ASC Topic 815-40, we have determined that these price protected units issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of these price protected units at issuance was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which unit holders are likely to exercise their warrants and the expected forfeiture rate. We use historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. At December 31, 2013 and 2012, the fair value of such price protected units was \$0 and \$2,512,868, respectively, which are included in the derivative financial instruments liability on our balance sheet.

At December 31, 2013 and 2012, the total fair value of all warrants and price protected units, valued using the Black-Scholes option-pricing model at December 31, 2013 and both the Black-Scholes option-pricing model and the Binomial option pricing model at December 31, 2012 was \$4,431,871 and \$8,765,628, respectively, which we classified as derivative financial instruments liability on our balance sheet.

Research and Development

Research and development costs, which include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, clinical samples as well as clinical collaborators and insurance, are accounted for in accordance with ASC Topic 730-10-55-2, *Research and Development*. Also, as prescribed by this guidance, patent filing and maintenance expenses are considered legal in nature and therefore classified as general and administrative expense. We are providing the following summary of our research and

Edgar Filing: Trovogene, Inc. - Form 10-K

development expenses to supplement the more detailed discussions under results of operations. Costs are not allocated to projects as the majority of the costs relate to employees and facilities costs and we do not track employees' hours by project or allocate facilities costs on a project basis.

	For the years ended December 31,			August 4, 1999
	2013	2012	2011	(Inception) to December 31, 2013
Salaries and staff costs	\$ 2,063,474	\$ 950,861	\$ 468,893	\$ 12,790,908
Outside services, consultants and lab supplies	1,301,190	594,342	283,350	4,543,692
Facilities	466,138	352,920	137,793	3,417,751
Other	116,787	22,175	20,649	644,689
Total Research and Development	\$ 3,947,589	\$ 1,920,298	\$ 910,685	\$ 21,397,040

While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have no history of successful commercialization of molecular diagnostic products to base any estimate of the number of future periods that would be benefited.

Table of Contents

ASC Topic 730, *Research and Development* requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. There are no non-refundable advance payments that are deferred and capitalized as of December 31, 2013 and 2012.

Stock-based Compensation

We rely heavily on incentive compensation in the form of stock options to recruit, retain and motivate directors, executive officers, employees and consultants. Incentive compensation in the form of stock options and warrants are designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage.

Stock-based compensation expense for employees and directors is recognized in the statement of operations based on estimated amounts, including the grant date fair value and the expected service period. For stock options, we estimate the grant date fair value using a Black-Scholes model. Share-based compensation recorded in our statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. We recognize the value of the awards on a straight-line basis over the awards' requisite service periods. The requisite service period is generally the time over which our share-based awards vest.

We account for equity instruments granted to non-employees in accordance with ASC Topic 505-50 *Equity-Based Payment to Non-Employees* where the value of the share-based compensation is based upon the measurement date as determined at either: a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

Fair value of financial instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, debt and derivative liabilities. We have adopted FASB ASC 820 *Fair Value Measurements and Disclosures* (ASC 820) for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. These financial instruments are stated at their respective historical carrying amounts which approximate to fair value due to their short term nature as they reflect current market interest rates. Debt is stated at its respective historical carrying amounts which approximates fair value as they reflect current market interest rates.

ASC 820 provides that the measurement of fair value requires the use of techniques based on observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. The inputs create the following fair value hierarchy:

- Level 1 Quoted prices for identical instruments in active markets.

- Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.

- Level 3 Instruments where significant value drivers are unobservable to third parties.

Off-Balance Sheet Arrangements

We do not believe that we have any off-balance sheet arrangements.

Inflation

It is our opinion that inflation has not had a material effect on our operations.

Table of Contents**Recent Accounting Pronouncements**

See Note 2 to the Notes to Financial Statements in Item 8 below for further discussion of recent accounting pronouncements.

Results of Operations**YEARS ENDED DECEMBER 31, 2013 AND 2012***Revenues*

Our total revenues were \$259,246 and \$450,404 for the years ended December 31, 2013 and 2012, respectively. Total revenues consisted of the following:

	2013	For the years ended December 31,		
		2012		(Decrease)/Increase
Royalty income	\$ 259,246	\$ 175,404	\$	83,842
Milestone		150,000		(150,000)
License fees		125,000		(125,000)
Total revenues	\$ 259,246	\$ 450,404	\$	(191,158)

Royalty income increased by \$83,842 in the year ended December 31, 2013 as a result of more royalty bearing agreements in 2013 compared to the same period in 2012 and more royalty payments earned in excess of minimum royalty payments in the current year compared to the year ended December 31, 2012. In accordance with our revenue recognition policy, we do not record royalty revenues in excess of minimum royalty amounts until we have received the payment.

There were no milestone payments received during the year ended December 31, 2013. During the prior year, we received a \$150,000 payment related to a milestone achievement with Ipsogen SAS.

There were no license fees earned during the year ended December 31, 2013. License fees in 2012 resulted from the signing of a new license agreement with Quest Diagnostics.

Edgar Filing: Trovogene, Inc. - Form 10-K

We expect our royalty income to fluctuate as the royalties are based on the portion of our partners' revenues earned utilizing the patents they have licensed from us. Milestone and license fee revenues are difficult to predict and can vary significantly from period to period. In addition, we expect to have revenues from our diagnostics tests in future periods, but as the revenue recognition will be based on cash receipts, the timing of these revenues are also uncertain.

Research and Development Expenses

Research and development expenses increased by \$2,027,291 to \$3,947,589 for the year ended December 31, 2013 from \$1,920,298 for the same period in 2012. Substantially all of the increase resulted from the expansion of our research and development efforts as we began commercialization, increased the average number of our internal research and development personnel from four to nine, and purchased additional laboratory equipment to support the clinical collaborations we have entered into related to validating our tests to detect certain types of cancer in urine samples. We also established a clinical advisory board during the year ended December 31, 2013.

Research and development expenses consisted of the following:

	For the years ended December 31,		
	2013	2012	Increase
Salaries and staff costs	\$ 2,063,474	950,861	\$ 1,112,613
Outside services, consultants and lab supplies	1,301,190	594,342	706,848
Facilities	466,138	352,920	113,218
Travel and scientific conferences	95,400	18,407	76,993
Other	21,387	3,768	17,619
Total research and development	\$ 3,947,589	\$ 1,920,298	\$ 2,027,291

Table of Contents

To date our costs have related to validating our tests and supporting existing collaborations. These costs are expected to increase as we expand current collaborations or enter into new collaborations and as we engage in research and development in areas other than detection of cancer in urine samples.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$3,622,936 to \$7,002,198 for the year ended December 31, 2013 from \$3,379,262 for the same period in 2012. This increase was primarily due to the building of our sales, marketing and business development infrastructure in preparation for commercial expansion of our diagnostics products. We have two commercially available tests as of December 31, 2013. We have increased our average internal headcount in these functional areas from two to five. In addition, continued patent filing and maintenance as well as the costs associated with being a publicly traded company, such as additional costs for insurance, NASDAQ fees and Sarbanes-Oxley compliance have added to our general and administrative expenses in comparison to the same period of the prior year.

Selling, general and administrative expenses consisted of the following:

	For the years ended December 31,		
	2013	2012	Increase
Salaries and staff costs	\$ 2,424,843	707,156	1,717,687
Outside services and Board of Director fees	2,498,075	1,552,227	945,848
Legal and accounting fees	1,008,857	663,281	345,576
Facilities and insurance	346,572	238,798	107,774
Marketing	245,466	59,065	186,401
Travel	268,225	83,875	184,350
Fees, licenses, taxes and other	210,160	74,860	135,300
	\$ 7,002,198	\$ 3,379,262	\$ 3,622,936

We expect our general and administrative expenses to increase as we expand commercialization of our current diagnostic tests and future tests. In addition, at times, due to the use of options and warrants for compensation of services, stock based compensation expenses can vary significantly as the expense is based on assumptions in place at the measurement date of the award.

Interest Expense

Interest expense was \$17,005 for the year ended December 31, 2013, while there was no interest expense incurred during the year ended December 31, 2012. The increase results from the \$1.0 million equipment line of credit agreement we entered into in June 2013. We expect interest expense to increase as we utilize the entire line of credit.

Change in Fair Value of Derivative Instruments - Warrants

The change in fair value of derivative instruments resulted in a \$1,084,114 loss in the year ended December 31, 2013 compared to a loss of \$6,720,805 in the same period of the prior year. The loss decreased as a result of a July 2013 closing of a public offering which removed the price protection feature that required 1,288,650 warrants to be treated as derivative liabilities and resulted in a reclassification of \$5,417,871 from derivative liability to additional paid in capital, and therefore no longer subject to changes in fair value. In addition, as of December 31, 2013, the remaining derivative liabilities related to warrants issued that are not price protected were revalued to \$4,431,871, based upon the change in our stock price from \$6.93 at December 31, 2012 to \$5.74 at December 31, 2013 and the changes in the expected term and risk free interest rates for the expected term, resulting in a decrease in value of \$1,820,888 from December 31, 2012. The decrease in value was recorded as non-operating gain for the year ended December 31, 2013, partially offsetting \$2,905,003 of non-operating losses recorded on the price protected warrants prior to the reclassification of the related derivative liability to additional paid in capital.

Net Loss

Net loss and per share amounts were as follows:

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

	For the years ended December 31,	
	2013	2012
Net loss and comprehensive loss attributable to common shareholders	\$ (11,840,778)	\$ (11,604,201)
Net loss per common share: basic and diluted	\$ (0.70)	\$ (0.89)
Weighted average shares: basic and diluted	16,978,212	13,066,600

The \$236,577 increase in net loss and comprehensive loss attributable to common shareholders for the year ended December 31, 2013 compared to the year ended December 31, 2012, resulted primarily from an increase in operating expenses offset in part by a decrease in the loss in the change in fair value of derivative instruments. Net loss per share decreased by \$0.19 to \$0.70 as a result of an increase in weighted average shares outstanding- both basic and diluted. Weighted average shares outstanding increased for the year ended December 31, 2013 due to the issuance of 3.4 million shares of common stock during the year as a result of public offering in July 2013, controlled equity offerings, and exercise of warrants and stock options during the year ended December 31, 2013.

YEARS ENDED DECEMBER 31, 2012 AND 2011

Revenues

Our total revenues were \$450,404 and \$257,696 for the years ended December 31, 2012 and 2011, respectively. Total revenues consisted of the following:

	2012	Years ended December 31, 2011	(Decrease)/Increase
Royalty income	\$ 175,404	\$ 227,696	\$ (52,292)
Milestone	150,000		150,000
License fees	125,000	30,000	95,000
Total revenues	\$ 450,404	\$ 257,696	\$ 192,708

Royalty income decreased by \$52,292 in the year ended December 31, 2012, primarily due to the termination of the license agreement with Sequenom, Inc. in late 2011. A milestone payment of \$150,000 in 2012 was received upon achievement of a milestone with Ipsogen SAS during 2012. License fees increased by \$95,000 in the year ended December 31, 2012 as there were more license agreements entered into during the year ended December 31, 2012 as compared to the same period in 2011.

Research and Development Expenses

Research and development expenses consisted of the following:

Edgar Filing: Trovogene, Inc. - Form 10-K

	For the years ended December 31,		
	2012	2011	Increase
Salaries and staff costs	\$ 950,861	468,893	\$ 481,968
Outside services, consultants and lab supplies	594,342	283,350	310,992
Facilities	352,920	137,793	215,127
Other	22,175	20,649	1,526
Total research and development	\$ 1,920,298	\$ 910,685	\$ 1,009,613

Research and development expenses increased by \$1,009,613 to \$1,920,298 for the year ended December 31, 2012 from \$910,685 for the same period in 2011. The \$481,968 increase in salaries and staff costs was comprised primarily of an increase of approximately \$160,000 related to the addition of personnel for our CLIA lab operations, \$170,000 increase from two new personnel added in 2012 as well as bonuses paid to existing personnel and accrued for a new bonus plan in 2012, and an increase of approximately \$126,000 in stock based compensation related to options granted to research and development personnel. Of the \$310,992 increase in outside services, consultants and lab supplies, approximately \$124,000 resulted from the start-up of our CLIA lab in February 2012, an increase of \$32,000 related to consultants primarily working on cancer projects, an \$111,000 increase in lab supplies purchased to support new projects, and \$32,000 related to an increase in research collaborations. The increase in facilities expense is comprised of approximately \$159,000 additional rent, maintenance, utilities, insurance and depreciation expenses related primarily to the addition and upgrade of the CLIA lab, and the remainder of the increase related to the expansion of our laboratory space at the end of 2011.

Table of Contents**General and Administrative Expenses**

General and administrative expenses consisted of the following:

	For the years ended December 31,		
	2012	2011	Increase/(Decrease)
Salaries and staff costs	\$ 925,166	524,514	400,652
Outside services and Board of Director fees	1,334,216	553,572	780,644
Legal and accounting fees	663,281	949,741	(286,460)
Facilities	155,069	115,321	39,748
Insurance	83,729	85,822	(2,093)
Other	217,801	94,844	122,957
	\$ 3,379,262	\$ 2,323,814	\$ 1,055,448

General and administrative expenses increased by \$1,055,448 to \$3,379,262 for the year ended December 31, 2012 from \$2,323,814 for the same period in 2011. The increase in salaries and staff costs consisted of an increase in salaries of approximately \$129,000 related to the addition of four personnel in 2012, an increase in accrued bonuses of approximately \$282,000 based on the 2012 bonus plan and an increase of approximately \$154,000 in stock based compensation, partially offset by a decrease of approximately \$157,000 in employment severance agreements. The increase in outside services resulted primarily from approximately \$165,000 of stock based compensation related to warrant and stock issuances for advisory and public relations services, approximately \$427,000 from the addition of our Chief Executive Officer and Chief Financial Officer in late 2011, as well as services provided by outside business development, investor relations, and finance individuals, an increase of \$104,000 related to public relations and an increase of \$62,000 in EDGAR and XBRL expenses associated with SEC filings. Legal and accounting fees decreased in the year ended December 31, 2012 compared to the prior year, as services related to assisting us with SEC compliance decreased as a result of completing our Form 10 early in 2012. Facilities expenses increased as a result of \$19,000 increase in rent and maintenance due to additional space, \$13,000 increase in office supplies related to new employees, and an \$8,000 increase in depreciation expense. The increase in other expenses resulted primarily from additional travel costs of approximately \$64,000, an increase in marketing expenses of approximately \$56,000 due to preparation for commercialization, approximately \$32,000 related to Delaware franchise taxes, slightly offset by a decrease in miscellaneous items.

Interest Expense

There was no interest expense in the year ended December 31, 2012 compared to \$56,636 in the same period of 2011. The interest expense in the year ended December 31, 2011 related to convertible debentures that were extinguished in July 2011.

Change in Fair Value of Derivative Instruments - Warrants

The change in fair value of derivative instruments resulted in a \$6,720,805 loss in the year ended December 31, 2012 compared to a gain of \$170,673 in the same period of the prior year. We issued securities that were accounted for as derivative liabilities at issuance during the years ended December 31, 2012 and 2011. On May 30, 2012 we closed an underwritten public offering that removed the condition that required the securities issued during the nine months ended September 30, 2012, as well as certain securities issued in prior periods, to be treated as derivative liabilities. Accordingly, the fair value of these securities of \$3,317,463 was reclassified from a liability to additional paid in capital.

Edgar Filing: Trovogene, Inc. - Form 10-K

During the quarter ended December 31, 2012, we issued additional securities that were accounted for as derivative liabilities at issuance. As of December 31, 2012, the remaining derivative liabilities were revalued to \$8,765,628, resulting in a net increase in value of \$6,720,805 from December 31, 2011, based primarily upon changes in the fair value as a result of the underwritten public offering and the increase in the fair value of our common stock at December 31, 2012.

Gain on Extinguishment of Debt

There was no gain on extinguishment of debt in year ended December 31, 2012, compared to \$623,383 in the same period of 2011. The amount in 2011 resulted from the settlement with the holders of convertible debentures as a result of conversion of the amount owed into shares of Common Stock as consideration for their agreement to extinguish the debt.

Net Loss

Net loss and per share amounts were as follows:

Table of Contents

	For the years ended December 31,	
	2012	2011
Net loss and comprehensive loss attributable to common shareholders	\$ (11,604,201)	\$ (2,277,452)
Net loss per common share: basic and diluted	\$ (0.89)	\$ (0.23)
Weighted average shares: basic and diluted	13,066,600	9,711,519

The \$9,326,749 increase in net loss and \$0.66 increase in net loss per share in 2012 compared to 2011 reflected a slight increase in revenues, more than offset by an increase in operating expenses and a loss from the change in fair value in derivative liabilities. Net loss per share in 2012 was also favorably impacted by the sale and issuance of 4.4 million shares of common stock and approximately 349,000 common shares issued for services and acquisition of assets.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2013, we had \$25,836,937 in cash and cash equivalents. Net cash used in operating activities for the year ended December 31, 2013 was \$7,317,248, compared to \$4,934,661 for the year ended December 31, 2012. Our use of cash was primarily a result of the net loss of \$11,810,938 for the year ended December 31, 2013, adjusted for non-cash items related to stock-based compensation of \$2,178,155, depreciation and amortization of \$130,520 and the loss from the change in fair value of derivatives of \$1,084,114. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses and prepaid expenses, and a decrease in accounts receivable and other assets. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years.

Investing activities consisted of purchases for capital equipment that used \$649,284 in cash during the year ended December 31, 2013, compared to \$270,080 for the same period in 2012. We expect to invest approximately \$800,000 in capital equipment over the next year. The investment will be predominantly for laboratory equipment.

Net cash provided by financing activities was \$22,983,688 during the year ended December 31, 2013, compared to \$15,324,148 during the year ended December 31, 2012. Financing activities during the year ended December 31, 2013 included \$18,829,644 from the sales of common stock, \$3,638,080 from proceeds related to the exercise of warrants and options, and \$515,964 from borrowings on equipment lines, while in 2012 the net cash provided by financing activities was from proceeds received related to the sale of common stock.

As of December 31, 2013 and 2012, we had working capital of \$24,059,854 and \$10,317,833, respectively. The increase in working capital is due to the increase in cash provided by financing activities. As of February 28, 2014, our working capital was \$22,408,822.

Our working capital requirements will depend upon numerous factors including but not limited to the nature, cost and timing of our research and development programs. We believe that we have sufficient cash and cash equivalents to fund our operations for at least the next twelve months. We do not anticipate that our existing working capital alone will be sufficient to fund our operations through the successful development and commercialization of products we develop. As a result, we will need to raise additional capital to fund our operations and continue to conduct activities to support our product development and commercialization. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures and debt borrowings. We cannot be certain that additional funding will be available on acceptable terms, or at

Edgar Filing: Trovogene, Inc. - Form 10-K

all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more of product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Our consolidated financial statements as of December 31, 2013 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our December 31, 2013 consolidated financial statements that included an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Table of Contents*Public Offering and Controlled Equity Offering*

On January 25, 2013 we filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, we entered into an agreement with Cantor Fitzgerald & Co. (Agent) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for their services, the Agent is entitled to a 3% commission on gross proceeds.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table is a summary of contractual obligations for the periods indicated that existed as of December 31, 2013, and is based on information appearing in the notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

(dollars in thousands)

	Total	Less than 1 Year	1-2 Years	3-5 Years	More than 5 Years
Operating leases	\$ 946,319	\$ 227,541	\$ 467,923	\$ 250,855	\$
Research agreements	662,355	662,355			
Long-term debt	521,164	198,166	322,998		
Purchase obligations - major vendors(1)	465,606	345,606	120,000		
Total obligations	\$ 2,595,444	\$ 1,433,668	\$ 910,921	\$ 250,855	\$

(1) Represents amounts that will become due upon future delivery of supplies and services from various suppliers under open purchase orders as of December 31, 2013.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*Interest Rate Risk*

Edgar Filing: Trovogene, Inc. - Form 10-K

Our cash and cash equivalent primary consists of securities issued by the U.S. government, deposits, and money market deposits managed by commercial banks. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term money marketable funds. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, a sudden change in interest rates would not have a material effect on the fair market value of our portfolio, nor our operating results or cash flows.

Recently, there has been concern in the credit markets regarding the value of a variety of mortgage-backed and auction rate securities and the resulting effect on various securities markets. We do not hold any auction rate securities. We do not believe our

Table of Contents

cash, and cash equivalents investments have significant risk of default or illiquidity, however, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits. Given the current instability of financial institutions, we cannot provide assurance that we will not experience losses on these deposits.

Foreign Currency Risk

We have no operations outside the U.S. and do not hold any foreign currency denominated financial instruments.

Effects of Inflation

We do not believe that inflation and changing prices during the years ended December 31, 2013, 2012 and 2011 had a significant impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

All financial information required by this Item is attached hereto at the end of this report beginning on page F-1 and is hereby incorporated by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the

Edgar Filing: Trovogene, Inc. - Form 10-K

SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, as of December 31, 2013, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2013, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 1992. Based on this assessment, our management concluded that, as of December 31, 2013, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Table of Contents

Changes in Internal Control

As required by Rule 13a-15(d) and Rule 15d-15(b) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the period covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The material weaknesses that were identified during management's assessment as of December 31, 2012 included an ineffective control environment and ineffective monitoring of controls over financial reporting. During the period covered by this Annual Report on Form 10-K, management, in coordination with the input, oversight and support of our Audit Committee, implemented the following internal controls to remediate our material weaknesses in our internal control over financial reporting:

(1) *Control Environment*

- We implemented an anti-fraud program designed to detect and prevent fraud that included:
- The issuance of a whistle-blower policy, ensuring every new employee signs a statement acknowledging and understanding our whistle-blower policy.
- Quarterly monitoring of any whistle-blower reports by the Chairman of our Audit Committee in conjunction with our outside counsel.
- Providing a direct channel of communication to the Chairman of our Audit Committee for any whistle-blowers to utilize.

(2) *Monitoring of Internal Control Over Financial Reporting*

- We hired additional personnel and consultants to ensure an appropriate level of accounting knowledge, experience, and training in the application of Generally Accepted Accounting Principles (GAAP) commensurate with our financial reporting requirements and business environment. These additional personnel and consultants enabled the following:
- The design and documentation of our policies and procedures with respect to the review, supervision and monitoring of our accounting operations.
- The creation and maintenance of an effective internal control monitoring function. Specifically, the documentation of our policies and procedures were monitored to determine the adequacy of our internal control over financial reporting and ongoing effectiveness through the entire year.

Table of Contents

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Trovagene, Inc.

San Diego, California

We have audited Trovagene, Inc. and Subsidiaries (a development stage company) (Trovagene) internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Trovagene's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting (Item 9A). Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Trovagene maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

Edgar Filing: Trovogene, Inc. - Form 10-K

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Trovogene as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2013 and for the period from August 4, 1999 (inception) to December 31, 2013 and the related statement of stockholders' equity (deficit) for the period from August 4, 1999 (inception) to December 31, 2013 and our report dated March 17, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

New York, New York
March 17, 2014

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

EXECUTIVE OFFICERS, DIRECTORS AND KEY EMPLOYEES

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each as of March 17, 2014.

Name	Age	Position
Thomas H. Adams, Ph.D.	71	Chairman of the Board
Antonius Schuh, Ph.D.	50	Chief Executive Officer and Director
Steve Zaniboni	56	Chief Financial Officer
John Brancaccio	66	Director
Gary S. Jacob	67	Director
Dr. Paul Billings	61	Director
Dr. Stanley Tennant	62	Director
Dr. Rodney S. Markin	57	Director

All directors hold office until the next annual meeting of stockholders and the election and qualification of their successors. Officers are elected annually by the board of directors and serve at the discretion of the board.

Executive Biographies

Edgar Filing: Trovogene, Inc. - Form 10-K

The principal occupations for the past five years (and, in some instances, for prior years) of each of our directors and executive officers are as follows:

Thomas H. Adams. Thomas H. Adams has been our Chairman of the Board since April 2009. Since June 2005 through 2011, Dr. Adams served as a director of IRIS International, Inc., a diagnostics company, and as Chief Technology Officer of IRIS from April 2006. Until November 2012, Dr. Adams was the Head of Iris Molecular Diagnostics since 2006 and the President of Iris

Table of Contents

Personalized Medicine since 2011. In November 2012, IRIS was acquired by Danaher Corporation. Dr. Adams served as Chairman and Chief Executive Officer of Leucadia Technologies, a privately held medical-device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly held biotechnology company in the field of antisense technology, and served as its Chief Executive Officer until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its Chief Executive Officer and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Dr. Adams is currently a director of Synergy Pharmaceuticals Inc., a biotechnology company. Dr. Adams holds a Ph.D. in Biochemistry from the University of California, at Riverside. Dr. Adams' executive leadership, particularly in the diagnostic field, and the extensive healthcare expertise he has developed qualifies Dr. Adams to serve as a director of our company.

Antonius Schuh. Antonius Schuh joined us in October 2011 as our Chief Executive Officer and was elected as a Director in December 2011. Since 2013, Dr. Schuh has served as Executive Director of Gensignia, Inc., a lung cancer diagnostics company. Dr. Schuh co-founded Sorrento Therapeutics, Inc., a biopharmaceutical company developing monoclonal antibodies, in January 2006. He served as Chairman of the Board and Chief Executive Officer of Sorrento from November 2008 to April 2011. From April 2006 to September 2008, Dr. Schuh served as Chief Executive Officer of AviraDx (now bioTheranostics, Inc., a bioMerieux company), a molecular diagnostic testing company that is focused on clinical applications in oncology. Since March 2009, Dr. Schuh has been a director of Diogenix, Inc., a privately held molecular diagnostic company, and since May 2009, he has served as a director of Transgenomic, Inc., a public biotechnology company focused on genetic analysis and molecular diagnostics. Dr. Schuh is a certified pharmacist and earned his Ph.D. in pharmaceutical chemistry from the University of Bonn, Germany.

Stephen Zaniboni. Stephen Zaniboni joined us as Chief Financial Officer in January 2012. Prior to joining us, since June 2010, Mr. Zaniboni has served as Chief Financial Officer of Awarepoint Corporation, a leading provider of healthcare software. Since 2013, Mr. Zaniboni has also served as Chief Financial Officer of Gensignia, Inc., a lung cancer diagnostics company. Prior to joining Awarepoint Corporation, Mr. Zaniboni served as Chief Financial Officer of XIFIN Inc., the leading provider of revenue cycle management for diagnostic service providers, from January 2009 through June 2010. Prior to joining XIFIN Inc. Mr. Zaniboni served as the Chief Financial Officer of Sorrento Therapeutics, Inc. from January 2006, and as a member of its board of directors from November 2008, through September 2009. From May 2006 to September 2008, Mr. Zaniboni served as Chief Financial Officer of AviraDx (now bioTheranostics, a bioMerieux company), a molecular diagnostic testing cancer profiling company that is focused on developing and commercializing molecular diagnostic technologies with proven clinical utility. Mr. Zaniboni has also held various financial management positions at Aspect Medical Systems, Behring Diagnostics, and Boston Scientific. He was a practicing CPA with Arthur Andersen and holds a B.S. in accounting from Boston University and an M.B.A. from Boston College.

John Brancaccio. John Brancaccio, a retired CPA, has served as a director of our company since December 2005. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio is currently a director of Tamir Biotechnology, Inc. (formerly Alfacell Corporation) as well as a director of Synergy Pharmaceuticals Inc. and ContraVir Pharmaceuticals, Inc., a subsidiary of Synergy. Mr. Brancaccio's chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as a director of our company.

Gary S. Jacob. Gary S. Jacob has served as a director of our company since February 2009. Since July 2008, Dr. Jacob has been President, Chief Executive Officer and a Director of Synergy Pharmaceuticals Inc. and Chairman since September 2013. Dr. Jacob has also been Chief Executive Officer and a director of ContraVir Pharmaceuticals, Inc. since May 2013. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob's broad management expertise in the pharmaceutical and biotechnology industries provides relevant experience in a number of strategic and operational areas and led to the Board's conclusion that he should serve as a director of our company.

Edgar Filing: Trovogene, Inc. - Form 10-K

Dr. Paul Billings. Paul Billings, MD, PhD was appointed to our Board in October 2013 and has been a member of our Scientific Advisory Board since November 2012. Dr. Billings is a board certified internist and clinical geneticist, and currently serves as Chief Medical Officer at Life Technologies Corporation. Dr. Billings has extensive healthcare experience in many aspects of genomics and molecular medicine. In addition to serving as Chief Medical Officer at Life Technologies, he also serves on the Scientific Advisory Board of the Food and Drug Administration, the Genomic Medicine Advisory Committee at the Department of Veterans Affairs, and the National Academy of Sciences Institute of Medicine's Roundtable on Genomics. In addition to Trovogene, he serves as an advisor or director for many companies including Omicia, BioScale, Applied Immunology, Aueon and PAX Neurosciences. Dr. Billings holds an M.D. from Harvard Medical School and a Ph.D. in immunology, also from Harvard University. Dr. Billings' medical and managerial experience in the diagnostic field qualifies him to serve as a director of our company.

Dr. Stanley Tennant. Dr. Tennant has served as a director of our company since December 2010. Since 1983, Dr Tennant has been a cardiologist in Greensboro, NC. He graduated from Wake Forest University School of Medicine in 1978 and completed postgraduate

Table of Contents

training in Internal Medicine and Cardiology at Vanderbilt University in 1983. Dr. Tennant's practical experience in the healthcare field led to the Board's conclusion that he should serve as a director of our company.

Dr. Rodney S. Markin. Dr. Markin has been a director of our company since February 2014. Dr. Markin is Chief Technology Officer and Associate Vice Chancellor for Business Development at the University of Nebraska Medical Center and a Professor of Pathology and Microbiology; David T. Purtilo Distinguished Professor Pathology and Microbiology and Courtesy Professor of Surgery. Dr. Markin is also a director on the Board of Children's Hospital and Medical Center Foundation and on the Board of Trustees for Keck Graduate Institute. Dr. Markin is Chairman of the Board of Transgenomic, Inc., a biotechnology company. The Board selected Dr. Markin to serve as a director because he has valuable executive experience in the healthcare business.

Family Relationships

None.

Involvement in Certain Legal Proceedings

To our knowledge, during the last ten years, none of our directors, executive officers (including those of our subsidiaries), promoters or control persons have:

- had a bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- been convicted in a criminal proceeding or been subject to a pending criminal proceeding, excluding traffic violations and other minor offenses;
- been subject to any order, judgment or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities;
- been found by a court of competent jurisdiction (in a civil action), the Securities and Exchange Commission, or SEC, or the Commodities Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended or vacated; and

- been the subject to, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization, any registered entity, or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Board Leadership Structure and Role in Risk Oversight

Since April 2009, we have separated the roles of Chairman of the Board and Chief Executive Officer (CEO). Although the separation of roles has been appropriate for us during that time period, in the view of the board of directors, the advisability of the separation of these roles depends upon the specific circumstances and dynamics of our leadership.

As Chairman of the Board, Dr. Adams serves as the primary liaison between the CEO and the independent directors and provides strategic input and counseling to the CEO. With input from other members of the board of directors, committee chairs and management, he presides over meetings of the board of directors. Mr. Adams has developed an extensive knowledge of our company, its challenges and opportunities and has a productive working relationship with our senior management team.

The board of directors, as a unified body and through committee participation, organizes the execution of its monitoring and oversight roles and does not expect its Chairman to organize those functions. Our primary rationale for separating the positions of Board Chairman and the CEO is the recognition of the time commitments and activities required to function effectively as Chairman and as the CEO of a company with a relatively flat management structure. The separation of roles has also permitted the board of directors to recruit senior executives into the CEO position with skills and experience that meet the board of director s planning for the position who may not have extensive public company board experience.

The board of directors has three standing committees Audit, Compensation and Corporate Governance/Nominating. The membership of each of the board committees is comprised of independent directors, with each of the committees having a separate chairman, each of whom is an independent director. Our non-management members of the board of directors meet in executive session at each board meeting.

Table of Contents

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. Management is responsible for the day-to-day management of risks the company faces, while the board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The board of directors believes that establishing the right tone at the top and that full and open communication between executive management and the board of directors are essential for effective risk management and oversight. Our CEO communicates frequently with members of the board to discuss strategy and challenges facing the company. Senior management usually attends our regular quarterly board meetings and is available to address any questions or concerns raised by the board of directors on risk management-related and any other matters. Each quarter, the board of directors receives presentations from senior management on matters involving our areas of operations.

Director Independence

Our board of directors has determined that a majority of the board consists of members who are currently independent as that term is defined under current listing standards of NASDAQ. The board of directors considers Messrs. Adams, Jacob, Billings, Tennant, Markin and Brancaccio to be independent.

Audit Committee

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent registered public accountants, (ii) appointing, replacing and discharging the independent auditors, (iii) pre-approving the professional services provided by the independent auditors, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent auditors, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent auditors. The Audit Committee also prepares the Audit Committee report that is required pursuant to the rules of the SEC.

The Audit Committee currently consists of John P. Brancaccio, chairman of the Audit Committee, Dr. Gary S. Jacob, and Thomas Adams. Our board of directors has determined that each of Mr. Brancaccio, Dr. Jacob and Dr. Adams is independent as that term is defined under applicable SEC and NASDAQ rules. Mr. Brancaccio is our audit committee financial expert. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee.

Compensation Committee

The Compensation Committee has responsibility for assisting the board of directors in, among other things, evaluating and making recommendations regarding the compensation of the executive officers and directors of our company; assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy; producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC; periodically evaluating the terms and administration of our incentive plans

and benefit programs and monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

The Compensation Committee currently consists of Dr. Stanley Tennant, chairman of the Compensation Committee, Dr. Gary S. Jacob and John P. Brancaccio. Our board of directors has determined that all of the members are independent under the current listing standards of NASDAQ. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee.

Corporate Governance/Nominating Committee

The Corporate Governance/Nominating Committee has responsibility for assisting the board of directors in, among other things, effecting board organization, membership and function including identifying qualified board nominees; effecting the organization, membership and function of board committees including composition and recommendation of qualified candidates; establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive officers; development and evaluation of criteria for Board membership such as overall qualifications, term limits, age limits and independence; and oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the Board of Directors based on the criteria, skills and qualifications that have been recognized by the Corporate Governance/Nominating Committee. While our nomination and corporate governance policy does not prescribe specific diversity

Table of Contents

standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, difference in viewpoints and skills, and personal qualities that will result in a well-rounded Board of Directors.

The Corporate Governance/Nominating Committee currently consists of John Brancaccio, chairman of the Corporate Governance/Nominating Committee, Thomas Adams and Stanley Tennant. The Board of Directors has determined that all of the members are independent under the current listing standards of NASDAQ. The Board of Directors has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee.

Code of Ethics

We have adopted a formal Code of Business Conduct and Ethics applicable to all Board members, executive officers and employees. A copy of our Code of Business Conduct and Ethics will be provided free of charge upon request to: Secretary, Trovagene, Inc. 11055 Flintkote Avenue, San Diego, California 92121.

Compliance With Section 16(A) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during 2013, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with, except that Stanley Tennant, Gary Jacob, Thomas Adams, Gabriele Cerrone, Chris McGuigan and Stephen Zaniboni each filed one Form 4 late and Antonius Schuh filed two Form 4 s late.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation Committee Report

Under the rules of the SEC, this Compensation Committee Report is not deemed to be incorporated by reference by any general statement incorporating this Annual Report by reference into any filings with the SEC.

Edgar Filing: Trovogene, Inc. - Form 10-K

The Compensation Committee has reviewed and discussed the following Compensation Discussion and Analysis with management. Based on this review and these discussions, the Compensation Committee recommended to the Board of Directors that the following Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Submitted by the Compensation Committee

Dr. Stanley Tennant

John Brancaccio

Dr. Gary S. Jacob

Compensation Discussion and Analysis

Overview

We compete with many other medical diagnostic companies in seeking to attract and retain a skilled work force. To meet this challenge, we have developed our compensation structure to enable our management to make decisions regarding our compensation programs, to manage these programs, and to effectively communicate the goals of these programs to our employees and stockholders.

Our compensation philosophy is to offer our employees compensation and benefits that are competitive and that meet our goals of attracting, retaining and motivating highly skilled employees so that we can achieve our financial and strategic objectives.

Utilizing this philosophy, our compensation programs are designed to:

- be market-based and reflect the competitive environment for personnel;

Table of Contents

- stress our pay for performance approach to managing pay levels;
- share risks and rewards with employees at all levels;
- be affordable, within the context of our operating expense model;
- align the interests of our employees with those of our stockholders;
- reflect our values; and
- be fairly and equitably administered.

In addition, as we administer our compensation programs, we plan to:

- evolve and modify our programs to reflect the competitive environment and our changing business needs;
- focus on simplicity, flexibility and choice wherever possible;
- openly communicate the details of our programs with our employees and managers to ensure that our programs and their goals are understood; and
- provide our managers and employees with the tools they need to administer our compensation programs.

Elements of Our Compensation Program

Edgar Filing: Trovogene, Inc. - Form 10-K

As a total rewards package, we design our compensation program to enable us to attract and retain talented personnel. The individual elements of our compensation program serve to satisfy this larger goal in specific ways as described below.

We design base pay to provide the essential reward for an employee's work, and is required to be competitive in attracting talent. Once base pay levels are initially determined, increases in base pay are provided to recognize an employee's specific performance achievements. Consistent with our compensation philosophy, we implement a pay for performance approach that provides higher levels of compensation to individual employees whose results merit greater rewards. Our managers typically make performance assessments throughout the year, and provide ongoing feedback to employees, provide resources and maximize individual and team performance levels.

We design equity-based compensation, including stock options, to ensure that we have the ability to retain talent over a longer period of time, and to provide optionees with a form of reward that aligns their interests with those of our stockholders.

We also utilize various forms of variable compensation, including cash bonuses that allow us to remain competitive with other companies while providing upside potential to those employees who achieve outstanding results.

Core benefits, such as our basic health benefits, are designed to provide a stable array of support to employees and their families.

The four key elements of our compensation structure are:

- base pay;
- variable pay;
- equity-based pay; and
- benefits.

Consistent with our compensation philosophy, we have structured each element of our rewards package as follows:

Base Pay

Edgar Filing: Trovogene, Inc. - Form 10-K

We create a set of base pay structures that are both affordable and competitive in relation to the market. We continuously monitor base pay levels within the market and make adjustments to our structures as needed. In general, an employee's base pay level should

Table of Contents

reflect the employee's overall sustained performance level and contribution to our company over time. We seek to structure the base pay for our top performers to be aggressive in relation to the market.

Variable Pay

We design our variable pay programs to be both affordable and competitive in relation to the market. We monitor the market and adjust our variable pay programs as needed. Our variable pay programs, such as our bonus program, are designed to motivate employees to achieve overall goals. Our programs are designed to avoid entitlements, to align actual payouts with the actual results achieved and to be easy to understand and administer.

Equity-Based Rewards

We design our equity programs to be both affordable and competitive in relation to the market. We monitor the market and applicable accounting, corporate, securities and tax laws and regulations and adjust our equity programs as needed. Stock options and other forms of equity compensation are designed to reflect and reward a high level of sustained individual performance over time. We design our equity programs to align employees' interests with those of our stockholders.

Benefits Programs

We design our benefits programs to be both affordable and competitive in relation to the market while conforming with local laws and practices. We monitor the market, local laws and practices and adjust our benefits programs as needed. We design our benefits programs to provide an element of core benefits, and to the extent possible, offer options for additional benefits, be tax-effective for employees in each country and balance costs and cost sharing between us and our employees.

Our stock options typically have annual vesting over a three-year period and a term of ten years, in order to encourage a long-term perspective and to encourage key employees to remain with us. We also use performance based vesting in our option grants. Generally, vesting and exercise rights cease upon termination of employment. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights and the right to receive dividends or dividend equivalents.

Timing of Equity Awards

Only the Compensation Committee may approve stock option grants to our executive officers. Stock options are generally granted at predetermined meetings of the Compensation Committee. On limited occasions, grants may occur upon unanimous written consent of the Compensation Committee, which occurs primarily for the purpose of approving a compensation package for newly hired or promoted executive.

Edgar Filing: Trovogene, Inc. - Form 10-K

The exercise price of a newly granted option is the closing price of our common stock on the date of grant.

Executive Equity Ownership

We encourage our executives to hold a significant equity interest in our company. However, we do not have specific share retention and ownership guidelines for our executives.

Performance-Based Compensation and Financial Restatement

We have not considered or implemented a policy regarding retroactive adjustments to any cash or equity-based incentive compensation paid to our executives and other employees where such payments were predicated upon the achievement of certain financial results that were subsequently the subject of a financial restatement.

Severance and Change in Control Arrangements

Several of our executives have employment and other agreements which provide for severance payment arrangements and/or acceleration of stock option vesting that would be triggered by an acquisition or other change in control of our company. See [Employment Agreements](#) below for a description of the severance and change in control arrangements for our named executive officers.

Table of Contents

Effect of Accounting and Tax Treatment on Compensation Decisions

In the review and establishment of our compensation programs, we consider the anticipated accounting and tax implications to us and our executives.

Section 162(m) of the Internal Revenue Code imposes a limit on the amount of compensation that we may deduct in any one year with respect to our chief executive officer and each of our next four most highly compensated executive officers, unless certain specific and detailed criteria are satisfied. Performance-based compensation, as defined in the Internal Revenue Code, is fully deductible if the programs are approved by stockholders and meet other requirements. We believe that grants of equity awards under our existing stock plans qualify as performance-based for purposes of satisfying the conditions of Section 162(m), thereby permitting us to receive a federal income tax deduction in connection with such awards. In general, we have determined that we will not seek to limit executive compensation so that it is deductible under Section 162(m). However, from time to time, we monitor whether it might be in our interests to structure our compensation programs to satisfy the requirements of Section 162(m). We seek to maintain flexibility in compensating our executives in a manner designed to promote our corporate goals and therefore our compensation committee has not adopted a policy requiring all compensation to be deductible. Our compensation committee will continue to assess the impact of Section 162(m) on our compensation practices and determine what further action, if any, is appropriate.

Role of Executives in Executive Compensation Decisions

Our board of directors and our Compensation Committee generally seek input from our Chief Executive Officer, Dr. Antonius Schuh, when discussing the performance of, and compensation levels for executives other than himself. The Compensation Committee also works with Dr. Schuh and our Chief Financial Officer evaluating the financial, accounting, tax and retention implications of our various compensation programs. Neither Dr. Schuh nor any of our other executives participates in deliberations relating to his or her compensation.

Chief Executive Officer Compensation for Fiscal Year 2013

In 2011, we entered into an executive agreement with Antonius Schuh, Ph.D. in which he agreed to serve as our Chief Executive Officer. The term of the agreement is effective as of October 4, 2011 and continues until October 4, 2015 and is automatically renewed for successive one year periods at the end of each term. Dr. Schuh's compensation is \$275,000 per year. During 2013, Dr. Schuh's compensation was increased to \$385,000. Dr. Schuh is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Dr. Schuh was granted 633,333 non-qualified stock options which have an exercise price of \$3.00 per share and vest annually in equal amounts over a period of four years. Dr. Schuh is also eligible to receive a realization bonus upon the occurrence of either of the following events, whichever occurs earlier;

(i) In the event that during the term of the agreement, for a period of 90 consecutive trading days, the market price of the common stock is \$7.50 or more and the value of the common stock daily trading volume is \$125,000 or more, we shall pay or issue Dr. Schuh a bonus in an amount of \$3,466,466 in either cash or registered common stock or a combination thereof as mutually agreed by Dr. Schuh and us; or

Edgar Filing: Trovogene, Inc. - Form 10-K

(ii) In the event that during the term of the agreement, a change of control occurs where the per share enterprise value of our company equals or exceeds \$7.50 per share, we shall pay Dr. Schuh a bonus in an amount determined by multiplying the enterprise value by 4.0%. In the event in a change of control the per share enterprise value exceeds a minimum of \$14.40 per share, \$22.80 per share or \$30.00 per share, Dr.Schuh shall receive a bonus in an amount determined by multiplying the incremental enterprise value by 2.5%, 2.0% or 1.5%, respectively.

If the executive agreement is terminated by us for cause or as a result of Dr. Schuh's death or permanent disability or if Dr. Schuh terminates his agreement voluntarily, Dr. Schuh shall receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus or realization bonus earned but not yet paid through the date of termination and (iii) all expenses reasonably incurred by Dr. Schuh prior to date of termination. If the executive agreement is terminated by us without cause Dr. Schuh shall receive a severance payment equal to base compensation for three months if termination occurs ten months after the effective date of the agreement and six months if termination occurs subsequent to ten months from the effective date. If the executive agreement is terminated as a result of a change of control, Dr. Schuh shall receive a severance payment equal to base compensation for twelve months and all unvested stock options shall immediately vest and become fully exercisable for a period of six months following the date of termination.

Table of Contents

2013 Bonus

On December 11, 2013, the Compensation Committee approved a bonus of \$210,000 for Dr. Schuh, which was 60% of such individual's base compensation. The Compensation Committee reviewed the following factors in determining the amount of the bonus awarded to Dr. Schuh.

- Clinical development progress
- Launching of diagnostic tests
- Financing of the company
- Recruiting of executives and clinical staff

Dr. Schuh's employment agreement allows for an annual bonus equal to 50% of his base compensation. The Compensation Committee believed that Dr. Schuh did an outstanding job during 2013 in a challenging environment with limited resources.

In making its determination as to whether Dr. Schuh achieved his performance objectives for awarding 2013 bonus, the Compensation Committee looked at the above-mentioned performance objectives in totality and what the achievement of those performance objectives meant to us and our business. The Compensation Committee did not assign actual levels of achievement to each objective.

2014 Bonus Criteria

The bonus criteria for 2014 includes, among other things:

- commencement of clinical studies using our diagnostic tests at major oncology centers,
- presentation of clinical study results at key conferences,
- publication of key study data, developing a protocol for a multi-institutional clinical trial
- launching of additional clinical tests entering into collaborations and partnerships incorporating our tests

Compensation Risk Management

We have considered the risk associated with our compensation policies and practices for all employees, and we believe we have designed our compensation policies and practices in a manner that does not create incentives that could lead to excessive risk taking that would have a material adverse effect on us.

SUMMARY COMPENSATION TABLE

The following table provides certain summary information concerning compensation awarded to, earned by or paid to our Principal Executive Officer and the two other highest paid executive officers whose total annual salary and bonus exceeded \$100,000 (collectively, the named executive officers) for fiscal year 2013.

Name & Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$) (1)	Total (\$)
Dr. Antonius Schuh, CEO (2)	2013	323,125	210,000	1,212,964	1,746,089
	2012	275,000	137,500	468,916	881,416
	2011	57,291		372,065	429,356
Stephen Zaniboni, CFO (3)	2013	201,750	132,000	492,727	826,477
	2012	199,333	80,000	107,331	386,664
Mark Erlander, CSO (4)	2013	169,692	100,000	1,366,187	1,635,879

(1) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts represent the aggregate grant date fair value of stock option awards determined in accordance with FASB ASC Topic 718. The valuation assumptions used in determining 2013 and 2012 amounts are Note 6 to our financial statements included in our Annual Reports on Form 10-K for the fiscal years ended December 31, 2013 and 2012. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) Dr. Schuh was appointed CEO in October 2011.

(3) Mr. Zaniboni was appointed CFO in February 2012.

(4) Mr. Erlander was appointed CSO in January 2013.

Table of Contents**OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END**

The following table sets forth information for the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the exercise prices and expiration dates thereof, as of December 31, 2013.

Name	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Weighted Average Option Exercise Price (\$)	Option Expiration Date
Dr. Antonius Schuh (1)	316,666	566,667	3.82	October 4, 2021-December 11, 2023
Stephen Zaniboni(2)	41,667	235,000	4.47	February 1, 2022-December 11, 2023
Mark Erlander (3)	5,000	310,000	6.43	September 13, 2022-December 11, 2023

(1) The unexercisable options of 566,667 vest as follows: 158,333 on October 4, 2014, 158,334 on October 4, 2015; 50,000 each on June 24, 2014, 2015, 2016 and 2017 and 12,500 each on December 11, 2014, 2015, 2016 and 2017.

(2) The unexercisable options of 235,000 vest as follows: 41,666 on February 1, 2014, and 41,667 on February 1, 2015 and 2016; 15,000 each on June 24, 2014, 2015, 2016 and 2017; and 12,500 each on December 11, 2014, 2015, 2016 and 2017.

(3) The unexercisable options of 310,000 vest as follows: 1,666 on September 12, 2014, and 1,667 on September 12, 2015; 3,333 on December 10, 2014, and 3,334 on December 10, 2015; 50,000 each on January 28, 2014, 2015, 2016 and 2017; and 25,000 each on December 11, 2014, 2015, 2016 and 2017.

DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2013 for services to our company.

Name	Fees Earned or Paid in Cash	Option Awards(1)	Total
Thomas H. Adams(2)	\$ 43,250	\$ 55,401	\$ 98,651
John P. Brancaccio(3)	\$ 54,000	\$ 104,006	\$ 158,006
Gary S. Jacob(4)	\$ 45,000	\$ 59,557	\$ 104,557
Gabriel M. Cerrone(5)	\$ 114,750	\$ 551,527	\$ 666,277
Stanley Tennant (6)	\$ 43,750	\$ 52,624	\$ 96,374
Christopher McGuigan (7)	\$ 26,000	\$ 85,835	\$ 111,835
Paul Billings (8)	\$ 4,083	\$ 35,580	\$ 39,663

Edgar Filing: Trovogene, Inc. - Form 10-K

(1) Amounts shown in this column do not reflect dollar amounts actually received by our non-employee directors. Instead, these amounts represent the aggregate grant date fair value of stock option awards determined in accordance with FASB ASC Topic 718. The valuation assumptions used in determining 2013 amounts are described in Note 6 to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) As of December 31, 2013, 323,281 stock options were outstanding, of which 256,143 were exercisable.

(3) As of December 31, 2013, 79,815 stock options were outstanding, of which 69,483 were exercisable.

(4) As of December 31, 2013, 86,970 stock options were outstanding, of which 76,638 were exercisable.

(5) No longer a director as of July 18, 2013. As of December 31, 2013, 513,928 stock options were outstanding, of which 513,928 were exercisable.

(6) As of December 31, 2013, 26,903 stock options were outstanding, of which 16,571 were exercisable.

Table of Contents

(7) As of December 31, 2013, 7,832 stock options were outstanding, of which none were exercisable. Dr. McGuigan resigned as a director on February 19, 2014.

(8) As of December 31, 2013, 23,333 stock options were outstanding, of which 15,000 were exercisable.

Employment Agreements

In January 2013, the Company entered into an employment agreement with Mark Erlander, Ph.D. in which he agreed to serve as Chief Scientific Officer. Dr. Erlander's initial salary was \$200,000 per year, increased to \$260,000 per year in December 2013. Dr. Erlander is eligible to receive a cash bonus of up to 50% of his base salary per year at the discretion of the Compensation Committee based on goals mutually agreed upon by Dr. Erlander, the CEO and the Board of Directors. In connection with his employment, Dr. Erlander was granted a stock option to purchase 200,000 shares of common stock at an exercise price of \$7.04. The option vests ratably over a four year period. If the Company terminates Dr. Erlander without cause, he is entitled to severance benefits equal to six months of his base salary.

During 2012, we entered into an executive agreement with Steve Zaniboni in which he agreed to serve as our Chief Financial Officer. The term of the agreement is effective as of February 1, 2012 and continues until February 1, 2013 and is automatically renewed for successive one year periods at the end to each term. Mr. Zaniboni's compensation is \$200,000 per year. During 2013, Mr. Zaniboni's compensation was increased to \$242,000. Mr. Zaniboni is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Mr. Zaniboni was granted 166,667 non-qualified stock options which have an exercise price of \$3.60 per share and vest annually in equal amounts over a period of four years.

If the executive agreement is terminated by us for cause or as a result of Mr. Zaniboni's death or permanent disability or if Mr. Zaniboni terminates his agreement voluntarily, Mr. Zaniboni shall receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus or realization bonus earned but not yet paid through the date of termination and (iii) all expenses reasonably incurred by Mr. Zaniboni prior to date of termination. If the executive agreement is terminated by us without cause Mr. Zaniboni shall receive a severance payment equal to base compensation for three months if termination occurs ten months after the effective date of the agreement and six months if termination occurs subsequent to ten months from the effective date. If the executive agreement is terminated as a result of a change of control, Mr. Zaniboni shall receive a severance payment equal to base compensation for twelve months and all unvested stock options shall immediately vest and become fully exercisable for a period of six months following the date of termination.

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of March 13, 2014 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) our named executive officers and (iv) all directors and executive officers as a group. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Name of Beneficial Owner	Amount and nature of beneficial ownership (1)	Percentage(2)
Executive officers and directors:		
Thomas Adams	639,931(3)	3.3
Antonius Schuh	316,666(4)	1.6
Paul Billings	15,000(4)	*
John Brancaccio	117,083(5)	*
Gary Jacob	223,221(6)	1.2
Stanley Tennant	263,248(7)	1.4
Rodney S. Markin		0
Stephen Zaniboni	83,334(4)	*
All Officers and Directors as a Group (8 persons)	1,658,483(8)	8.3
5% or greater holders:		
Bridger Management, LLC	2,142,857(9)	11.3
R. Merrill Hunter	1,510,834(10)	7.7
Gabriele Cerrone	1,544,203(11)	7.8

*less than 1%

(1) The address of each person is c/o Trovagene, Inc., 11055 Flintkote Avenue, Suite A, San Diego, CA 92121 unless otherwise indicated herein.

(2) The calculation in this column is based upon 18,902,991 shares of common stock outstanding on March 13, 2014. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or exercisable within 60 days of March 13, 2014 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

(3) Includes (i) 267,759 shares of common stock issuable upon exercise of stock options and (ii) 45,686 shares of common stock issuable upon exercise of warrants.

Edgar Filing: Trovogene, Inc. - Form 10-K

- (4) Consists of shares of common stock issuable upon exercise of stock options.
- (5) Includes (i) 89,417 shares of common stock issuable upon exercise of stock options and (ii) 13,833 shares of common stock issuable upon exercise of warrants.
- (6) Includes (i) 89,721 shares of common stock issuable upon exercise of stock options and (ii) 10,500 shares of common stock issuable upon exercise of warrants.
- (7) Includes (i) 75,000 shares of common stock issuable upon exercise of warrants and (ii) 27,207 shares of common stock exercisable upon exercise of stock options.

Table of Contents

(8) Includes (i) 889,104 shares of common stock issuable upon exercise of stock options and (ii) 145,019 shares of common stock issuable upon exercise of warrants.

(9) As per the Schedule 13G/A filed January 13, 2014.

(10) Includes 666,667 shares of common stock issuable upon exercise of warrants.

(11) Consists of (i) 725,776 shares of common stock held by Panetta Partners, Ltd., (ii) 10,833 shares of common stock held by Mr. Cerrone, (iii) 513,928 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, (iv) 287,416 shares of common stock issuable upon exercise of warrants held by Panetta and (v) 6,250 shares of common stock issuable upon exercise of warrants held by Mr. Cerrone. Mr. Cerrone is a director of Panetta and in such capacity only exercises voting and dispositive control over securities owned by Panetta, despite him having only a small pecuniary interest in such securities.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Any future transactions with officers, directors or 5% stockholders will be on terms no less favorable to us than could be obtained from independent parties. Any affiliated transactions must be approved by a majority of our independent and disinterested directors who have access to our counsel or independent legal counsel at our expense.

Board Determination of Independence

Our board of directors has determined that a majority of the board consists of members who are currently independent as that term is defined under current listing standards of NASDAQ.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Audit and Non-Audit Fees

The aggregate fees billed to the Company by BDO USA, LLP, the Company's independent registered public account firm, for the indicated services for each of the last two fiscal years were as follows:

Edgar Filing: Trovagene, Inc. - Form 10-K

	2013		2012
Audit fees (1)	\$ 284,720	\$	386,125
Tax fees (2)	35,646		7,643
	\$ 320,366	\$	393,768

(1) Audit fees consist of fees for professional services performed by BDO USA, LLP for the audit and review of the Company's financial statements included in SEC filings, and services that are normally provided in connection with regulatory filings or engagements.

(2) Tax fees consist of fees for professional services performed by BDO USA, LLP with respect to tax compliance.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. No non-audit services were performed by our principal accountants during the fiscal years ended December 31, 2013 and 2012. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

ITEM 15. EXHIBITS.

**Exhibit
Number**

Description of Exhibit

(a)(1) *Financial Statements*

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this annual report.

Edgar Filing: Trovagene, Inc. - Form 10-K

Table of Contents

b) Exhibits

Exhibit Number	Description
1.2	Controlled Equity Offering SM Sales Agreement dated January 25, 2013 by and between Trovagene, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to Form S-3 filed on January 25, 2013).
3.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to Trovagene, Inc.'s Proxy Statement on Schedule 14A filed March 20, 2012).
3.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Form 10-12G filed on November 25, 2011).
4.1	Form of Common Stock Certificate of Trovagene, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 10-12G filed on November 25, 2011).
4.2	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on July 19, 2004).+
4.3	Form of Registration Rights Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on April 16, 2012).
4.4	Form of Warrant Agency Agreement by and between Trovagene, Inc. and Broadridge Corporate Issuer Solutions, Inc. and Form of Warrant Certificate (incorporated by reference to Exhibit 4.5 to Amendment No. 3 to Form S-1 filed on May 22, 2012).
4.5	Form of Unit Agency Agreement by and between Trovagene, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.6 to Amendment No. 3 to Form S-1 filed on May 22, 2012).
10.2	Executive Agreement between Trovagene, Inc. and Antonius Schuh dated October 4, 2011 (incorporated by reference to Exhibit 10.2 to the Company's Form 10-12G filed on November 25, 2011).+
10.3	Summary of Terms of Lease Agreement dated as of October 28, 2009 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.3 to the Company's Form 10-12G/A filed on February 15, 2012).
10.4	Form of First Amendment to Standard Industrial Net Lease dated September 28, 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.4 to the Company's Form 10-12G/A filed on February 15, 2012).
10.5	Form of Second Amendment to Standard Industrial Net Lease dated October 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.5 to the Company's Form 10-12G/A filed on February 15, 2012).
10.6	Co-Exclusive Sublicense Agreement dated October 22, 2007 between Trovagene, Inc. and Asuragen, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Form 10-12G/A filed on February 15, 2012).

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

- 10.7 Amendment to Co-Exclusive Sublicense Agreement dated June 1, 2010 between Trovogene, Inc. and Asuragen, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.8 Sublicense Agreement dated as of August 27, 2007 between Trovogene, Inc. and Ipsogen SAS (incorporated by reference to Exhibit 10.8 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.9 Amendment to Co-Exclusive Sublicense Agreement dated as of September 1, 2010 between Trovogene, Inc. and Ipsogen SAS (incorporated by reference to Exhibit 10.9 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.10 Sublicense Agreement dated as of January 8, 2008 between Trovogene, Inc. and Warnex Medical Laboratories (incorporated by reference to Exhibit 10.10 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.11 Sublicense Agreement dated as of July 20, 2011 between Trovogene, Inc. and Fairview Health Services (incorporated by reference to Exhibit 10.11 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.13 Sublicense Agreement dated as of December 1, 2008 by and between Trovogene, Inc. and InVivoScribe Technologies, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.14 Sublicense Agreement dated as of August 25, 2008 by and between Trovogene, Inc. and Laboratory Corporation of America Holdings. (incorporated by reference to Exhibit 10.14 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.15 Form of Sublicense Agreement effective as of February 8, 2011 by and between Trovogene, Inc. and MLL Munchner Leukamielabor GmbH. (incorporated by reference to Exhibit 10.15 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.16 Sublicense Agreement effective as of June 15, 2010 by and between Trovogene, Inc. and Skyline Diagnostics BV (incorporated by reference to Exhibit 10.16 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.17 Asset Purchase Agreement dated as of January 6, 2012 by and among Trovogene, Inc. and MultiGEN Diagnostics Inc. (incorporated by reference to Exhibit 10.1 to Form 8-K filed February 3, 2012).
- 10.18 Amendment No. 1 to Asset Purchase Agreement dated as of February 1, 2012 by and among Trovogene, Inc. and MultiGEN Diagnostics Inc. (incorporated by reference to Exhibit 10.2 to Form 8-K filed February 3, 2012).
- 10.19 Reagent Supply Agreement dated as of February 1, 2012 by and among Trovogene, Inc. and MultiGEN Diagnostics Inc. (incorporated by reference to Exhibit 10.3 to Form 8-K filed February 3, 2012).
- 10.20 Exclusive License Agreement effective as of December 12, 2011 by and between Columbia University and Trovogene, Inc. (incorporated by reference to Exhibit 10.20 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.21 Form of Exclusive License Agreement effective as of October 2011 by and between Gianluca Gaidano, Robert Foa and Davide Rossi and Trovogene, Inc. (incorporated by reference to Exhibit 10.21 to the Company's Form 10-12G/A filed on February 15, 2012).
- 10.22 Executive Agreement between Trovogene, Inc. and Steve Zaniboni dated February 1, 2012 (incorporated by reference to Exhibit 10.22 to the Company's Form 10-12G/A filed on February 15, 2012).

Edgar Filing: Trovogene, Inc. - Form 10-K

10.23

Exclusive License Agreement effective as of May 2006 by and between Brunangelo Falini, Cristina Mecucci and Trovogene, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Form 10-

Edgar Filing: Trovagene, Inc. - Form 10-K

Table of Contents

	12G/A filed on February 15, 2012).
10.24	Form of First Amendment to Exclusive License Agreement effective as of August 2010 by and among Brunangelo Falini, Cristina Mecucci and Trovagene, Inc. (incorporated by reference to Exhibit 10.24 to the Company's Form 10-12G/A filed on February 15, 2012).
10.25	Research and Development Agreement between PerkinElmer Health Sciences, Inc. and Trovagene, Inc. dated as of April 25, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed on May 14, 2013) *
10.26	Form of Securities Purchase Agreement dated as of July 30, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on July 31, 2013).
10.27	Research Agreement between Trovagene, Inc. and Illumina, Inc. dated June 20, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed on August 14, 2013)*
14	Code of Business Conduct and Ethics Amended and Restated 2011 (incorporated by reference to Exhibit 14 to the Company's Form 10-12G filed on November 25, 2011).
21	List of Subsidiaries.
23.1	Consent of BDO USA, LLP
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Financial statements from the annual report on Form 10-K of Trovagene for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL) : (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statement of Stockholders' Equity (Deficiency) (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.

+ Indicates a management contract or compensatory plan or arrangement

*Portions of this exhibit were omitted and filed separately with the U.S. Securities and Exchange Commission pursuant to a request for confidential treatment.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

TROVAGENE, INC.

March 17, 2014

/s/ Dr. Antonius Schuh
Chief Executive Officer

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Dr. Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2014
/s/ Stephen Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	March 17, 2014
Thomas H. Adams	Chairman of the Board	March 17, 2014
/s/ John P. Brancaccio	Director	March 17, 2014
/s/ Gary S. Jacob	Director	March 17, 2014
/s/ Paul Billings	Director	March 17, 2014
/s/ Stanley Tennant	Director	March 17, 2014
/s/ Rodney S. Markin	Director	March 17, 2014

Table of Contents

TROVAGENE, INC.

(A Development Stage Company)

Index to Consolidated Financial Statements

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2013 and 2012</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Loss for each of the three years in the period ended December 31, 2013 and for the period from August 4, 1999 (Inception) to December 31, 2013</u>	F-4
<u>Consolidated Statements of Stockholders' Equity (Deficiency) for the period from August 4, 1999 (Inception) to December 31, 2013</u>	F-5
<u>Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2013, and for the period from August 4, 1999 (Inception) to December 31, 2013</u>	F-13
<u>Notes to Consolidated Financial Statements</u>	F-15

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Trovogene, Inc.

San Diego, California

We have audited the accompanying consolidated balance sheets of Trovogene, Inc. and Subsidiaries (a development stage company) (Trovogene) as of December 31, 2013 and 2012 and the related consolidated statements of operations and comprehensive loss, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2013 and for the period from August 4, 1999 (inception) to December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Trovogene, Inc. and Subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 and the period from August 4, 1999 (inception) to December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and will continue to incur losses in the future that raise substantial doubt about their ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Trovogene's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 17, 2014 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
New York, New York
March 17, 2014

F-2

Table of Contents**Trovogene, Inc. and Subsidiaries****(A development stage company)****CONSOLIDATED BALANCE SHEETS**

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,836,937	\$ 10,819,781
Accounts receivable	78,994	168,381
Prepaid expenses and other assets	152,789	60,041
Total current assets	26,068,720	11,048,203
Property and equipment, net	750,565	254,742
Other assets	336,450	362,081
Total Assets	\$ 27,155,735	\$ 11,665,026
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 286,608	\$ 175,679
Accrued expenses	1,524,092	554,691
Current portion of long-term debt	198,166	
Total current liabilities	2,008,866	730,370
Long-term debt, less current portion	322,998	
Derivative financial instruments	4,431,871	8,765,628
Total liabilities	6,763,735	9,495,998
Commitments and contingencies (Note 11)		
Stockholders equity		
Preferred stock, \$0.001 par value, 20,000,000 shares authorized, 60,600 and 95,600 shares outstanding at December 31, 2013 and 2012, respectively; designated as Series A Convertible Preferred Stock with liquidation preference of \$606,000 and \$956,000 at December 31, 2013 and 2012, respectively	60	96
Common stock, \$0.0001 par value, 150,000,000 shares authorized at December 31, 2013 and 2012; 18,902,782 and 15,478,177 issued and outstanding at December 31, 2013 and 2012, respectively	1,890	1,547
Additional paid-in capital	87,433,460	57,370,017
Deficit accumulated during development stage	(67,043,410)	(55,202,632)
Total stockholders equity	20,392,000	2,169,028
Total Liabilities and Stockholders Equity	\$ 27,155,735	\$ 11,665,026

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

Trovogene, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,			August 4, 1999 (Inception) to December 31, 2013
	2013	2012	2011	
Royalty income	\$ 259,246	\$ 175,404	\$ 227,696	\$ 1,184,720
Milestone fees		150,000		150,000
License fees		125,000	30,000	1,383,175
Total revenues	259,246	450,404	257,696	2,717,895
Costs and expenses:				
Research and development	3,947,589	1,920,298	910,685	21,397,040
Purchased in-process research and development - related party				2,666,869
Selling, general and administrative	7,002,198	3,379,262	2,323,814	32,922,314
Total operating expenses	10,949,787	5,299,560	3,234,499	56,986,223
Loss from operations	(10,690,541)	(4,849,156)	(2,976,803)	(54,268,328)
Interest income	3,663		171	270,546
Interest expense	(17,005)		(56,636)	(1,342,377)
Loss (gain) on disposal of equipment	(22,941)	4,000		(18,941)
Amortization of deferred debt costs and original issue discount				(2,346,330)
Change in fair value of derivative instruments warrants	(1,084,114)	(6,720,805)	170,673	(6,578,913)
Gain on extinguishment of debt			623,383	623,383
Liquidated damages and forbearance agreement settlement costs				(1,758,111)
Net loss and comprehensive loss	(11,810,938)	(11,565,961)	(2,239,212)	(65,419,071)
Preferred stock dividend	(29,840)	(38,240)	(38,240)	(375,998)
Series A Convertible Preferred stock conversion rate change accreted as a dividend				(792,956)
Cumulative effect of early adopting ASC Topic 815-40				(455,385)
Net loss and comprehensive loss attributable to common stockholders	\$ (11,840,778)	\$ (11,604,201)	\$ (2,277,452)	\$ (67,043,410)
Net loss per common share-basic and diluted	\$ (0.70)	\$ (0.89)	\$ (0.23)	
Weighted average shares outstanding-basic and diluted	16,978,212	13,066,600	9,711,519	

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Condensed Consolidated Statements of Stockholders Equity (Deficiency)**

	Common Stock		Treasury Shares		Additional	Deferred	Deficit	Total
	Shares	Amount	Shares	Amount	Paid-In	Stock	Accumulated	Stockholders
					Capital	Based	During	Equity
						Compensation	Development	(Deficiency)
							Stage	
Balance, August 4, 1999 (Inception)		\$		\$	\$	\$	\$	\$
Issuance of common stock to founders for cash at \$0.0012 per share	37,000,000	3,700			38,300			42,000
Net loss							(14,760)	(14,760)
Balance, January 31, 2000	37,000,000	\$ 3,700		\$	\$ 38,300		(14,760)	27,240
Net loss							(267,599)	(267,599)
Balance, January 31, 2001	37,000,000	\$ 3,700		\$	\$ 38,300		(282,359)	(240,359)
Capital contribution of cash					45,188			45,188
Net loss							(524,224)	(524,224)
Balance, January 31, 2002	37,000,000	\$ 3,700		\$	\$ 83,488		(806,583)	(719,395)
Issuance of common stock for cash at \$0.003 per share	1,258,000	126			3,274			3,400
Capital contribution of cash					2,500			2,500
Net loss							(481,609)	(481,609)
Balance, January 31, 2003	38,258,000	\$ 3,826		\$	\$ 89,262		(1,288,192)	(1,195,104)
Net loss							(383,021)	(383,021)
Balance, January 31, 2004	38,258,000	\$ 3,826		\$	\$ 89,262		(1,671,213)	(1,578,125)
Waiver of founders deferred compensation					1,655,031			1,655,031
Private placement of common stock	440,868	44			2,512,906			2,512,950
Redemption of shares held by Panetta Partners, Inc.	(36,477,079)	(3,648)			(496,352)			(500,000)
Costs associated with recapitalization					(301,499)			(301,499)
Share exchange with founders	376,334	38			(38)			
Issuance of treasury shares			58,333	6	(6)			
Issuance of treasury shares to escrow	58,333	6	(58,333)	(6)				
Issuance of common stock and warrants for cash at \$11.70 per share	228,026	23			2,667,877			2,667,900
					403,038			403,038

Edgar Filing: Trovogene, Inc. - Form 10-K

Issuance of 20,610
warrants to selling
agents

Finders warrants charged to cost of capital						(403,038)				(403,038)			
Deferred stock-based compensation						1,937,500	(1,937,500)						
Amortization of deferred stock-based compensation								245,697		245,697			
Options issued to consultants						1,229,568				1,229,568			
Warrants issued to consultants						2,630,440				2,630,440			
Net loss								(5,371,027)		(5,371,027)			
Balance, January 31, 2005	2,884,482	\$	289		\$	\$	11,924,689	\$	(1,691,803)	\$	(7,042,240)	\$	3,190,935

The accompanying notes are an integral part of these consolidated financial statements.

F-5

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Condensed Consolidated Statements of Stockholders Equity (Deficiency)**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Treasury Shares Shares	Treasury Shares Amount	Additional Paid-In Capital	Deferred Stock Based Compensation	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
Balance, January 31, 2005		\$	2,884,482	\$ 289		\$	\$ 11,924,689	\$ (1,691,803)	\$ (7,042,240)	\$ 3,190,935
Private placement of common stock			17,094	2		\$	\$ 199,998			200,000
Payment of selling agents fees and expenses in cash							(179,600)			(179,600)
Common stock issued to selling agents			4,077							
Private placement of common stock			252,564	25			2,954,974			2,954,999
Payment of selling agents fees and expenses in cash							(298,000)			(298,000)
Issuance of 20,205 warrants issued to selling agents							222,188			222,188
Selling agents warrants charged to cost of capital							(222,188)			(222,188)
Private placement of preferred stock and warrants for cash at \$10.00 per share (restated)	277,100	277					2,770,723			2,771,000
Accretion of preferred stock dividends (restated)							792,956	(792,956)		
Value of warrants reclassified to derivative financial instrument liability							(567,085)			(567,085)
Payment of selling agents fees and expenses in cash							(277,102)			(277,102)
Issuance of 17,572 warrants issued to selling agents							167,397			167,397
Selling agents warrants charged to cost of capital							(167,397)			(167,397)
Return of treasury shares from escrow			(58,333)	(6)	58,333	6				
Retirement of treasury shares					(58,333)	(6)	6			
Common stock issued for services			833				16,500			16,500

Edgar Filing: Trovogene, Inc. - Form 10-K

Stock-based compensation expense for non-employees							2,928,298			2,928,298					
Amortization of deferred stock-based compensation							645,832			645,832					
Preferred stock dividend									(60,741)	(60,741)					
Net loss									(7,844,326)	(7,844,326)					
Balance, January 31, 2006	277,100	\$	277	3,100,717	\$	310	\$	\$	20,266,357	\$	(1,045,971)	\$	(15,740,263)	\$	3,480,710

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders' Equity (Deficiency)****(continued)**

	Preferred Stock		Common Stock		Additional	Deferred	Deficit	Total	Temporary	
	Shares	Amount	Shares	Amount	Paid-In	Stock	Accumulated	Stockholders	Equity	Unregistered
					Capital	Based	During	Equity	Common Stock	Amount
						Compensation	Development	(Deficiency)	Shares	
							Stage			
Balance, January 31, 2006	277,100	\$ 277	3,100,717	\$ 310	\$ 20,266,367	\$ 1,045,971	\$ (15,740,263)	\$ 3,480,710		\$
Conversion of Series A preferred stock and issuance of common stock	(174,000)	(174)	137,739	14	160					
Implementation of ASC 718					(1,045,971)	1,045,971				
Private placement of common stock			125,787	13	943,388			943,401		
Payment of selling agents fees and expenses in cash					(118,341)			(118,341)		
Issuance of 15,779 warrants to selling agents					55,568			55,568		
Selling agents warrants charged to cost of capital					(55,568)			(55,568)		
Issuance of common stock and warrants for cash at \$6.00 per share									166,667	1,000,000
Payment of finder's fees and expenses in cash										(80,000)
Value of warrants classified as derivative financial instrument liability										(15,000)
Issuance of 27,425 units to finder					167,856			167,856		
Common Stock issued for services			1,449		9,566			9,566		
Value attributed to warrants issued with 6% convertible debentures					1,991,822			1,991,822		
Reclassification of derivative financial instruments to stockholders' equity upon adoption of					567,085		(455,385)	111,700		

Edgar Filing: Trovogene, Inc. - Form 10-K

ASC 815-40															
Warrants issued for services				101,131				101,131							
Donated services				62,500				62,500							
Stock based compensation				1,572,545				1,572,545							
Preferred stock dividend							(59,164)	(59,164)							
Net loss							(7,134,067)	(7,134,067)							
Balance, January 31, 2007	103,100	\$	103	3,365,692	\$	337	\$	24,518,098	\$	(23,388,879)	\$	1,129,659	166,667	\$	905,000

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders Equity (Deficiency)****(continued)**

	Preferred Stock		Common Stock		Additional	Deficit	Total	Temporary Equity	
	Shares	Amount	Shares	Amount	Paid-In	Accumulated	Stockholders	Shares	Amount
					Capital	During	Equity		
						Development	(Deficiency)		
						Stage			
Balance, January 31, 2007	103,100	\$ 103	3,365,692	\$ 337	\$ 24,518,098	\$ (23,388,879)	1,129,659	166,667	\$ 905,000
Conversion of preferred stock to common stock	(7,500)	(7)	7,813	1	6				
Private placement of common stock			283,333	28	849,972		850,000		
Payment of selling agent fees and expenses					(51,733)		(51,733)		
Issuance of warrants to selling agents					45,403		45,403		
Selling agent warrants charged to cost of capital					(45,403)		(45,403)		
Derivative liability warrants at issuance					(45,371)		(45,371)		
Donated services					275,000		275,000		
Stock-based compensation expense					914,847		914,847		
Preferred stock dividend						(35,054)	(35,054)		
Net loss						(4,683,141)	(4,683,141)		
Balance, December 31, 2007	95,600	\$ 96	3,656,838	\$ 366	\$ 26,460,819	\$ (28,107,074)	(1,645,793)	166,667	\$ 905,000
Reclassification of common stock initially recorded as temporary equity			166,667	17	904,983		905,000	(166,667)	(905,000)
Private placement of common stock			330,682	33	1,144,967		1,145,000		
Payment of selling agents fees and expenses					(74,500)		(74,500)		
Conversion of debenture to common stock			31,214	3	93,638		93,641		
Derivative liability warrants at issuance					(201,122)		(201,122)		
Donated services					390,750		390,750		

Edgar Filing: Trovogene, Inc. - Form 10-K

Stock based compensation					543,697				543,697		
Preferred stock dividend								(38,240)	(38,240)		
Net loss								(5,166,240)	(5,166,240)		
Balance, December 31, 2008	95,600	\$	96	4,185,401	\$	419	\$	29,263,232	\$ (33,311,554)	\$ (4,047,807)	\$

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders Equity (Deficiency)****(continued)**

	Preferred Stock		Common Stock		Additional	Deficit	Total
	Shares	Amount	Shares	Amount	Paid-In	Accumulated	Stockholders
					Capital	During	Equity
						Development	(Deficiency)
						Stage	
Balance December, 31, 2008	95,600	\$ 96	4,185,401	\$ 419	\$ 29,263,232	\$ (33,311,554)	\$ (4,047,807)
Issuance of shares of common stock in connection with convertible debenture forbearance agreement			906,245	91	1,739,868		1,739,959
Issuance of shares of common stock in payment of convertible debenture interest			60,147	6	112,285		112,291
Private placements of common stock			488,333	49	1,464,951		1,465,000
Issuance of common stock pursuant to a non-exclusive selling agent's agreement			68,897	7	306,730		306,737
Issuance of shares of common stock re settlement for consulting services rendered			159,630	16	478,874		478,890
Stock based compensation expense					177,836		177,836
Preferred stock dividend						(38,240)	(38,240)
Derivative liability warrants and price protected units upon issuance					(1,497,568)		(1,497,568)
Net loss						(2,483,807)	(2,483,807)
Balance, December 31, 2009	95,600	\$ 96	5,868,653	\$ 588	\$ 32,046,208	\$ (35,833,601)	\$ (3,786,709)

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders Equity (Deficiency)****(continued)**

	Preferred Stock		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-In	Deficit	Stockholders
					Capital	During	Equity
						Development	(Deficiency)
						Stage	
Balance, December 31, 2009	95,600	\$ 96	5,868,653	\$ 588	\$ 32,046,208	(35,833,601)	\$ (3,786,709)
Issuance of shares of common stock in payment of convertible debenture interest			85,619	9	115,962		115,971
Issuance of common stock to selling agents			79,333	8	(8)		
Private placement of units			578,233	58	1,734,642		1,734,700
Derivative liability price protected units upon issuance					(1,010,114)		(1,010,114)
Consulting services settled via issuance of stock			70,833	7	212,493		212,500
Shares issued in settlement of legal fees			29,240	3	99,997		100,000
Stock issued in payment of deferred salary to former CEO			12,745	1	28,345		28,346
Shares issued in connection with Agreement & Plan of Merger with Etherogen, Inc.			2,043,797	204	2,771,185		2,771,389
Stock Based Compensation expense					325,930		325,930
Preferred stock dividend						(38,240)	(38,240)
Net loss						(5,449,138)	(5,449,138)
Balance, December 31, 2010	95,600	\$ 96	8,768,453	\$ 878	\$ 36,324,640	(41,320,979)	\$ (4,995,365)

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders' Equity (Deficiency)****(continued)**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
Balance, December 31, 2010	95,600	\$ 96	8,768,453	\$ 878	\$ 36,324,640	\$ (41,320,979)	\$ (4,995,365)
Issuance of shares of common stock in payment of convertible debenture interest in accordance with Forbearance Agreement			64,214	6	85,269		85,275
Private placement of units			857,833	85	2,573,415		2,573,500
Derivative liability-fair value of warrants and price protected units issued					(1,298,618)		(1,298,618)
Shares issued in connection with Board Compensation			41,750	4	125,246		125,250
Issuance of common stock to shareholder as finder's fees			90,258	9	(9)		
Issuance of common stock in connection with consulting services			58,333	6	174,994		175,000
Stock issued in connection with conversion of convertible debentures			856,185	85	1,130,079		1,130,164
Stock based compensation					250,978		250,978
Preferred stock dividend						(38,240)	(38,240)
Net loss						(2,239,212)	(2,239,212)
Balance, December 31, 2011	95,600	\$ 96	10,737,026	\$ 1,073	\$ 39,365,994	\$ (43,598,431)	\$ (4,231,268)
Units issued via registered underwritten direct public offering and private placement of units			4,383,333	438	16,899,562		16,900,000
Fees and expenses related to financing transactions					(1,576,452)		(1,576,452)
Derivative liability-fair value of warrants and price protected units issued					(1,796,610)		(1,796,610)
Correction of error in derivative liability fair value of warrants price protected units issued					274,967		274,967
Warrants reclassified to additional paid in capital					3,317,463		3,317,463
Issuance of common stock and warrant to shareholder			214,100	21	(21)		

Edgar Filing: Trovogene, Inc. - Form 10-K

as finder's fees									
Issuance of common stock in connection with Asset Purchase Agreement with MultiGen Diagnostics, Inc.	125,000	13	187,487					187,500	
Issuance of common stock in connection with consulting services	9,916	1	22,380					22,381	
Issuance of warrants in connection with advisory services			142,508					142,508	
Stock based compensation			532,140					532,140	
Issuance of common stock upon exercise of stock options	200		600					600	
Issuance of common stock upon net exercise of warrant	8,602	1	(1)						
Preferred stock dividend							(38,240)	(38,240)	
Net loss							(11,565,961)	(11,565,961)	
Balance, December 31, 2012	95,600	\$ 96	15,478,177	\$ 1,547	\$ 57,370,017	\$ (55,202,632)	\$ 2,169,028		

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Stockholders Equity (Deficiency)****(continued)**

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
Balance, December 31, 2012	95,600	\$ 96	15,478,177	\$ 1,547	\$ 57,370,017	\$ (55,202,632)	\$ 2,169,028
Sale of common stock, net of expenses			2,631,332	263	18,829,381		18,829,644
Issuance of warrants in connection with services					198,791		198,791
Stock based compensation					1,979,364		1,979,364
Derivative liability - Warrants reclassified to additional paid in capital					5,417,871		5,417,871
Issuance of common stock upon conversion of preferred stock	(35,000)	(36)	36,458	4	32		
Issuance of common stock upon net exercise of warrant			7,284	1	(1)		
Issuance of common stock upon exercise of warrants			715,743	72	3,599,759		3,599,831
Issuance of common stock upon net exercise of stock options			22,955	2	(2)		
Issuance of common stock upon exercise of stock options			10,833	1	38,248		38,249
Preferred stock dividend						(29,840)	(29,840)
Net loss						(11,810,938)	(11,810,938)
Balance, December 31, 2013	60,600	\$ 60	18,902,782	\$ 1,890	\$ 87,433,460	\$ (67,043,410)	\$ 20,392,000

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents**Trovogene, Inc. and Subsidiaries****(A Development Stage Company)****Consolidated Statements of Cash Flows**

	Year ended December 31, 2013	Year ended December 31, 2012	Year ended December 31, 2011	For the period August 4, 1999 (Inception) to December 31, 2013
Operating activities				
Net loss	\$ (11,810,938)	\$ (11,565,961)	\$ (2,239,212)	\$ (65,419,071)
Adjustments to reconcile net loss to net cash used in operating activities:				
Loss (gain) on disposal of fixed assets	22,941	(4,000)		18,941
Depreciation and amortization	130,520	41,842	10,285	394,161
Stock based compensation expense	1,979,364	532,140	250,978	13,991,829
Founders compensation contributed to equity				1,655,031
Donated services contributed to equity				829,381
Settlement of consulting services in stock				478,890
Amortization of deferred debt costs and original issue discount				2,346,330
Liquidated damages and other forbearance agreement settlement costs paid in stock				1,758,111
Interest expense on convertible debentures paid in stock			56,636	757,198
Change in fair value of financial instruments	1,084,114	6,720,805	(170,673)	6,578,913
Gain on extinguishment of debt			(623,383)	(623,383)
Purchased in process research and development expense-related party				2,666,869
Stock issued in connection with payment of deferred salary				28,346
Stock issued in connection with settlement of legal fees				100,000
Stock and warrant issued in connection with consulting services	198,791	164,889	175,000	651,180
Changes in operating assets and liabilities:				
Decrease (increase) in other assets	25,631		21,648	(44,250)
Decrease (increase) in accounts receivable	89,387	(69,241)	(24,140)	(78,995)
(Increase) decrease in prepaid expenses	(92,748)	(17,383)	108,374	(152,789)
Increase (decrease) in accounts payable and accrued expenses	1,055,690	(737,752)	504,186	1,734,309
Net cash used in operating activities	(7,317,248)	(4,934,661)	(1,930,301)	(32,328,999)
Investing activities:				

Edgar Filing: Trovogene, Inc. - Form 10-K

Assets acquired in Etherogen, Inc. merger				(104,700)
Capital expenditures	(649,284)	(270,080)	(1,528)	(1,163,667)
Net cash used in investing activities	(649,284)	(270,080)	(1,528)	(1,268,367)
Financing activities				
Proceeds from sale of 6% convertible debenture				2,335,050
Debt issuance costs				(297,104)
Proceeds from sale of common stock, net of expenses	18,829,644	15,323,548	2,573,500	51,585,195
Proceeds from exercise of warrants	3,599,831			3,599,831
Proceeds from exercise of options	38,249	600		38,849
Proceeds from a non-exclusive selling agent's agreement				142,187
Borrowings under equipment line of credit	515,964			515,964
Costs associated with recapitalization				(362,849)
Proceeds from sale of preferred stock				2,771,000
Payment of finders' fee on preferred stock				(277,102)
Redemption of common stock				(500,000)
Payment of preferred stock dividends				(116,718)
Net cash provided by financing activities	22,983,688	15,324,148	2,573,500	59,434,303
Net change in cash and cash equivalents	15,017,156	10,119,407	641,671	25,836,937
Cash and cash equivalents Beginning of period	10,819,781	700,374	58,703	
Cash and cash equivalents End of period	\$ 25,836,937	\$ 10,819,781	\$ 700,374	\$ 25,836,937

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

Trovogene, Inc. and Subsidiaries
(A Development Stage Company)

Consolidated Statements of Cash Flows

	Year ended December 31, 2013	Year ended December 31, 2012	Year ended December 31, 2011	For the period August 4, 1999 (Inception) to December 31, 2013
Supplementary disclosure of cash flow activity:				
Cash paid for taxes	\$ 7,650	\$	\$	\$ 7,650
Cash paid for interest	\$ 9,459	\$	\$	\$ 9,459
Supplemental disclosure of non-cash investing and financing activities:				
Issuance of 41,750 shares of common stock for prior year Board of Directors fees in lieu of cash payment	\$	\$	\$ 125,250	\$ 125,250
Conversion of \$2,335,050 of 6% debentures	\$	\$	\$ 1,130,164	\$ 1,130,164
Issuance of 125,000 shares of common stock pursuant to Asset Purchase Agreement with Multigen Diagnostics, Inc.	\$	\$ 187,500	\$	\$ 187,500
Issuance of 2,043,797 shares of common stock pursuant to Agreement and Plan of Merger with Etherogen, Inc.	\$	\$	\$	\$ 2,771,389
Reclassification of derivative financial instruments to additional paid in capital	\$ (5,417,871)	\$ (3,317,463)	\$	\$ (8,735,334)
Correction of error in derivative financial instruments	\$	\$ (274,967)	\$	\$ (274,967)
Series A Preferred beneficial conversion feature accreted as a dividend	\$	\$	\$	\$ 792,956
Preferred stock dividends accrued	\$ 29,840	\$ 38,240	\$ 38,240	\$ 221,040
Interest paid in common stock	\$	\$	\$ 128,421	\$ 1,325,372

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

Trovagene, Inc. and Subsidiaries

(A Development Stage Company)

Notes to Consolidated Financial Statements

1. Business Overview and Going Concern

Trovagene, Inc. (Trovagene or the Company) is a development stage molecular diagnostic company that focuses on the development and commercialization of a proprietary urine-based molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. Trovagene s primary internal focus is to leverage its novel urine-based molecular diagnostic platform to facilitate improvements in the field of oncology, while the Company s external focus includes entering into collaborations to develop the Company s technology in areas such as infectious disease, transplant medicine, and prenatal genetics. The Company s goal is to improve treatment outcomes for cancer patients using its proprietary technology to detect and quantitatively monitor cell-free DNA in urine.

Underwritten Public Offering of Common Stock

On May 30, 2012, the Company completed an underwritten public offering in which an aggregate of 1,150,000 units, with each unit consisting of two shares of its common stock and one warrant to purchase one share of common stock were sold at a purchase price of \$8.00 per unit. On June 13, 2012, the underwriters exercised their overallocation option in full for an additional 172,500 units. The Company raised a total of \$9.1 million in net proceeds after deducting underwriting discounts and commissions of \$0.7 million and offering expenses of \$0.7 million. The units began trading on The NASDAQ Capital Market on May 30, 2012 under the symbol TROVU . The common stock and warrants became separately transferable upon the exercise in full of the underwriters overallocation. Each warrant has an exercise price of \$5.32 per share, and expires five years from the closing of the offering. The warrants trade on The NASDAQ Capital Market under the symbol TROVW . Warrants issued in connection with the underwritten public offering and sale of units in May 2012 are not considered derivatives based on our analysis of the criteria of ASC 815, as the Company is not required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of warrant shares.

Since inception on August 4, 1999, Trovagene s efforts have been principally devoted to research and development, securing and protecting patents and raising capital. From inception through December 31, 2013, the Company has sustained cumulative net losses attributed to common stockholders of \$67,043,410. The Company s losses have resulted primarily from expenditures incurred in connection with research and development activities, stock based compensation expense, patent filing and maintenance expenses, outside accounting and legal services and regulatory, scientific and financial consulting fees, amortization and liquidated damages. From inception through December 31, 2013, the Company has generated only limited revenue from operations and expects to incur additional losses to perform further research and development activities as well as selling and marketing expenses related to the diagnostic tests it has commercially available as of December 31, 2013.

Going Concern

Edgar Filing: Trovogene, Inc. - Form 10-K

Trovogene's consolidated financial statements as of December 31, 2013 have been prepared under the assumption that the Company will continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to generate additional revenue. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. The Company will be

F-15

Table of Contents

required to raise additional capital within the next twelve to eighteen months to complete the development and commercialization of current product candidates and to continue to fund operations at its current cash expenditure levels.

Cash used in operating activities was \$7,317,248, \$4,934,661 and \$1,930,301, for the years ended December 31, 2013, 2012, and 2011, respectively. During the years ended December 31, 2013, 2012, and 2011, the Company incurred net loss and comprehensive loss attributable to common stockholders of \$11,840,778, \$11,604,201 and \$2,277,452, respectively.

To date, Trovogene's sources of cash have been primarily limited to the sale of debt and equity securities, as well as proceeds from warrant and option exercises. Net cash provided by financing activities for the years ended December 31, 2013, 2012 and 2011 was \$22,983,688, \$15,324,148 and \$2,573,500, respectively. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct its business.

If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of its product candidates. The Company may also be required to:

- Seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- Relinquish licenses or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize themselves, on unfavorable terms.

2. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying consolidated financial statements of Trovogene, which include its wholly owned subsidiaries Xenomics, Inc., a California corporation, Xenomics Europa Ltd, (an inactive subsidiary formed in the United Kingdom and liquidated) and Etherogen, Inc., have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). All intercompany balances and transactions have been eliminated. Certain items in the comparable prior period's financial statements have been reclassified to conform to the current period's presentation.

On March 15, 2012, the Board of Directors and on April 27, 2012 a majority of the stockholders approved a proposal to amend the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's issued and outstanding common stock at a ratio of not less than one-for-two and not greater than one-for-six at any time prior to April 27, 2013 at the discretion of the Board of Directors. On May 24, 2012, the Board of Directors approved a 1-for-6 reverse stock split of the Company's issued and outstanding common stock effective on May 29, 2012. All the relevant information relating to number of shares and per share information contained in these consolidated financial statements has been retrospectively adjusted to reflect the reverse stock split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of operating accounts as of December 31, 2013 and 2012 on deposit with U.S. commercial banks. Cash equivalents are considered by the Company to be highly liquid investments purchased with original maturities of three months or less from the date of purchase. Cash and cash equivalents include money market accounts at December 31, 2013.

Concentration of credit risk

The Company maintains its cash in financial institutions, which at times may exceed the amount insured by the Federal Deposit Insurance Corporation (FDIC). All of the Company's noninterest bearing cash balances were insured up to \$250,000 at December 31, 2013 and fully insured at December 31, 2012 due to a temporary federal program in effect through December 31, 2012.

Table of Contents

Revenues

We license and sublicense our patent rights to healthcare companies, medical laboratories and biotechnology partners. These agreements may involve multiple elements such as license fees, royalties and milestone payments. Revenue is recognized for each element when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

- Up-front nonrefundable license fees pursuant to agreements under which we have no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is reasonably assured.
- Minimum royalties are recognized as earned, and royalties in excess of minimum amounts are recognized upon receipt of payment when collection is assured.
- Milestone payments are recognized when both the milestone is achieved and the related payment is received.

Diagnostic Service Revenues

Revenue for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, bill third-party payors for testing.

Diagnostic services revenues earned by us will be recognized upon receipt of payment when collection is assured due to the lack of contractual reimbursement agreements with third-party payors for a significant portion of our services and limited collections experience.

We have not recognized any revenue for our clinical laboratory tests to date.

Allowance for Doubtful Accounts

The Company reviews the collectability of accounts receivable based on an assessment of historic experience, current economic conditions, and other collection indicators. At December 31, 2013 and 2012, the Company has not recorded an allowance for doubtful accounts. When accounts are determined to be uncollectible, they are written off against the reserve balance and the reserve is reassessed. When payments are received on reserved accounts, they are applied to the individual s account and the reserve is reassessed.

Derivative Financial Instruments Warrants

The Company has issued common stock warrants in connection with the execution of certain equity financings. Such warrants are classified as derivative liabilities under the provisions of FASB ASC 815 *Derivatives and Hedging* (ASC 815) and are recorded at their fair market value as of each reporting period. Such warrants do not meet the exemption that a contract should not be considered a derivative instrument if it is (1) indexed to its own stock and (2) classified in stockholders' equity. Changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption Change in fair value of derivative instruments.

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of Trovogene's common share price, remaining life of the warrant, and risk-free interest rates at each period end. The Company thus uses model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820, *Fair Value Measurements*. At December 31, 2013 and 2012, the fair value of these warrants was \$4,431,871 and \$6,252,760, respectively, and are included in the derivative financial instruments liability on the balance sheet.

The Company has issued units that were price protected. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovogene has determined that these price protected units issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of these price protected units was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which unit holders are likely to exercise their warrants and the expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. At December 31, 2013 there were no warrants that were required to be valued using the

Table of Contents

binomial option pricing model, while at December 31, 2012 the fair value of the warrants was \$2,512,868, and is included in the derivative financial instruments liability on the balance sheet.

At December 31, 2013 and 2012, the total fair value of the above warrants, valued using the Black-Scholes option-pricing model and the Binomial option pricing model was \$4,431,871 and \$8,765,628, respectively, and is classified as derivative financial instruments liability on the balance sheet.

Stock-Based Compensation

ASC Topic 718 *Compensation Stock Compensation* requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is recognized over the period during which an employee is required to provide services in exchange for the award. ASC Topic 718 did not change the way Trovogene accounts for non-employee stock-based compensation. Trovogene continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with ASC Topic 505-50 *Equity -Based Payment to Non-Employees* and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. Accordingly the fair value of these options is being marked to market quarterly until the measurement date is determined.

Fair value of financial instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, debt and derivative liabilities. We have adopted FASB ASC 820 *Fair Value Measurements and Disclosures* (ASC 820) for financial assets and liabilities that are required to be measured at fair value, and non-financial assets and liabilities that are not required to be measured at fair value on a recurring basis. These financial instruments are stated at their respective historical carrying amounts which approximate to fair value due to their short term nature as they reflect current market interest rates. Debt is stated at its respective historical carrying amounts which approximates fair value as they reflect current market interest rates.

In accordance with ASC subtopic 820-10, the Company measures certain assets and liabilities at fair value on a recurring basis using the three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers include:

- Level 1 Quoted prices for identical instruments in active markets.
- Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations where inputs are observable or where significant value drivers are observable.
- Level 3 Instruments where significant value drivers are unobservable to third parties.

Property, equipment and depreciation and amortization

Expenditures for additions, renewals and improvements are capitalized at cost. Depreciation and amortization is generally computed on a straight-line method based on the estimated useful lives of the related assets. Amortization of leasehold improvements is computed based on the shorter of the life of the asset or the term of the lease. The estimated useful lives of the major classes of depreciable assets are 3 to 5 years for lab equipment and furniture and fixtures. Expenditures for repairs and maintenance are charged to operations as incurred.

Impairment of Indefinite and Long-Lived Assets

The Company reviews its long and indefinite lived assets to determine if any event has occurred that may indicate its intangible assets with indefinite lives and other long-lived assets are potentially impaired. If indicators of impairment exist, the Company performs an impairment test to assess the recoverability of the affected assets by determining whether the carrying amount of such assets exceeds the undiscounted expected future cash flows. If the affected assets are not recoverable, the Company estimates the fair value of the assets and records an impairment loss if the carrying value of the assets exceeds the fair value. Factors that would indicate potential impairment include a significant decline in the Company's stock price and market capitalization compared to its net book value, significant changes in the ability of a particular asset to generate positive cash flows, and significant changes in the Company's strategic business objectives and utilization of a particular asset. The Company noted no indications of impairment for the years ended December 31, 2013, 2012, and 2011.

Table of Contents

Income Taxes

Income taxes have been determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes result from differences between the financial statement and tax bases of Trovogene's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. The assessment of whether or not a valuation allowance is required often requires significant judgment.

Contingencies

In the normal course of business, Trovogene is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with FASB ASC Topic 450, *Accounting for Contingencies*, Trovogene records such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. Trovogene, in accordance with this guidance, does not recognize gain contingencies until realized.

Research and Development

Research and development costs, which include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research and insurance, are accounted for in accordance with ASC Topic 730-10-55-2, *Research and Development*. Also, as prescribed by this guidance, patent filing and maintenance expenses are considered legal in nature and therefore classified as general and administrative expense, if any.

While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that Trovogene has no history of successful commercialization of molecular diagnostic products to base any estimate of the number of future periods that would be benefited.

ASC Topic 730, *Research and Development* requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense. There were no non-refundable advance payments as of December 31, 2013 and 2012.

Net Loss Per Share

Edgar Filing: Trovogene, Inc. - Form 10-K

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, for all periods presented. In accordance with this guidance, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. In a period where there is a net loss position, diluted weighted-average shares are the same as basic weighted-average shares. Shares used in calculation basic and diluted net loss per common share exclude as antidilutive the following share equivalents:

	2013	December 31, 2012	2011
Options to purchase Common Stock	4,287,545	3,711,303	2,426,192
Warrants to purchase Common stock	6,233,483	6,985,070	3,601,474
Series A Convertible Preferred Stock	63,125	99,583	99,583
	10,584,153	10,795,956	6,127,249

Recent Accounting Pronouncements

In February 2013, the FASB issued ASU No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. This newly issued accounting standard requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. This ASU is effective for reporting periods beginning after December 15, 2012. The Company adopted this standard in the first quarter of 2013 and the adoption of this standard did not have an impact on its financial position or results of operations.

Table of Contents

3. Merger and Asset Purchase Activities

On August 4, 1999, Xenomics Sub was incorporated by its founders and promoters, L. David Tomei, Samuil Umansky and Hovsep Melkonyan. Xenomics Sub was organized in order to develop and commercialize Tr-DNA technology. Since inception, Xenomics Sub's efforts have been principally devoted to research and development, securing and protecting our patents and raising capital.

On April 26, 2002, the Company was incorporated under the name Used Kar Parts, Inc. in the State of Florida and planned to develop an on-line marketplace for used car parts.

On February 24, 2004, the Company's then principal shareholder and control person entered into a Capital Stock Purchase Agreement with Panetta Partners Ltd., a limited partnership affiliated with the Company's former Co-Chairman and current director, Gabriele M. Cerrone, pursuant to which Panetta purchased approximately 97% of the Company's outstanding shares of common stock at the time.

On April 12, 2004, the founders of Xenomics Sub consisting of Messrs. Tomei, Umansky and Melkonyan, who are no longer with the Company, contributed \$1,655,031 in deferred compensation to Xenomics Sub stockholders' equity.

On July 2, 2004, Used Kar Parts, Inc. acquired all of the outstanding common stock of Xenomics Sub by issuing 376,334 shares of Used Kar Parts, Inc. common stock to Xenomics Sub's five shareholders (the Exchange). The Exchange was made according to the terms of a Securities Exchange Agreement dated May 18, 2004. For accounting purposes, the acquisition has been treated as an acquisition of Used Kar Parts, Inc. by Xenomics Sub and as a recapitalization of Xenomics Sub. Accordingly, the historical financial statements prior to July 2, 2004 are those of Xenomics Sub.

In connection with the Exchange, Used Kar Parts, Inc.:

- 1) Redeemed 36,477,079 shares from Panetta Partners Ltd., a principal shareholder, for \$500,000 or \$0.0138 per share.
- 2) Amended its articles of incorporation to change its corporate name to Xenomics, Inc. and to split its stock outstanding 111 for 1 (effective July 26, 2004), immediately following the redemption.
- 3) Entered into employment agreements with two of the former Xenomics Sub shareholders and a consulting agreement with one of the former Xenomics Sub shareholders.

Edgar Filing: Trovogene, Inc. - Form 10-K

- 4) Entered into a Voting Agreement with certain investors, the former Xenomics Sub shareholders and certain principal shareholders.

- 5) Entered into a Technology Acquisition Agreement with the former Xenomics Sub shareholders under which Xenomics granted an option to the former Xenomics Sub holders to re-purchase Xenomics Sub technology if Xenomics fails to apply at least 50% of the net proceeds of financing it raises to the development of Xenomics Sub technology during the period ending July 1, 2006 in exchange for all Xenomics shares and share equivalents held by the former Xenomics Sub holders at the time such option is exercised. This agreement was terminated on June 30, 2006.

- 6) Issued and transferred 58,333 shares of common stock to be held in escrow, in the name of the Company, to cover any undisclosed liabilities of Xenomics Sub. Such shares were treated as treasury shares. The escrow period was for one year to July 2, 2005 at which time a determination of liability was determined to be none and the shares were released.

In connection with the merger and recapitalization of the Company, the Company incurred costs of \$301,499 which was accounted for as a reduction of additional paid in capital.

On August 6, 2010, Trovogene acquired all of the outstanding common stock of Etherogen, Inc. (Etherogen), a related party, in exchange for 2,043,797 shares of Trovogene common stock pursuant to the terms of the Agreement and Plan of Merger dated August 10, 2010 among Trovogene, E ACQ Corp. and Etherogen (the Merger). The fair value of the shares issued to effect the Merger was \$2,771,389, based on the fair value of Trovogene s common stock on the date of the Merger.

The Merger was accounted for as an acquisition of assets for accounting purposes primarily because there were no processes acquired. The assets acquired consisted primarily of diminimus property, plant and equipment, patents, trademarks and other intellectual property, and in-process research and development. In addition, the Company assumed a note in the amount of \$104,700

Table of Contents

which was converted into shares on the date of acquisition. In accordance with ASC Topic 805, Business Combinations, the Company recorded the total fair value of an indefinite lived asset related to the patent of \$104,700 on the Company's consolidated balance sheet. The excess of the fair value of the consideration issued over the fair value of the net assets acquired was \$2,666,869. The total excess of the fair value of the net assets acquired and the conversion of the note was recorded as purchased in process research and development expense-related party on the Company's consolidated statement of operations.

On February 1, 2012 the Company entered into an asset purchase agreement with MultiGen Diagnostics, Inc. The Company determined that the acquired asset did not meet the definition of a business, as defined in ASC 805, *Business Combinations* and was accounted for under ASC 350, *Intangibles- Goodwill and Other*. In connection with the acquisition, the Company issued 125,000 shares of restricted common stock to MultiGEN. In addition, up to an additional \$3.7 million may be paid in a combination of common stock and cash to MultiGEN upon the achievement of specific sales and earnings targets. In addition, in connection with the acquisition, the Company entered into a Reagent Supply Agreement dated as of February 1, 2012 pursuant to which MultiGEN will supply and deliver reagents to be used in connection with a Clinical Laboratory Improvement Amendment (CLIA) laboratory. The total purchase consideration was determined to be \$187,500 which was paid in the Company's common stock and allocated to an indefinite lived intangible asset related to the CLIA license.

Under ASC Topic 805, Business Combinations, the Company was required to assess the fair value of the assets acquired and the contingent consideration at the date of acquisition. Therefore, the Company assessed the fair value of the assets purchased and concluded that the purchase price would be allocated entirely to one intangible asset, a CLIA license. The contingent consideration of the \$3.7 million milestone was determined to have no fair value by applying a weighted average probability on the achievement of the milestones developed during the valuation process. The Company assesses the fair value of the contingent consideration at each quarter and makes adjustments as necessary until the milestone dates have expired. As of December 31, 2013 and 2012, no adjustments to the fair value of the contingent consideration have been necessary, and therefore the fair value of the contingent consideration remains unchanged.

4. Property and Equipment

Fixed assets consist of laboratory, testing and computer equipment and fixtures stated at cost. Depreciation and amortization expense for the years ended December 31, 2013, 2012 and 2011 and for the period August 4, 1999 (inception) to December 31, 2013 was \$130,520, \$41,842, \$10,285, and \$394,161, respectively. Property and equipment consisted of the following:

	As of December 31,	
	2013	2012
Furniture and office equipment	\$ 236,645	\$ 81,438
Leasehold Improvements	36,371	11,207
Laboratory equipment	826,151	421,738
	1,099,167	514,383
Less accumulated depreciation and amortization	(348,602)	(259,641)
Property and equipment, net	\$ 750,565	\$ 254,742

5. Stockholders' Equity (Deficiency)

Edgar Filing: Trovogene, Inc. - Form 10-K

All share and per share amounts have been restated to reflect the 111 for 1 stock split which was effective July 26, 2004 as described in Note 3 and the one-for six reverse stock split effected on May 29, 2012 as described in Note 2.

The note below summarizes the Company's equity financings since July 2004. The equity sales were often accompanied by warrants that were required to be accounted for as derivative liabilities. In July 2013, the Company closed a public offering which removed the price protection feature that required 1,288,650 warrants issued in the fourth quarter of 2012 (see F-35) to be treated as derivative liabilities and resulted in a reclassification of the warrants to equity. The 1,013,961 warrants related to the forbearance agreement (see F-31) continue to be accounted for as derivative liabilities.

Common Stock

On July 2, 2004, the Company completed a private placement of 440,868 shares of its common stock for aggregate proceeds of \$2,512,950, or \$5.70 per share. The sale was made to 17 accredited investors directly by the Company without any general solicitation or broker and thus no selling agents' fee were paid.

On January 10, 2005, Trovogene entered into a service agreement with Trilogy Capital Partners, Inc. (Trilogy) pursuant to which Trilogy provided marketing, financial, and public relations services. Pursuant to this service agreement, Trovogene issued warrants to Trilogy to purchase 166,667 shares of Common Stock of Trovogene at an exercise price of \$17.70 per share. The exercise price was determined to be consistent with the price of the warrants being offered to purchasers as part of an investment unit in the then operative private placement memorandum. The warrants issued to Trilogy were exercisable upon issuance and expired on January 10, 2008. The fair value of the Trilogy warrants using the Black-Scholes methodology was \$2,630,440 which was immediately expensed. The following inputs to the Black-Scholes option pricing model were used to determine fair value: (i) stock

Table of Contents

price \$25.20 per share, (ii) no dividend, (iii) risk free interest rate 4.5% and (iv) volatility of 80%. This service agreement was terminated by Trovogene on June 12, 2006.

On January 28, 2005, the Company closed the first tranche of a private placement selling 228,026 shares of common stock and 57,007 warrants to certain investors (the Investors). The securities were sold as a unit at a price of \$11.70 per unit for aggregate proceeds of \$2,667,900. Each Unit consisted of one share of common stock and one quarter of a warrant to purchase one quarter share of common stock. The Investor warrants were immediately exercisable at \$17.70 per share and were exercisable at any time within five years from the date of issuance. The fair value of these Investor warrants using a market price of \$25.20 per share on the date of issuance was \$1,198,373 using Black Scholes assumptions of 80% volatility, a risk free interest rate of 4.25%, no dividend, and an expected life of five years. The fair value of the Investor warrants was recorded as additional paid in capital during the year ended January 31, 2005. The Company also issued an aggregate of 20,610 warrants to purchase common stock to various selling agents, which were immediately exercisable at \$12.90 per share and expired five years after issuance. The selling agent warrants had a fair value of \$403,038 on the date of issuance and this amount was recorded as a cost of raising capital.

On February 5, 2005, the Company completed the second tranche of the private placement described above selling an additional 17,094 shares of common stock and 4,274 warrants to the Investors at a price of \$11.70 per unit for aggregate proceeds of \$200,000. In addition, the Company paid an aggregate \$179,600 in cash and issued 4,077 shares of common stock to certain selling agents, in lieu of cash, which had a fair value of \$47,699 capitalized at \$11.70 per share. The Investor and selling agent warrants had the same terms as the warrants described above issued in the first tranche.

In connection with the offer and sale of securities to the Investors the Company also entered into a Registration Rights Agreement, dated as of January 28, 2005, with the Investors pursuant to which the Company agreed to file, within 120 days after the closing, a registration statement covering the resale of the shares of common stock sold to the Investors and the shares of common stock issuable upon exercise of the Warrants issued to the Investors. In the event a registration statement covering such shares of Common Stock was not filed with the SEC by the 120th day after the final closing of the Offering (May 28, 2005), the Company shall have paid to the investors, at the Company's option in cash or common stock, an amount equal to 0.1125% of the gross proceeds raised in the Offering for each 30 day period that the registration statement was not filed with the SEC. On August 1, 2005 the Company filed a Form SB-2 registration statement with the Securities and Exchange Commission and the resulting liquidated damages in the amount of \$16,304 was paid to the Investors and charged to other expense. Pursuant to this January 28, 2005 Registration Rights Agreement there are no additional liquidated damages for failure to have the registration statement declared effective by a specified date, or for failure to maintain its effectiveness for any specified period of time.

On April 7, 2005, the Company closed the third and final tranche of the private placement described above of 252,564 shares of common stock and 63,141 warrants to certain additional Investors. The securities were sold as a unit at a price of \$11.70 per unit for aggregate proceeds of \$2,954,999. The warrants issued to the selling agents were immediately exercisable at \$12.90 per share and expired five years after issuance. The warrants issued to Investors have the same terms as the warrants described above issued in the first tranche.

Each unit consisted of one share of common stock and a warrant to purchase one quarter share of common stock. The warrants were immediately exercisable at \$17.70 per share and are exercisable at any time within five years from the date of issuance. The fair value of these Investor warrants using a market price of \$15.66 per share on the date of issuance date was \$694,335 using Black Scholes assumptions of 80% volatility, a risk free interest rate of 4.25%, no dividend, and an expected life of five years. The fair value of the Investor warrants was recorded as additional paid in capital during the year ended January 31, 2006.

Edgar Filing: Trovogene, Inc. - Form 10-K

The Company paid an aggregate \$298,000 and issued an aggregate 20,205 warrants to purchase common stock to a selling agent. The warrants issued to the selling agent were immediately exercisable at \$12.90 per share, expire five years after issuance. The warrants had a fair value of \$222,188 on the date of issuance and this amount was recorded as a cost of raising capital. These April 7, 2005 Investors became parties to the same Registration Rights Agreement as the January 28, 2005 Investors.

Pursuant to ASC Topic 815-40, the warrants issued in the three tranches described above were classified as permanent equity and the fair value of \$222,188 of the selling agent warrants upon issuance was recorded as additional paid in capital.

On July 20, 2006, the Company issued 106,667 shares of common stock and 53,333 warrants at \$7.50 per unit and received gross proceeds of \$800,000. Each unit consisted of one share of common stock and one-half a warrant to purchase one-half a share of common stock. The warrants had an exercise price of \$12.00 per share and expired on July 20, 2008. In connection with this transaction, the Company paid \$104,000 and issued 13,867 warrants to a selling agent. The warrants issued to selling agents have the same terms as those issued to the purchasers of common stock.

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

On August 14, 2006, the Company issued 19,120 shares of common stock and 9,560 warrants at \$7.50 per unit and received gross proceeds of \$143,401. Each unit consisted of one share of common stock and half a warrant to purchase half a share of common stock. The warrants had an exercise price of \$12.00 per share and expired on August 14, 2008. In connection with this transaction, the Company paid \$14,341 and issued 1,912 warrants to a selling agent. The warrants have the same terms as those issued to the purchasers of common stock.

Pursuant to the provisions of ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, the warrants issued to the selling agents on July 20, 2006 and August 14, 2006 were classified as permanent equity and the fair value allocated to such warrants upon issuance of \$55,568 was recorded as additional paid in capital.

Under the terms of the securities purchase agreement applicable to the issuance of common stock and warrants on July 20, 2006 and August 14, 2006, the Company agreed to: a) file a registration statement on or before October 18, 2006 covering the resale of the shares of the common stock and the underlying shares of the common stock issuable upon exercise of the warrants; b) use commercially reasonable efforts to cause the registration statement to be declared effective by the SEC no later than November 17, 2006 if there was no review of the registration statement performed by the SEC or December 16, 2006 if there was a review performed by the SEC; and c) use commercially reasonable efforts to keep the registration statement continuously effective. If any of the above obligations are not met (a Breach), the Company shall pay monthly liquidated damages in an amount equal to 1% of the gross proceeds of the amount raised in these offering for the period from the date of a breach until it is cured. Such liquidated damages may not exceed 8% of the gross proceeds or \$75,472. As of the date of these financial statements, a registration statement has not been filed and the Company has recorded liquidated damages of \$75,472 through December 31, 2010.

On December 21, 2006, the Company closed a private placement of 166,667 shares of common stock and 83,333 warrants to an institutional investor for aggregate gross proceeds of \$1,000,000 pursuant to a Securities Purchase Agreement dated as of December 21, 2006. The warrants were immediately exercisable at \$7.50 per share, were exercisable at any time within six (6) months from the date of issuance, and were recorded at their fair value of \$15,000. The Company paid an aggregate \$80,000 to a selling agent. Proceeds from the issuance of these instruments were allocated to common stock and warrants based upon their relative fair value. This resulted in an allocation of \$905,000 to temporary equity (see below) and \$15,000 to the warrants classified as derivative financial instruments. Under the terms of the Securities Purchase Agreement applicable to the issuance of common stock and warrants on December 21, 2006, the Company had an obligation to file a registration statement covering the resale of the shares of the common stock and the underlying shares of the common stock issuable upon exercise of the warrants on or prior to 15 days after the earlier of a financing or a series of financings wherein the Company raises an aggregate of \$5,000,000 or May 14, 2007. Additionally, the Company had the obligation to use commercially reasonable efforts to cause the registration statement to be declared effective no later than 45 days after it is filed. However, the Securities Purchase Agreement was silent as to any penalties or liquidated damages if the obligations described above were not met. Consequently, since the Company's ability to meet the above obligations were not within its control and the penalties were not determinable and could result in the Company having to settle in cash, they were classified as temporary equity in accordance with the provisions of ASC Topic 480 *Distinguishing Liabilities from Equity*. The warrants were marked to market from \$15,000 to \$20,000 at January 31, 2007, with \$5,000 recorded as a change in fair value of derivative financial instruments.

On May 21, 2007, the Company modified the terms of the warrants issued in connection with the December 21, 2006 private placement and extended the term of those warrants from June 21, 2007 to August 21, 2007. This had an immaterial impact on the consolidated financial statements.

On February 15, 2008, the common shares were no longer deemed Registrable Securities under the Securities Purchase Agreement because of newly enacted shorter Rule 144 holding requirements which removed the requirement for registration and the eliminated risk of a cash settlement. Accordingly, the Company reclassified the common stock to permanent equity on that date.

Edgar Filing: Trovogene, Inc. - Form 10-K

On October 12, 2007 and October 16, 2007, the Company closed private placements of 233,333 shares and 50,000 shares of common stock, respectively, for aggregate gross proceeds of \$850,000. The Company issued a five year warrant to purchase 16,667 shares of common stock at an exercise price of \$3.00 per share to a selling agent. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company determined that the warrants issued in connection with this private placement must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of these warrants on the date of issuance was \$45,371. This derivative liability has been marked to market at the end of each reporting period.

The Company paid \$51,733 to a selling agent in connection with this transaction and issued warrants to purchase 16,667 shares of common stock at an exercise price of \$3.00 per share which expire five years after issuance. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company determined that the warrants issued in connection with this private placement must be recorded as derivative liabilities with a charge to additional paid in capital. The selling agent warrants had a

Table of Contents

fair value of \$45,403 on the date of issuance and this amount was charged to additional paid in capital as a cost of raising capital. This derivative liability has been marked to market at the end of each reporting period.

On February 1, 2008, the Company closed a private placement of 179,167 shares of common stock and 53,750 warrants to investors for aggregate gross proceeds of \$645,000 pursuant to a Securities Purchase Agreement dated February 1, 2008 (the "Private Placement"). The warrants have a two-year term and were exercisable at prices of \$4.50 per share in the first year and \$9.00 per share in the second year. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company determined that the warrants issued in connection with this private placement must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of these warrants on the date of issuance was \$60,295. This derivative liability has been marked to market at the end of each reporting period.

On June 12, 2008, the Company raised an additional \$500,000 from an investor, less a total of \$74,500 for selling agent fees and expenses in connection with this transaction, of which \$350,000 was invested at the closing and an additional \$150,000 was to be invested on or before August 15, 2008. The purchase price for the 151,515 shares was \$3.30 per share, and the investor received warrants to purchase up to 75,758 shares of the Company's common stock at a price of \$4.50 per share. The warrants have a three-year term and are exercisable at a price of \$4.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company determined that the warrants issued in connection with this registered direct offering must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of these warrants on the dates of issuance was \$80,632. This derivative liability has been marked to market at the end of each reporting period through the date of expiration on June 12, 2011.

On June 9, 2009 and July 2, 2009, the Company closed two private placement financings which raised gross proceeds of \$275,000. The Company issued 91,667 shares of its common stock and warrants to purchase 91,667 shares of common stock. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after five years and are exercisable at \$4.20 per share. These were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method.

During the period from October 2, 2009 to December 16, 2009, the Company closed seven private placement financings which raised gross proceeds of \$1,190,000. The Company issued 396,667 shares of its common stock and warrants to purchase 396,667 shares of common stock. The purchase price paid by the investor was \$3.00 for each unit. The warrants expire after six to nine years and are exercisable at \$3.00 per share. These warrants were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method.

On August 19, 2009, in accordance with a debt conversion agreement for settlement of consulting services rendered by Gabriele Cerrone the Company issued 159,630 units consisting of 159,630 shares of common stock and warrants to purchase 159,630 shares of common stock, in settlement of a \$478,890 obligation related to a consulting agreement with Gabriele M. Cerrone. The total fair value of the stock and warrants was \$478,890 based on a price of \$3.00 per unit. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovagene has determined that the warrants issued in connection with this transaction should not be recorded as a derivative liability and have been recorded as equity. See Note 13.

On June 30, 2009 and October 2, 2009, in accordance with an exchange agreement, a selling agent invested \$164,550 in exchange for the issuance of a) 68,897 shares of common stock, b) warrants to purchase 69,809 shares of common stock and c) \$164,550 principal amount of 6% convertible debenture. The warrants expire in three years and are exercisable at \$3.00 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovagene has determined that the warrants issued in connection with this transaction should not be recorded as a derivative liability and have been recorded as equity. The fair value of the common stock and warrants issued above totaled

Edgar Filing: Trovagene, Inc. - Form 10-K

\$306,737 and was charged to operations as consideration for services rendered, with a corresponding credit to additional paid in capital.

During the twelve months ended December 31, 2010, 79,333 shares of common stock and warrants to purchase 79,333 shares of common stock were issued to a shareholder as finders' fees in accordance with a Board of Directors resolution dated November 6, 2009. The issuance of these shares was recorded as a cost of capital and had only a nominal par value effect on total stockholders' equity.

In connection with the merger with Etherogen, Inc. in August 2010, the Company issued 2,043,797 shares of common stock, which shares had a fair value of \$2,711,389 at issuance (see Note 3). A total of 43,797 warrants to purchase 43,797 shares of common stock were also issued.

During the year ended December 31, 2010, the Company closed twelve private placement financings which raised gross proceeds of \$1,734,700. The Company issued 578,233 shares of its common stock and warrants to purchase 578,233 shares of common stock in these transactions. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after eight

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

years and are exercisable at \$3.00 per share. These were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method.

During the year ended December 31, 2010, the Company issued 70,833 shares and warrants to purchase 70,833 shares of common stock in connection with consulting agreements. The fair value used to measure compensation expense was \$3.00 for each unit, based on recent private placement transactions, totaling \$212,500. The warrants expire after eight to nine years and are exercisable at \$3.00 per share. These were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method. A total of \$112,500 was charged to general and administrative expense in the Company's consolidated statements of operations in 2010. The remainder of \$100,000 was accrued and charged to general and administrative expense in the year ended December 31, 2011.

In July 2010, 12,745 shares of common stock and warrants to purchase 12,745 shares of common stock were issued to a former CEO in settlement of a severance obligation totaling \$28,346, which amount was charged to general and administrative expense in the Company's consolidated statement of operations.

In August 2010, the Company issued 29,240 shares of common stock in settlement of \$100,000 of legal fees, which amount was charged to general and administrative expense in the Company's consolidated statements of operations.

During the year ended December 31, 2011, 90,258 shares of common stock and warrants to purchase 90,258 shares of common stock were issued to a shareholder as finder's fees in accordance with a Board of Directors resolution dated November 6, 2009. The issuance of these shares was recorded as a cost of capital and had only a nominal par value effect on total stockholders' equity. The fair value of the warrants on the date of issuance was \$113,376.

During the year ended December 31, 2011, the Company closed eighteen private placement financings which raised gross proceeds of \$2,573,500. The Company issued 857,833 shares of its common stock and warrants to purchase 857,833 shares of common stock in these transactions. The purchase price paid by the investors was \$3.00 for each unit. The warrants expire after seven years and are exercisable at \$3.00 per share. These warrants were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of the warrants on the date of issuance was \$1,059,600. This derivative liability has been marked to market at the end of each reporting period through May 30, 2012 when the price protection was removed which required these warrants to be treated as derivative liabilities.

During the year ended December 31, 2011, the Company issued 58,333 shares and warrants to purchase 58,333 shares of common stock in connection with consulting agreements. The fair value used to measure compensation expense for the stock issued was \$3.00 per share, based on recent private placement transactions. A total of \$175,000 was charged to general and administrative expense in the Company's consolidated statement of operations in 2011. The warrants expire after seven to eight years and are exercisable at \$3.00 per share.

These were price-protected units and therefore are derivative liabilities in accordance with ASC Topic 815-40 to be valued using the binomial option method. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, the Company determined that the warrants

Edgar Filing: Trovogene, Inc. - Form 10-K

issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The fair value of the warrants on the date of issuance was \$75,500. This derivative liability has been marked to market at the end of each reporting period through May 30, 2012 when the price protection was removed which required these warrants to be treated as derivative liabilities.

During the year ended December 31, 2011, 41,750 shares of common stock and warrants to purchase 41,750 shares of common stock were issued to members of the Board of Directors in lieu of cash payment related to their services in 2010. The amount owed to the Board of Directors for their fees were accrued and recorded in general and administrative expense in 2010.

During the year ended December 31, 2012, the Company closed five private placement financings which raised gross proceeds of \$6,320,000. In total, the Company issued 1,738,333 shares of its common stock and warrants to purchase 1,738,333 shares of common stock (units).

The purchase price paid by the investors for 633,333 of the units sold in the period January 2012 through May 2012 was \$3.00 each, determined by the price paid by investors in recent private placements. The warrants expire after eight years and are exercisable at \$3.00 per share. The Company paid \$96,500 in cash for a finder's fee. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovogene determined that the warrants issued in connection with these private placements should be recorded as derivative liabilities at the time of issuance since they are all price protected however the completion of the

Table of Contents

underwritten public offering on May 30, 2012 removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital.

The purchase price paid by the investors for 1,105,000 of the units sold in the fourth quarter of 2012 was \$4.00 each, determined by the market price on NASDAQ. The warrants expire after five years and are exercisable at \$5.32 per share. The Company paid \$24,989 in cash for a finder's fee. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovogene has determined that the warrants issued in connection with these private placements should be recorded as derivative liabilities at the time of issuance since they are all price protected. The fair value of the warrants on the date of issuance was \$1,031,281. This derivative liability has been marked to market at the end of the reporting period.

On May 30, 2012, the Company completed an underwritten public offering in which an aggregate of 1,150,000 units, with each unit consisting of two shares of its common stock and one warrant to purchase one share of common stock were sold at a purchase price of \$8.00 per unit. On June 13, 2012 the underwriters exercised their overallotment option in full for an additional 172,500 units. In addition, the Company issued 92,000 warrants to selling agents at an exercise price of \$7.00. The warrants were immediately exercisable and expire on May 29, 2017. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging - Contracts in an Entity's Own Equity, Trovogene determined that the warrants issued in connection with this transaction were not derivative liabilities. The Company raised a total of \$9.1 million in net proceeds after deducting underwriting discounts and commissions of \$0.7 million and offering expenses of \$0.7 million.

During the year ended December 31, 2012, the Company issued in total 174,100 units to a selling agent, who is also a shareholder of the Company, consisting of 174,100 shares of common stock and warrants to purchase 174,100 shares of common stock. Of the total warrants issued, 30,450 issued in the period January 2012 through May 2012 have an exercise price of \$3.00 per share, are immediately exercisable and expire December 31, 2018. The remaining 143,650 warrants issued in the fourth quarter of 2012, have an exercise price of \$5.32, are immediately exercisable, and expire five years from the date of issuance. The units were issued as a finder's fee in connection with certain private placements closed during the year ended December 31, 2012. The issuance of these units was treated as a non-compensatory cost of capital.

During the year ended December 31, 2012, the Company issued 40,000 units to Panetta Partners, Ltd., consisting of 40,000 shares of common stock and warrants to purchase 40,000 shares of common stock. Gabriele Cerrone, previously a member of the Board of Directors of Trovogene, is a director of Panetta Partners, Ltd. The warrants have an exercise price of \$5.32, are immediately exercisable, and expire five years from the date of issuance. The units were issued for advisory services in connection with the private placements closed in the fourth quarter of 2012. The issuance of these units was treated as a non-compensatory cost of capital. In addition, the Company issued a warrant to purchase 50,000 shares of common stock to Panetta Partners, Ltd. at an exercise price of \$4.14 for consulting services. The warrant was immediately exercisable and expires on December 10, 2017. The fair value of the warrant issued was determined using the Black-Scholes method. A total of approximately \$133,000 was charged to general and administrative expenses in the Company's consolidated statement of operations in 2012.

During the year ended December 31, 2012, the Company issued 125,000 shares of common stock in connection with an asset purchase agreement with MultiGen Diagnostics, Inc. See Note 3.

During the year ended December 31, 2012, the Company issued 9,916 shares of common stock in connection with consulting agreements. The fair value of the stock issued was determined using the Black-Scholes method. A total of \$22,381 was charged to general and administrative expense in the Company's consolidated statement of operations in 2012.

Edgar Filing: Trovogene, Inc. - Form 10-K

In December 2012, a Trovogene warrant holder exercised warrants to purchase 16,667 on a net exercise basis and received a total of 8,602 shares of common stock. The exercise price of the warrants was \$3.00.

In December 2012, a Trovogene option holder exercised his option and purchased a total of 200 shares of common stock. Trovogene raised gross proceeds of \$600 as a result of the option exercise. The purchase price paid by the option holder was \$3.00.

On January 25, 2013, the Company filed a Form S-3 Registration Statement to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price not exceeding \$150,000,000. The preferred stock, warrants, and units may be convertible or exercisable or exchangeable for common stock or preferred stock or other Trovogene securities. This form was declared effective on February 4, 2013. In addition, in connection with the Form S-3, the Company entered into an agreement with Cantor Fitzgerald & Co. (Agent) on January 25, 2013 to issue and sell up to \$30,000,000 of shares of common stock through them. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds. The Company has received gross proceeds of approximately \$4.2 million from the sale of 488,476 shares of its common stock during the year ended December 31, 2013 under the agreement with the Agent. In addition, the Company has received gross proceeds of approximately \$15.0 million from the sale of 2,142,857 shares of its common stock through a registered direct offering that occurred in July 2013.

During the year ended December 31, 2013, the Company issued a total of 3,424,605 shares of common stock. The Company sold 2,631,332 shares of Common Stock for net proceeds of \$18,829,644. In addition, 36,458 shares were issued upon conversion of Series A Preferred Stock, 715,743 shares were issued upon exercise of 715,743 warrants for a weighted average price of \$5.02 and 7,284 shares were issued upon net exercise of 12,745 warrants at an exercise price of \$3.00. The remaining 33,788 shares include 22,955 shares that were issued upon net exercise of an option for 41,667 shares at an exercise price of \$4.50 and the exercise of an option for 10,833 shares at a weighted average exercise price of \$3.53.

Table of Contents**Warrants**

During the years ended December 31, 2013, 2012, and 2011, warrant activity was as follows:

	Number of Warrants	Weighted Average Exercise price	Term
Warrants Outstanding 12/31/2010	2,629,056	\$ 3.24	3 - 9 years
Granted	1,048,175	\$ 3.00	
Expired	(75,757)	\$ 4.50	
Warrants Outstanding 12/31/2011	3,601,474	\$ 3.18	1 - 8 years
Granted	3,416,934	\$ 4.88	
Exercised	(16,667)	\$ 3.00	
Expired	(16,671)	\$ 3.00	
Warrants Outstanding 12/31/2012	6,985,070	\$ 3.96	1 - 6 years
Granted	50,000	\$ 8.00	
Exercised	(728,488)	\$ 4.99	
Expired	(73,099)	\$ 4.50	
Warrants Outstanding 12/31/2013	6,233,483	\$ 3.87	1 - 5 years

On October 29, 2008, the Company entered into a license agreement with Sequenom, Inc. In connection with this agreement, the Company issued a warrant to purchase 73,159 shares of the Company's common stock at an exercise price of \$4.50 per share. The warrant expired October 29, 2013. The Company has determined that the warrant meets the criteria of a derivative liability in accordance with ASC 815-40 effective January 1, 2009. The estimated fair value of this warrant as of the grant date was \$60,195, which was charged to additional paid-in-capital in 2008, based on the Black-Scholes option pricing model. The assumptions used were as follows: (i) stock price at date of grant \$1.86, (ii) term 5 years, (iii) volatility 75% and (iv) risk-free interest rate 2.77%. This fair value was expensed beginning in the fourth quarter of 2008 and charged to general and administrative expense with the offset to additional paid-in-capital. Subsequent changes in fair value are included in the change in fair value of derivative liabilities on the statement of operations. The change in fair values during the years ended December 31, 2013, 2012, 2011, and from inception (August 4, 1999) to December 31, 2013 was a gain of \$246,633, a loss of \$225,922, a gain of \$100,243, and a gain of \$60,195, respectively. See Note 11.

The Company granted 1,048,175 and 784,942 warrants that were price protected during the years ended December 31, 2011 and 2010. These warrants had an exercise price of \$3.00 per share and had expiration dates ranging from June 30, 2014 to December 31, 2018. The fair value of these warrants was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which warrant holders are likely to exercise their warrants and the expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. The completion of the underwritten public offering on May 30, 2012 removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital. See Note 7.

The Company granted a total of 3,416,934 warrants during the year ended December 31, 2012. Of the total warrants granted, 713,784 were warrants that were price protected. These warrants had an exercise price of \$3.00 per share and expire on December 31, 2018. The fair value of these warrants was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which warrant holders are likely to exercise their warrants and the

Edgar Filing: Trovogene, Inc. - Form 10-K

expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. The completion of the underwritten public offering on May 30, 2012 removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital. See Note 7. In connection with underwritten public offering and sale of units in May 2012, 1,414,500 warrants were issued with exercise prices ranging from \$5.32 to \$7.00 and an expiration date five years after date of issuance. Warrants issued in connection with the underwritten public offering and sale of units are not considered derivatives based on Trovogene's analysis of the criteria of ASC 815, as the Company is not required to make any cash payments or net cash settlement to the registered holder in lieu of issuance of warrant shares. An additional 1,288,650 warrants in the fourth quarter of 2012 were

Table of Contents

warrants that are price protected. These warrants have an exercise price of \$5.32 per share and have an expiration date of five years from issuance. The fair value of these warrants was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which warrant holders are likely to exercise their warrants and the expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. See Note 7.

The Company issued a warrant to purchase 50,000 shares of common stock at an exercise price of \$8.00 per share, during the year ended December 31, 2013. The warrants were issued in connection with an agreement to provide services related to investor and public relations materials and expire three years from date of grant. The estimated fair value of the warrant was determined on the date of grant using the Black-Scholes option valuation model using the following assumptions: a risk-free interest rate of 0.42%, dividend yield of 0%, expected volatility of 97% and expected term of three years. The resulting fair value of \$198,791 was recorded as stock based compensation expense.

Series A Convertible Preferred Stock

On July 13, 2005, the Company closed a private placement of 277,100 shares of Series A Convertible Preferred Stock (the Series A Convertible Preferred Stock) and 64,442 warrants to certain investors for aggregate gross proceeds of \$2,771,000 pursuant to a Securities Purchase Agreement dated as of July 13, 2005. The warrants sold to the Investors were initially immediately exercisable at \$19.50 per share and are exercisable at any time within five years from the date of issuance. These investor warrants had a fair value of \$567,085 on the date of issuance using a market price of \$14.40 on that date. In addition the Company paid an aggregate of \$277,102 and issued an aggregate of 17,572 warrants to purchase common stock to certain selling agents. The warrants issued to the selling agents were immediately exercisable at \$15.00 per share and expired five years after issuance. The selling agent warrants had a fair value of \$167,397 on the date of issuance and this amount was recorded as a cost of raising capital.

The material terms of the Series A Convertible Preferred Stock consist of:

1) *Dividends.* Holders of the Series A Convertible Preferred Stock shall be entitled to receive cumulative dividends at the rate per share of 4% per annum, payable quarterly on March 31, June 30, September 30 and December 31, beginning with September 30, 2005. Dividends shall be payable, at the Company's sole election, in cash or shares of common stock. As of December 31, 2013 and 2012, the Company had \$221,040 and \$191,200, respectively in accrued cumulative unpaid preferred stock dividends, included in Accrued Expenses in the Company's consolidated balance sheets, and \$29,840, \$38,240, and \$38,240, was recorded during the years ended December 31, 2013, 2012, and 2011, respectively.

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

Edgar Filing: Trovagene, Inc. - Form 10-K

3) *Liquidation.* Upon any liquidation, dissolution or winding-up of the Company, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is \$10 per share plus any accrued and unpaid dividends.

4) *Conversion Rights.* Each share of Series A Convertible Preferred Stock shall be convertible at the option of the holder into that number of shares of common stock determined by dividing the Stated Value, currently \$10 per share, by the conversion price, originally \$2.15 per share.

5) *Registration Rights.* In connection with the offer and sale of the Series A Convertible Preferred Stock the Company also entered into a Registration Rights Agreement pursuant to which the Company agreed to file a registration statement covering the resale of the common stock attributable to conversion of Series A Convertible Preferred Stock and the shares of common stock issuable upon exercise of the preferred warrants, within 30 days of the closing date and declared effective by October 25, 2005. In the event a registration statement covering such shares of common stock was not filed within 30 days of the closing date, the Company would pay to the investors an amount equal to 0.125% of the gross proceeds raised in the Offering for each 30 day period that the registration statement was not filed. In the event a registration statement

Table of Contents

covering such shares of common stock was not declared effective by October 25, 2005 Company will pay to the investors, at the Company's option in cash or common stock, an amount equal to 1% of the gross proceeds raised in the Offering for each 30 day period that the registration statement was not declared effective by the SEC. The registration statement was filed on August 1, 2005 and was not declared effective until March 17, 2006. The resulting liquidated damages of \$181,279 related to the registration statement not being declared effective until March 17, 2006 was recorded in the amounts of \$62,601 and \$118,678 during the years ended January 31, 2007 and 2006, respectively, as other expense. These amounts were paid in full as of January 31, 2007.

6) *Subsequent Equity Sales.* The conversion price is subject to adjustment for dilutive issuances for a period of 12 months beginning upon registration of the common stock underlying the Series A Convertible Preferred Stock. The relevant registration statement became effective March 17, 2006 and during the following twelve month period the conversion price was adjusted to \$9.60 per share.

7) *Automatic Conversion.* Beginning July 13, 2006, if the price of the common stock equals \$25.80 per share for 20 consecutive trading days, and an average of 8,333 shares of common stock per day shall have been traded during the 20 trading days, the Company shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price. As of the date of these financial statements, such conditions have not been met.

As per ASC 470-20 *Application of Issue 98-5 to Certain Convertible Instruments* the Company evaluated if the instrument had a beneficial conversion feature. The cash purchase and existing conversion rights were found to contain a beneficial conversion feature totaling \$792,956 and the preferred stock was further discounted by this amount. The beneficial conversion amount was then accreted back to the preferred stock because the preferred stock was 100% convertible immediately. The total amount accreted back to the preferred as a dividend and charged to Deficit Accumulated during Development Stage was \$792,956.

The fair value of the warrants issued in connection with this transaction was \$567,085 on the date of issuance. This amount was recorded as a liability in accordance with ASC 815-40 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, because the cash liquidated damages were unlimited, which was tantamount to a cash settlement. These warrants have been marked-to-market and the liability has been adjusted with a corresponding charge or benefit recorded in the statement of operations through October 31, 2006. As of November 1, 2006, the Company early adopted ASC 825-20 *Registration Payment Arrangements* which allows for registration payment arrangements to be accounted for separately in accordance with ASC 450 *Contingencies*. Therefore, the financial instrument subject to the registration payment arrangement shall be recognized and measured without regard to the contingent obligation to transfer consideration pursuant to registration payment arrangement. As a result of the adoption of ASC 825-20, the Company reclassified the liability related to these warrants, (\$111,700 at November 1, 2006) to equity in the amount of \$567,085, with the remainder of \$455,385 being adjusted to accumulated deficit. There were no additional liquidated damages required to be accrued as of January 31, 2007. Since inception to date, the Company recorded a net benefit for the change in fair value of this derivative financial instrument of \$455,385.

During the twelve months ended January 31, 2007, 174,000 shares of Series A Convertible Preferred Stock were converted into 137,739 shares of common stock. During the eleven months ended December 31, 2007, an additional 7,500 shares of preferred stock were converted into 7,813 shares of common stock. As of December 31, 2012 and 2011 there remained 95,600 shares of Series A Convertible Preferred Stock outstanding.

During the year ended December 31, 2013, 35,000 shares of Series A Convertible Preferred Stock were converted into 36,458 shares of common stock, on a net converted basis. As of December 31, 2013 and 2012, there were 60,600 and 95,600 shares of Series A Convertible Preferred Stock outstanding.

Convertible Debentures

On November 14, 2006, the Company sold \$2,225,500 aggregate principal amount of newly authorized 6% convertible debentures due November 14, 2008 (the "Debenture" or "Debentures") and issued warrants for the purchase of 674,394 shares of the Company's common stock at an exercise price of \$4.20 per share, subject to adjustment for certain dilutive issuances and are exercisable at any time on or prior to the sixth anniversary date of issuance. The debentures paid interest at the rate of 6% per annum, payable semi-annually on April 1 and November 1 of each year beginning November 1, 2007. The Company may, in its discretion, elect to pay interest on the Debentures in cash or in shares of its common stock, subject to certain conditions related to the market for shares of its common stock and the registration of the shares issuable upon conversion of the Debentures under the Securities Act. The debentures were convertible at any time at the option of the holder into shares of the Company's common stock at an initial price of \$3.30 per share, subject to adjustment for certain dilutive issuances. As a result of the October 2007 private placements the anti-

Table of Contents

dilution provisions in the Debentures and the warrants were triggered. As a result, the conversion price of the debentures and the exercise price of the warrants were reduced to \$3.00 per share and the number of common shares issuable upon conversion of the debentures and exercise of the warrants increased to 741,833 and 944,152, respectively.

The Company incurred debt issuance costs totaling \$464,960. Such costs were deferred and amortized over the two year life of the Debentures through November 2008.

In connection with the issuance of the Debentures, the Company entered into a registration rights agreement with the purchasers of the Debentures. The registration rights agreement grants registration rights to holders of shares of the Company's common stock issuable upon conversion of the convertible debentures and upon exercise of the warrants. Pursuant to the registration rights agreement, the Company was required to file a registration statement under the Securities Act covering the resale of the registrable securities on or prior to the 15th calendar day following the earlier of May 14, 2007 or the completion of an additional \$5,000,000 of sales of securities. To the extent a registration statement was not filed prior to the 15th calendar day the following the earlier of May 14, 2007 or the completion of an additional \$5,000,000 of sales of securities, the Company was obligated to pay liquidated damages in the amount of 1.5% of the aggregate proceeds for each thirty day period until a registration statement is filed up to a maximum amount of 24% or \$520,920. The Company did not file a registration statement by May 14, 2007, and recorded the maximum liquidated damages of \$520,920 as of that date.

In accordance with ASC 815-40, as a result of the anti-dilution provisions in the conversion option and the warrants these instruments were classified as liabilities. At the time of issuance the Company recorded an original issue discount of \$1,991,882, which was calculated based on the \$1,157,260 fair value of the conversion option and the \$834,562 fair value of the warrants. This discount was amortized to interest expense utilizing the interest method through the original maturity date of the debentures, November 14, 2008.

In connection with the debenture transaction, the Company issued a warrant to a finder, exercisable for 27,425 units, consisting of one share of common stock and one six-year warrant to purchase one share of common stock at an initial exercise price of \$4.20 per share, subject to certain adjustments. The initial exercise price of the warrant was \$3.30 per unit, subject to certain adjustments. The estimated fair value of the warrant of \$167,856 on the date of issuance was amortized to interest expense utilizing the interest method through the maturity date of the debentures, November 14, 2008.

On November 14, 2008, the maturity date of the Debentures, the Company failed to pay the aggregate principal amount of \$2,170,500, plus interest and penalties. Such failure represented an Event of Default under the Debentures Agreement. The Debenture holders also claimed other Events of Default under the Debentures. On January 30, 2009, the Company entered into a Forbearance Agreement with the holders of the Company's Debentures.

Pursuant to the Forbearance Agreement, the Company issued 906,245 shares of its common stock to the Debenture holders in full settlement of amounts claimed due for interest, penalties, late fees and liquidated damages totaling \$2,042,205. The fair value of the shares on January 30, 2009 was \$1.92 based on quoted market prices totaling \$1,739,959. The difference between the carrying value of the interest, penalties, late fees and liquidated damages and the fair value of the shares of \$302,246 was recorded as settlement costs on the statement of operations.

Edgar Filing: Trovogene, Inc. - Form 10-K

The aggregate initial principal amount of \$2,170,500 plus two additional issuances of \$164,550 in 2009 due under the Debentures remained outstanding totaling \$2,335,050. Other significant provisions of the Forbearance Agreement included the following:

- an extension of the Debentures' maturity date to December 31, 2010;
- an increase in the interest rate payable on the Debentures from 6% to 11%;
- the payment of interest in the form of Company common stock on a quarterly basis;
- rights of certain holders of a majority of the Debentures regarding the appointment of two persons to the Company's Board of Directors;
- conditions regarding the determination of compensation to be paid to the Company's officers and directors; and
- a total of 1,013,961 shares of common stock purchase warrants, expiring November 14, 2012, continued to be outstanding.

Table of Contents

The carrying value of the Debentures before modification in the amount of \$2,335,050 was exchanged for the fair value of the new debt in the amount of \$1,910,710 and the difference of \$424,299 was recorded as a gain in the statement of operations.

On July 18, 2011 the Company settled with the holders of the Debentures by converting the amounts outstanding by issuing 778,350 shares of common stock pursuant to a note and warrant agreement and the Company issued an additional 77,835 shares of common stock to the Debenture Holders as consideration to extinguish their debt. This resulted in a \$1.2 million gain on extinguishment based on the fair value of the stock being \$1.32 a share as of the date of the transaction. In addition, the 1,013,961 warrants, originally issued in 2006 with the Debentures with an expiration date of November 12, 2012, were exchanged for 1,013,961 new warrants with a new expiration date of December 31, 2018. The additional charge for this modification to the expiration date was \$581,503 which offset the gain, resulting in a net gain on extinguishment of \$623,383 for year ended December 31, 2011 on the Consolidated Statements of Operations.

During the years ended December 31, 2013 and 2012 the Company did not incur any interest expense related to the Debentures, while in the year ended December 31, 2011, the Company incurred \$128,421 of interest expense that was paid in shares of Common Stock. From inception (August 4, 1999) through December 31, 2013, the Company incurred interest expense of \$1,325,372 that was paid in 209,980 shares of Common Stock. The total value of the shares was \$629,939 based on the stock price allocation in the fair value of the price protected units issued during the years ended December 31, 2011 and 2010. The difference in the fair value of the consideration given and the amounts due to the Debenture holders was \$71,791 and \$316,402 for the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, respectively, which was recorded as a reduction of the interest expense in the Company's Consolidated Statements of Operations.

The 1,013,961 warrants had registration rights and in accordance with ASC 815 *Derivatives and Hedging*, (*ASC 815*), we have determined that these warrants were derivative liabilities. The fair value of these warrants on January 1, 2009, the date of adoption of ASC 815, was \$884,277. This derivative liability has been marked to market at the end of each reporting period since January 1, 2009. The change in fair value for the years ended December 31, 2013, 2012, and 2011, and inception (August 4, 1999) to December 31, 2013 was a gain of \$1,582,450, a loss of \$5,043,257, a loss of \$546,376, and a loss of \$3,547,596, respectively. The losses for year ended December 31, 2011 and the gain from inception (August 4, 1999) to December 31, 2013 exclude the \$581,503 charge for the modification in the change in fair value of the derivative liability on the Consolidated Statements of Operations.

Former Chief Executive Warrants

On November 14, 2006, the Company also issued to the Company's former Chief Executive (the holder) and the lead investor in the Debenture financing, a warrant to purchase up to an aggregate of 583,333 units, containing one share of its common stock and one warrant, at an initial purchase price of \$3.30 per unit; provided, on or prior to the time of exercise, the Company receives an aggregate of \$5.0 million of financing (the financing condition) in addition to the above. If the financing condition was not attained on or before May 17, 2007, these lead investor's warrants would terminate and be of no further force or effect.

On November 30, 2006 the Company amended the November 14, 2006 warrant to allow the holder to purchase until December 31, 2007 up to an aggregate of 1,060,606 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$3.30 per unit; provided, on or prior to the time of exercise, the Company attained the Financing Condition. The common stock purchase warrants had an initial exercise price, subject to certain adjustments, of \$4.20 per share and were exercisable at any time prior to the sixth anniversary date of the grant. If the Financing Condition was not fulfilled on or before August 31, 2007, the amended and restated warrant would terminate and be of no further force or effect.

Edgar Filing: Trovogene, Inc. - Form 10-K

On November 30, 2006, the Company also entered into a warrant and put option agreement with the Company's former Chief Executive. The warrant and put option agreement allowed the holder thereof to purchase up to 454,545 additional units as described above until December 31, 2007, at an initial purchase price of \$3.30 per unit, provided, on or prior to the time of exercise, the Financing Condition was attained. The fair value of this warrant at the date of grant was \$2,108,647. Upon written notice from the Company at any time after June 1, 2007 and ending the earlier of the satisfaction of the Financing Condition or December 31, 2007, the holder would, within 30 days from the date designated in the notice, purchase the number of Units specified in such notice up to the Maximum Put Amount divided by the applicable exercise price. The Maximum Put Amount was defined as the sum of \$5,000,000 less the amount from the sale of securities during the period beginning on December 1, 2006 to the date of measurement including any such sales pursuant to the Company's prior exercise in part of the put option on or before August 31, 2007. In no event shall the Maximum Put Amount exceed \$500,000 in a period of thirty calendar days or \$1,500,000 in the aggregate. If the Financing Condition was not fulfilled on or before August 31, 2007, the warrant and put option agreement would terminate and be of no further force or effect. Because the performance condition related to the above was not met, no expense was recorded by the Company.

On August 29, 2007, the Company and the former Chief Executive of the Company entered into an amendment (the Amendment) to the Warrant and Put Option Agreement originally dated as of November 30, 2006 pursuant to which the

Table of Contents

Amendment extended the date the holder of the warrant has the right to purchase up to an aggregate 454,545 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$3.30 per unit to June 30, 2008 from December 31, 2007. Such warrant was only exercisable, provided, on or prior to the time of exercise, the Financing Condition was attained. The Amendment also extended the date the Financing Condition must be met to February 29, 2008 from August 31, 2007. If the Financing Condition had not been met on or before such date, the Warrant and Put Option Agreement would terminate and be of no further force or effect.

In addition, on August 29, 2007, the Company and the former Chief Executive entered into an amendment (the Amended Warrant Agreement) to the Amended and Restated Warrant Agreement originally dated as of November 30, 2006 pursuant to which the Amended Warrant Agreement extended the date the holder of the warrant had the right to purchase up to an aggregate 1,060,606 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$3.30 per unit to June 30, 2008 from December 31, 2007. The Amended Warrant Agreement also extended the date the Financing Condition must be met to February 29, 2008 from August 31, 2007. If the Financing Condition had not been met on or before such date, the Amended and Restated Warrant Agreement shall terminate and be of no further force or effect.

In connection with the June 12, 2008 financing, the Company entered into Amendment No. 7, dated as of June 12, 2008, to the Warrant and Put Option Agreement originally dated as of November 30, 2006. This Amendment No. 7 extended to September 1, 2008, the date on which the Company may, at its sole discretion, exercise a put option (the Put Option) to require the former Chief Executive (who is the Lead Investor under the warrant agreement) to invest in the Company up to an additional \$1,500,000 for the purchase of common stock at a purchase price of \$3.30 per share (the Shares). The Amendment No. 7 also credits the former Chief Executive with amounts raised to reduce his obligation under the Put Option, so that the Put Option obligation is, as of this time, reduced to \$1,150,000. This extension of the put option did not have any impact on the Company's financial statements. See Note 11, Related Party Transactions.

Concurrent with completing the Forbearance Agreement, See Note 5 Convertible Debentures above, the Company and Dr. Gianluigi Longinotti-Buitoni, the Company's former Chief Executive, entered into a mutual release agreement under which each party delivered general releases of the other, including releases of the Company from contracts and claims related to Dr. Longinotti-Buitoni's service to the Company and a release by the Company of its rights under the Warrant and Put Option Agreement between the parties originally dated as of November 30, 2006, as amended (the Warrant Agreement), including any rights resulting from the October 2, 2007 exercise by the Company of its put option under the Warrant Agreement.

6. Stock Option Plan

In June 2004 the Company adopted the Trovagene Stock Option Plan, as amended (the Plan). The Plan authorizes the grant of stock options to directors, eligible employees, including executive officers and consultants. Generally, vesting for options granted under the Plan is from three to four years, and options expire after a 10-year period. Options are granted at an exercise price not less than the fair market value at the date of grant.

On April 4, 2006, at the Company's annual meeting, stockholders approved a proposal to increase the number of shares available for grant under the Plan from 833,333 to 2,000,000. In December 2009, the Board authorized an increase in the number of shares to be issued pursuant to the 2004 Stock Option Plan, as amended, from 2,000,000 to 3,666,667. The options granted under the Plan may be either incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended or non-qualified stock options at the discretion of the Board of Directors.

Edgar Filing: Trovogene, Inc. - Form 10-K

On May 24, 2005, the Compensation Committee, in recognition of the substantial time and effort to the Company's affairs during the prior twelve months by each of Gabriele M. Cerrone, former Co-Chairman, L. David Tomei, former Co-Chairman and President of SpaXen Italia, srl, our former joint venture with the Spallanzani National Institute for Infectious Diseases in Rome, Italy, Samuil Umansky, former President and the late Hovsep Melkonyan, former Vice President, Research, accelerated the vesting of outstanding stock options dated June 24, 2004 previously granted to each such officers in the amounts of 175,000, 168,750, 168,750 and 112,500, respectively, so that such options vested as of May 24, 2005. The acceleration did not result in the affected employees (Mr. Umansky and Mr. Melkonyan) being able to exercise options that would have otherwise expired unexercised, therefore no change to the original accounting treatment was required under ASC 505-50

Equity-Based Payments to Non-Employees.

In addition, in May of 2005 the Compensation Committee granted additional nonqualified stock options to Messrs. Cerrone, Tomei, Umansky and Melkonyan in the amounts of 40,000, 42,500, 37,500 and 12,500, respectively, pursuant to the Plan, as an additional incentive to perform in the future on behalf of the Company and its stockholders. Such options were exercisable at \$15.00 per share with 33 1/3% of the options granted to each officer vesting on each of the first three anniversaries of the date of grant. The options pertaining to Messrs. Umansky and Melkonyan remain valid and exercisable until their expiration date of May 2015 as stipulated in the 2010 settlement agreement (see Note 11). The options for Messrs. Cerrone and Tomei were fully vested by May of

Edgar Filing: Trovagene, Inc. - Form 10-K

Table of Contents

2008. Mr. Tomei left the Company in November 2006, and in accordance with his stock option agreement his options expired in November 2010. The stock based compensation expense for all of the options issued in May 2005 totaled \$1,045,846 for the three years ended December 31, 2008 and inception to December 31, 2011.

The acceleration of these options fixed the measurement date prior to the original vesting therefore the Company expensed the remaining balance of deferred stock based compensation attributable to those options totaling \$3,197,694 during the year ended January 31, 2006.

On June 1, 2007, Gianluigi Longinotti-Buitoni, the Company's former Chief Executive, and Dr. David Sidransky, an independent director, entered into consulting agreements with the Company wherein they would provide strategic planning, fund raising, management, and technology development services over a three year period beginning June 1, 2007. Compensation would be in form of options to purchase 166,667 and 106,667 shares, respectively, of common stock at an exercise price of \$4.74 per share for a period of ten years. Such options vested in varying amounts depending upon level of assistance the individuals provided to the Company and the attainment of certain revenue and per share value thresholds. The fair value of these options as of the date of the grant, assuming Mr. Buitoni and Dr. Sidransky provided assistance to the Company over a three year period and all thresholds were attained, were approximately \$358,000 and \$229,000 for Messers. Longinotti-Buitoni and Sidransky, respectively, utilizing the Black-Scholes model. The stock based compensation expense recorded was \$0 for the years ended December 31, 2010 and 2009 and for inception to date has been approximately \$179,000 and \$115,000 for Mr. Buitoni and Dr. Sidransky, respectively. On November 19, 2008, Mr. Buitoni and Dr. Sidransky resigned their positions as members of the Board of Directors. All previously unvested options, which numbered 111,111 and 71,111 for Mr. Buitoni and Dr. Sidransky, respectively, were terminated on this date.

In November 2010, Mr. Umansky and the estate of the late Mr. Melkonyan, settled their employment lawsuits against the Company which included the issuance of stock options.

During 2013, the Company issued 260,000 options over the authorized number of options in the Plan. As per ASC Topic 815-40, the options were accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company's statement of operations. Stockholder approval was obtained on July 18, 2013 to increase the number of authorized shares in the Plan from 3,666,667 to 6,000,000. Accordingly, the options were remeasured as of the date of stockholder approval with the change recorded in stock based compensation expense and the \$23,024 liability was reclassified to additional paid in capital.

In July 2013, an option to purchase 90,000 shares of common stock was granted to a Board Director for services provided outside of routine Board of Directors' services. These options were immediately vested. The fair value of this option was approximately \$500,000 and is included in general and administrative expenses.

Stock-based compensation has been recognized in operating results as follows:

	Years ended December 31,		
	2013	2012	2011
In research and development expenses	\$ 549,465	\$ 136,148	\$ 10,828
In general and administrative expenses	1,429,899	395,992	240,150
Total stock based compensation	\$ 1,979,364	\$ 532,140	\$ 250,978

Edgar Filing: Trovogene, Inc. - Form 10-K

The estimated fair value of stock option awards was determined on the date of grant using the Black-Scholes option valuation model with the following assumptions during the years indicated below:

	Years ended December 31,		
	2013	2012	2011
Risk-free interest rate	.74%-1.5%	.62% - 1.04%	.85% - 2.48%
Dividend yield			
Expected volatility	82%-100%	90%-97%	90%
Expected term (in years)	5.0 yrs	5.0 yrs	5.0 yrs
Stock price	\$5.53-\$8.15	\$0.50 - \$4.87	\$1.32

Risk-free interest rate Based on the daily yield curve rates for U.S. Treasury obligations with maturities which correspond to the expected term of the Company's stock options.

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

Dividend yield Trovogene has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility Based on the historical volatility of a group of peer companies with attributes similar to Trovogene.

Expected term The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin (SAB) No. 107, *Share-Based Payment*, (SAB No. 107), which averages an award's weighted-average vesting period and expected term for plain vanilla share options. Under SAB No. 107, options are considered to be plain vanilla if they have the following basic characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

Forfeitures ASC Topic 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on its historical experience.

The weighted-average fair value per share of all options granted during the years ended December 31, 2013, 2012, and 2011 estimated as of the grant date using the Black-Scholes option valuation model was \$4.54, \$2.12, and \$0.72 per share, respectively.

The unrecognized compensation cost related to non-vested stock options outstanding at December 31, 2013 and December 31, 2012 was \$3,733,753 and \$1,239,552, respectively. The weighted-average remaining contractual term at December 31, 2013 for options outstanding and vested options was 6.7 and 4.8 years, respectively.

A summary of stock option activity and of changes in stock options outstanding is presented below:

	Number of Options	Weighted Average Exercise Price Per Share	Intrinsic Value
Balance outstanding, December 31, 2010	2,409,609	\$ 5.40	\$ 143,500
Granted	737,833	\$ 3.00	
Exercised			
Forfeited	(721,250)	\$ 3.00	
Balance outstanding, December 31, 2011	2,426,192	\$ 5.22	\$
Granted	1,294,668	\$ 3.74	
Exercised	(200)	\$ 3.00	
Forfeited	(9,357)	\$ 3.00	
Balance outstanding, December 31, 2012	3,711,303	\$ 4.69	\$ 8,301,484
Granted	1,144,760	\$ 6.33	
Exercised	(52,500)	\$ 4.30	

Edgar Filing: Trovogene, Inc. - Form 10-K

Forfeited	(516,018)	\$	4.35	
Balance outstanding, December 31, 2013	4,287,545	\$	5.18	\$ 5,896,329
Exercisable at December 31, 2013	2,364,577	\$	5.51	\$ 3,511,817

ASC Topic 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to Trovogene's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

7. Derivative Financial Instruments - Warrants

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Contracts in Entity's Own Equity, Trovogene has determined that certain warrants issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital as they were issued with other equity instruments. In accordance with ASC Topic 815-40, the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant change in fair value is being recorded in the Company's statement of operations. The Company estimates the fair value of (i) certain of these warrants using the Black-Scholes option pricing model and (ii) estimates the fair value of the price protected units using the Binomial option pricing model in order to determine the associated derivative instrument liability and change in fair value described above.

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

Warrants - Black-Scholes Option Pricing Model

The range of assumptions used to determine the fair value of the warrants valued using the Black-Scholes option pricing model during the periods indicated was:

	Year ended December 31, 2013	Year ended December 31, 2012	Year ended December 31, 2011
Estimated fair value of Trovogene common stock	\$5.74 to \$7.18	\$0.02 to \$5.93	\$3.00 to \$15.00
Expected warrant term	1 months 5.8 years	10 months to 6 years	5 years
Risk-free interest rate	0.03-1.75%	.06%-1.54%	1.07% - 1.23%
Expected volatility	82 -100%	90%-97%	90%-
Dividend yield	0%	0%	0%

Expected volatility is based on the volatility of a peer group of companies with attributes similar to Trovogene. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, Trovogene used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates consistent with the expected remaining term of the warrants at each balance sheet date.

The following table sets forth the components of changes in the Company's derivative financial instruments liability balance, valued using the Black-Scholes option pricing method, for the periods indicated:

Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2011	Balance of derivative financial instruments liability	1,103,727	\$ 994,627
	Expired warrants	(16,667)	
	Change in fair value of warrants during the year recognized as a loss in the statement of operations		5,258,133
December 31, 2012	Balance of derivative financial instruments liability	1,087,060	6,252,760
	Expired warrants	(73,099)	
	Change in fair value of warrants during the year recognized as a gain in the statement of operations		(1,820,889)
December 31, 2013	Balance of derivative financial instruments liability	1,013,961	\$ 4,431,871

Warrants - Binomial Option Pricing Model

During the year ended 2011 and through May 2012, the Company issued 713,784 and 1,048,175 units, respectively, at \$3.00 per unit. The units had a per unit price protection clause whereby from the date of issuance until the earlier of (i) thirty months from the final Closing or (ii) the closing date of a Subsequent Financing which generates within a one year period an amount equal to or in excess of \$5,000,000, if the Company shall issue any Common Stock or Common Stock Equivalents, in a Subsequent Financing at an effective price per share less than the Per Unit

Edgar Filing: Trovagene, Inc. - Form 10-K

Purchase Price, the Company shall issue to such the number of additional Units equal to (a) the Subscription Amount Investor at the Closing divided by the Discounted Purchase Price, less (b) the Units issued to such Investor at the Closing. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Contracts in Entity's Own Equity, Trovagene has determined that these price protected units issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The price protected unit's warrants had an exercise price of \$3.00 per share and had expiration dates ranging from June 30, 2014 to December 31, 2018. The fair value of these price protected units was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which unit holders are likely to exercise their warrants and the expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. However, the completion of the underwritten public offering on May 30, 2012 removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital.

In addition, during the fourth quarter of 2012, the Company issued a total of 1,288,650 units at \$4.00 per unit. The units had a per unit price protection clause whereby from the date of issuance until the earlier of (i) forty-eight months from the final Closing or (ii) the closing date of a Subsequent Financing which generates within a one year period an amount equal to or in excess of \$10,000,000, if the Company shall issue any Common Stock or Common Stock Equivalents, in a Subsequent Financing at an effective price per share less than the Per Unit Purchase Price, the Company shall issue to such the number of additional Units equal to (a) the Subscription Amount Investor at the Closing divided by the Discounted Purchase Price, less (b) the Units issued to such Investor at the

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

Closing. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Contracts in Entity's Own Equity, Trovogene has determined that these price protected units issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. The price protected unit's warrants had an exercise price of \$5.32 per share and had expiration dates five years from date of issuance. The fair value of these price protected units was estimated using the binomial option pricing model. The binomial model requires the input of variable inputs over time, including the expected stock price volatility, the expected price multiple at which unit holders are likely to exercise their warrants and the expected forfeiture rate. The Company uses historical data to estimate forfeiture rate and expected stock price volatility within the binomial model. The risk-free rate for periods within the contractual life of the warrant is based on the U.S. Treasury yield curve in effect at the date of grant for the expected term of the warrant. However, the completion of the public offering in July 2013 removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through July 18, 2013 and then reclassified from a liability to additional paid in capital.

The fair value of the warrants granted during the year ended December 31, 2012 was estimated under the binomial method using the following weighted average assumptions:

	2012	2011
Range of risk-free interest rates	0.53% to 1.61%	1.35% to 2.8%
Range of expected volatility	90%- 97%	90%
Expected fair value of the stock	\$0.25 - \$3.21	\$1.38 - \$1.50
Expected warrant term	2 years to 6.75 years	5 years

The following table sets forth the components of changes in the Company's derivative financial instruments liability balance, valued using the Binomial option pricing method, for the periods indicated:

Date	Number of Price Protected Units	Derivative Liability For Issued Units	Change In Fair value of Derivative Liability For Previously Outstanding Price Protected Units	Ending Balance Derivative Liability
December 31, 2011	2,321,451	\$ 2,967,283	\$ (121,266)	\$ 2,846,017
Correction of error	(224,087)	(274,967)		2,571,050
Fair value of new warrants issued during the year	1,921,984	1,796,610		4,367,660
Reclassification of derivative liability to equity	(2,730,698)	(3,317,463)		1,050,197
Change in fair value of warrants during the year recognized as a loss in the statement of operations			1,462,671	2,512,868
December 31, 2012	1,288,650	1,171,463	1,341,405	2,512,868
Reclassification of derivative liability to equity	(1,288,650)		(5,417,871)	(2,905,003)
Change in fair value of warrants during the year recognized as a loss in the statement of operations			2,905,003	

Edgar Filing: Trovogene, Inc. - Form 10-K

December 31, 2013	\$	1,171,463	\$	(1,171,463)	\$
-------------------	----	-----------	----	-------------	----

During the quarter ended March 31, 2012 the Company recorded an adjustment of approximately \$275,000 to derivative liabilities based on a correction to the number of previously issued price protected units. The effect of this correction on the statement of operations for the quarter ended March 31, 2012 and the year ended December 31, 2012 was de minimus.

F-36

Table of Contents

The weighted average remaining contractual term of all of the Company's warrants outstanding at December 31, 2013 and 2012 was approximately four and five years, respectively.

At December 31, 2013 and 2012, the total fair value of the above warrants accounted for as derivative financial instruments, valued using the Black-Scholes option pricing model and the Binomial option pricing model was \$4,431,871 and \$8,765,628, respectively, and is classified as derivative financial instruments liability on the balance sheet.

8. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2013 and 2012:

	Fair Value Measurements at December 31, 2013			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets:				
Money market fund (1)	\$ 25,703,330	\$	\$	\$ 25,703,330
Total Assets	\$ 25,703,330	\$	\$	\$ 25,703,330
Liabilities:				
Derivative liabilities related to warrants		\$	\$ 4,431,871	\$ 4,431,871
Total Liabilities	\$	\$	\$ 4,431,871	\$ 4,431,871

	Fair Value Measurements at December 31, 2012			Total
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Liabilities:				
Derivative liabilities related to warrants	\$	\$	\$ 8,765,628	\$ 8,765,628
Total Liabilities	\$	\$	\$ 8,765,628	\$ 8,765,628

(1) Included as a component of cash and cash equivalents on the accompanying consolidated balance sheet.

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the years ended December 31, 2013 and 2012:

Edgar Filing: Trovogene, Inc. - Form 10-K

Description	Balance at December 31, 2012	Fair Value of Warrants Reclassified to Additional Paid in Capital	Unrealized (gains) or losses	Balance as of December 31, 2013
Derivative liabilities related to Warrants	\$ 8,765,628	\$ (5,417,871)	\$ 1,084,114	\$ 4,431,871

Description	Balance at December 31, 2011	Correction of error	Fair Value of Warrants Reclassified to Additional Paid in Capital	Fair value of New Warrants Issued During the Period	Unrealized (gains) or losses	Balance as of December 31, 2012
Derivative liabilities related to Warrants	\$ 3,840,644	\$ (274,967)	\$ (3,317,463)	\$ 1,796,609	\$ 6,720,805	\$ 8,765,628

F-37

Table of Contents

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

9. Debt

Equipment Line of Credit

In June 2013, the Company entered into a Loan and Security Agreement with Silicon Valley Bank that provides for cash borrowings for equipment of up to \$1.0 million, secured by the equipment financed. As of December 31, 2013, \$515,964 has been borrowed under the agreement. As of December 31, 2013, amounts due under the agreement include \$198,166 in current liabilities and \$322,998 in long-term liabilities, which includes \$5,200 of accrued interest.

Under the terms of the agreement, interest is the greater of 5% or 4.6% above the U.S. Treasury Note as of the date of each borrowing. The weighted average interest rate of the borrowings is 5.28%. Interest only payments are due on borrowings through December 31, 2013, with both interest and principal payments commencing in January 2014. Any equipment advances after December 31, 2013 are subject to principal and interest payments immediately over a 30 month period following the advance. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date and the final payment is being accrued over the term of the loans using the effective-interest method.

At December 31, 2013, Trovogene was in compliance with all covenants under the Loan Agreement. The Company is subject to certain nonfinancial covenants and a material adverse change clause.

The Company recorded \$17,005 in interest expense related to the Loan and Security Agreement during the year ended December 31, 2013. Closing costs were not material and were expensed to general and administrative expenses in June 2013.

Future maturities of long-term debt at December 31, 2013 are as follows:

2014	\$	198,166
2015		209,032
2016		113,966
Total long-term obligations	\$	521,164

10. Income Taxes

Edgar Filing: Trovogene, Inc. - Form 10-K

At December 31, 2013, Trovogene has federal net operating loss carryforwards (NOLs) of approximately \$36.2 million, which, if not used, expire beginning in 2020. Trovogene also has California NOLs of approximately \$16.9 million which begin to expire in 2021 and New Jersey NOLs of \$21.6 million which started to expire on January 31, 2013. Trovogene also has R&D credits available for federal purposes for \$235,300. The federal R&D credits will begin to expire January 31, 2025. The utilization of these NOLs and R&D tax credits is subject to limitations based on past and future changes in ownership of Trovogene pursuant to Internal Revenue Code Section 382. The Company has determined that ownership changes have occurred for Internal Revenue Code Section 382 purposes and therefore, the ability of the Company to utilize its NOLs is limited.

Significant components of the Company's deferred tax assets as of December 31, are shown below:

	Years ended December 31,	
	2013	2012
Deferred tax assets		
Tax loss carryforwards	\$ 14,211,400	\$ 10,913,700
R&D credits and other tax credits	235,300	123,300
Share based compensation	1,547,500	723,900
Other	230,400	65,000
Total deferred tax assets	16,224,600	11,825,900
Valuation allowance	(16,224,600)	(11,825,900)
Net deferred tax asset	\$	\$

The difference between the statutory rate of 35% on taxable income and the actual income tax rate of zero is a result of the full deferred tax asset valuation allowance. The valuation allowance increased by \$4,398,700 and \$1,992,100 during the years ended December 31, 2013 and 2012, respectively.

Table of Contents

Trovagene records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to Trovagene's ability to continue as a going concern and utilize its deferred tax assets, the Company recorded a valuation allowance against the deferred tax.

ASC 740-10-30-7, *Accounting for Income Taxes* had no effect on Trovagene's financial position, cash flows or results of operations upon adoption, as Trovagene does not have any unrecognized tax benefits. Trovagene's practice is to recognize interest and/or penalties related to income tax matters in income tax expense and none have been incurred to date. Xenomics Europa LTD did not file the required Form 5471 with the Internal Revenue Service. The potential exposure for not filing the Form 5471 is estimated to be approximately \$40,000 plus interest and penalties.

11. Commitments and Contingencies

Significant Research Agreements

During 2012, the Company entered into research agreements with University of Texas MD Anderson Cancer Center (MDACC) to provide samples and evaluate methods used by the Company in identification of pancreatic cancer mutations, as well as to measure the degree of concordance between results of cell-free DNA mutations analysis from urine samples and tumor tissue. During 2013, the agreements were amended to increase the scope of the agreements. Under these agreements, the Company has committed to pay approximately \$266,000 for the services performed by MDACC. As of December 31, 2013, the Company has incurred and recorded approximately \$142,000 of research and development expenses related to these agreements. There were no expenses incurred during the year ended December 31, 2013.

In April 2013, the Company entered into a Research and Development Agreement with PerkinElmer Health Sciences, Inc. (PerkinElmer) pursuant to which the Company will design an assay, based on the Company's urine-based cell-free molecular diagnostic technology, to determine the risk for developing hepatocellular carcinoma. In addition, the Company has granted PerkinElmer an exclusive option (the HCC Option) to obtain an exclusive royalty-bearing license to use the Company's technology within the hepatocellular carcinoma field (the HCC Field) as well as other fields. Together with PerkinElmer we will jointly validate the assay and evaluate the potential of combining our urine-based cell-free molecular diagnostic technology with PerkinElmer's technology for automation of nucleic acid isolation. PerkinElmer will pay us milestone payments. The Company recognizes milestone payments received from PerkinElmer as a reduction in research and development costs as the services are performed. Amounts received in advance of services performed are recorded as accrued liabilities until the services for which the payment has been received have been performed. The Company has received milestone payments related to this agreement of approximately \$90,000 and incurred approximately \$63,000 of research and development costs during the year ended December 31, 2013.

In June 2013, the Company entered into a Research Agreement with Illumina, Inc. (Illumina) pursuant to which the parties will work together to evaluate the potential for integrating the Company's transrenal technology for isolating, extracting and genetic analysis of nucleic acids from urine with Illumina's genetic analysis sequencing technology (the Research Plan). The parties have agreed that all results and reagents from the Research Plan will be shared between the parties. The Agreement will terminate upon the earlier of 30 days after completion of the Research Plan or the one year anniversary of the Agreement unless extended by mutual written agreement.

Edgar Filing: Trovagene, Inc. - Form 10-K

In August 2013, the Company entered into a Clinical Trial Agreement with the University of Southern California (USC), pursuant to which USC will provide the principal investigator and conduct the clinical trial related to the genetic characterization of metastatic colorectal cancers. Under the agreement, the Company is committed to pay USC approximately \$232,000 for services provided. As of December 31, 2013 the Company has not incurred any expense related to this agreement.

In December 2013, the Company entered into a Clinical Trial Agreement with US Oncology Research LLC (USOR), pursuant to which USOR will provide the principal investigator and conduct the clinical trial related to the examining the utility of transrenal quantitative KRAS testing in disease monitoring in patients with metastatic pancreatic cancer. Under the agreement, the Company is committed to pay USOR approximately \$270,000 for services provided. As of December 31, 2013 the Company has incurred and recorded approximately \$29,000 of research and development expense related to this agreement.

License Agreements

In May 2006, the Company entered into a license agreement with Drs. Falini and Mecucci, wherein it obtained the exclusive rights for the genetic marker for Acute Myeloid Leukemia (AML) and intends to utilize these rights for the development of new diagnostic tools. In connection with this agreement, the Company paid \$70,000 to Drs. Falini and Mecucci and is obligated to pay

Table of Contents

royalties of 6% of royalty revenues and/or 10% of any sublicense income. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty expenses of approximately \$30,000, \$24,000, and \$15,000, and \$87,000, respectively.

Additionally, the Company paid \$100,000 and issued warrants for the purchase of 16,667 shares of common stock at \$10.80 per share as a finder's fee to an independent third party. These warrants had a value of \$101,131 on the date of issuance utilizing the Black-Scholes model and expire June 29, 2014. All such payments and the value of the warrants were immediately expensed as research and development expenses.

During August 2007, the Company signed a sublicensing agreement with IPSOGEN SAS, a leading molecular diagnostics company with operations in France and the United States for the co-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification and monitoring of patients with acute myeloid leukemia (AML). Upon execution of this agreement, IPSOGEN paid an initial licensing fee of \$120,000 and may make milestone payments upon the attainment of certain regulatory and commercial milestones. IPSOGEN will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty, milestone and license fee revenues of approximately \$60,000, \$180,000, and \$50,000, and \$487,000, respectively. The Company has no license fee expense during the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded license fee expenses of approximately \$4,000.

In October 2007, the Company signed a sublicensing agreement with ASURAGEN, Inc. for the co-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification and monitoring of patients with AML. ASURAGEN paid an initial licensing fee of \$120,000 upon execution of the agreement and may make future payments to the Company upon the attainment of certain regulatory and commercial milestones. ASURAGEN will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$50,000, \$50,000, and \$50,000, and \$455,000, respectively. During the years ended December 31, 2013, 2012, and 2011, the Company had no license fee expenses related to this agreement, and from inception (August 4, 1999) to December 31, 2013, the Company recorded license fee expenses of approximately \$16,000. In March 2007, we signed amendment No. 2 to the co-exclusive sublicense agreement with ASURAGEN. The amendment limited the field of use to research use only (RUO) kits. ASURAGEN was also granted a non-exclusive sublicense for NPM1 laboratory testing services.

In January 2008, the Company signed a sublicensing agreement with Warnex Medical Laboratories for the non-exclusive rights to develop and market lab testing services for nucleophosmin protein (NPM1), for the diagnosis and monitoring of patients with AML. Warnex Medical Laboratories will pay the Company a royalty on any net revenues during the term of the agreement. The Company did not receive any royalty and license fee revenues nor record any license fee expenses in connection with this license agreement. Warnex Medical Laboratories sold off its laboratory business in 2013 and this agreement has been cancelled.

In August 2008, the Company signed a sublicensing agreement with LabCorp for the non-exclusive rights to develop and market lab testing services for NPM1, for the diagnosis and monitoring of patients with AML. LabCorp paid an initial licensing fee of \$20,000 upon execution of the agreement. LabCorp will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends August 25, 2018. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$20,000, \$5,000, and \$20,000, and \$92,000, respectively. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company has not recorded any license fee expenses.

Edgar Filing: Trovogene, Inc. - Form 10-K

In October, 2008, the Company signed a licensing agreement with Sequenom, Inc. for the rights to three patents for the methods for detection of nucleic acid sequences in urine. Sequenom paid an initial licensing fee of \$1 million upon execution of the agreement. Sequenom also agreed to pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. As the agreement was terminated in March 2011, there were no revenues related to the agreement for the year ended December 31, 2013 and 2012. During the year ended December 31, 2011, the Company recorded royalty revenues of approximately \$40,000. From inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$1,179,000. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company has not recorded any license fee expenses.

In December 2008, the Company signed a sublicensing agreement with InVivoScribe Technologies, Inc. for the non-exclusive rights to develop and market lab testing services for NPM1 for the diagnosis and monitoring of patients with AML. InVivoScribe Technologies paid an initial licensing fee of \$10,000 upon execution of the agreement. InVivoScribe Technologies will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31,

Table of Contents

2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$25,000, \$27,000, and \$20,000, and \$100,000, respectively. During the years ended December 31, 2013, 2012, and 2011 and from inception (August 4, 1999) to December 31, 2013, the Company has not recorded any license fee expenses.

In June 2010, the Company signed a sublicensing agreement with Skyline Diagnostics BV for the non-exclusive rights to develop, commercialize and market, research and diagnostic laboratory services for the stratification and monitoring of patients with AML. Skyline Diagnostics BV paid an initial licensing fee of \$10,000 upon execution of the agreement and may make future payments to the Company upon the attainment of certain regulatory and commercial milestones. Skyline Diagnostics BV will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$0, \$0, and \$20,000, and \$40,000, respectively. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company has not recorded any license fee expenses.

In January 2011, the Company entered into an asset purchase agreement with TTFactor S.r.l. for a hybridoma able to produce a monoclonal antibody targeting the NPM1 biomarker for \$10,000. In addition the Company agreed to pay the seller of the hybridoma for a period of seven years commencing with the first sale of the antibody, annual royalties on a country by country basis. In addition, the Company agreed to pay a percentage of all cash consideration received from licensees as an upfront license fee pursuant to any licenses of the product and a percentage of all cash consideration received from licensees as milestone payments. The agreement was terminated in 2013. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, there were no royalty expense, license fee or milestone payments recorded related to this agreement.

In February 2011, the Company entered into a sublicense agreement with MLL Münchner Leukämie Labor, or MLL for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. MLL paid an initial license fee of \$20,000 upon execution of the agreement and will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. MLL is obligated to pay a royalty with annual minimums of \$15,000 for the first year and \$20,000 thereafter. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$85,000, \$71,000, and \$35,000, and \$191,000, respectively.

In July 2011, the Company entered into a sublicense agreement with Fairview Health Services (Fairview) for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Fairview paid an initial license fee of \$10,000 upon execution of the agreement and will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. Fairview is obligated to pay a royalty with annual minimums of \$1,000 each year. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$1,000, \$2,000, and \$10,000, and \$13,000, respectively.

In October 2011, the Company entered into an exclusive license agreement with Gianluca Gaidano, Robert Foa and Davide Rossi for the patent rights to a specific gene mutation with respect to chronic lymphoblastic leukemia. In consideration of the license, the Company paid \$1,000 as an upfront license fee and agreed to make royalty payments in the single digits on net sales if sales are made by the Company or a single digit royalty on sublicense income received by the Company if sales are made by sublicensees. The Company has an option to purchase the licensed patent rights in the event the licensor decides to sell such licensed patent rights. The license agreement shall continue until September 29, 2031 which is the date of the last to expire of the licensed patent rights covering the license product. The license agreement may also be terminated upon a material breach by any party or by the Company if it is determined that it is not commercially or scientifically appropriate to further

Edgar Filing: Trovogene, Inc. - Form 10-K

develop the license product rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, no royalty expense has been recorded related to this agreement.

In December 2011, the Company entered into an exclusive license agreement with Columbia University to license the patent rights to hairy cell leukemia biomarkers. In consideration of the license, the Company paid \$1,000 as an upfront license fee and agreed to make royalty payments in the single digits on net sales if sales are made by the Company or a single digit royalty on sublicense income received by the Company if sales are made by sublicensees. The license agreement shall continue until May 10, 2021 which is the date of the last to expire of the licensed patent rights covering the license product. The license agreement may also be terminated upon a material breach by any party or by the Company if we determine that it is not commercially or scientifically appropriate to further develop the license product rights. During the years ended December 31, 2013, 2012, and 2011, and from inception (August 4, 1999) to December 31, 2013, no royalty expense has been recorded related to this agreement.

Table of Contents

In September 2012, the Company entered into a sublicense agreement with Quest Diagnostics for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, the Company has granted a license to certain NPM1 patents in exchange for a one time license fee of \$20,000 due upon execution of the agreement and royalty payments on net sales of Quest Diagnostics and its affiliates. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$14,000, \$20,000, and \$34,000, respectively.

In September 2012, the Company entered into a collaboration and license agreement with Strand Life Sciences (Strand) related to the validation and commercial launch of a urine based DNA test for Human Papillomavirus (HPV). Under this agreement, the Company has granted a license for use of its tests to Strand in exchange for royalty payments on net sales earned in the territory specified in the agreement. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, the Company has recorded no royalty and license fee revenues related to this agreement.

In November 2012, the Company entered into a sublicense agreement with Duke University and Duke University Health Systems for non-exclusive rights to develop and market laboratory testing services for NPM1 for diagnosis and monitoring of patients with AML. Under this agreement, the Company has granted a license to certain NPM1 patents in exchange for a one time license fee of \$5,000 due upon execution of the agreement and royalty payments on net revenues. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, the Company has recorded \$0, \$5,000, and \$5,000, respectively, of royalty and license fee revenues related to this agreement.

In December, 2012, the Company entered into a sublicense agreement with Genoptix, Inc. for non-exclusive worldwide rights to develop and market laboratory testing services for NPM1 for diagnosis and monitoring of patients with AML. Under this agreement, the Company has granted a license to certain NPM1 patents in exchange for a one time license fee of \$100,000 due upon execution of the agreement and royalty payments on net revenues. During the years ended December 31, 2013 and 2012, and from inception (August 4, 1999) to December 31, 2013, the Company recorded royalty and license fee revenues of approximately \$10,000, \$100,000, and \$110,000, respectively.

In total, during the years ended December 31, 2013, 2012, and 2011, the Company recorded \$0, \$125,000, and \$30,000 of license fees, \$259,246, \$175,404, and \$227,696 of royalty income, and \$0, \$150,000, and \$0 of milestone fees, respectively. From inception (August 4, 1999) to December 31, 2013, the Company recorded \$1,383,175 of license fees, \$1,184,720 of royalty income, and \$150,000 of milestone fees.

Litigation

Trovogene does not believe that the Company has legal liabilities that are probable or reasonably possible that require either accrual or disclosure. From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

We are not currently a party to any material legal proceedings.

Employment and Consulting Agreements

On June 24, 2005, Trovogene entered into an agreement with Gabriele M. Cerrone, the Company's former Co-Chairman, to serve as a consultant for a term of three years effective July 1, 2005 with automatic renewal for successive one year periods unless either party gives notice to the other not to renew the agreement. The duties of Mr. Cerrone pursuant to the agreement consisted of business development, strategic planning, capital markets and corporate financing consulting advice. Mr. Cerrone's compensation under the agreement was \$16,500 per month. Pursuant to the agreement the Company paid Mr. Cerrone a \$50,000 signing bonus in July 2005. In August 2009, the Company and Mr. Cerrone agreed to terminate this consulting agreement. The fair value of the amount owed (the obligation) to Mr. Cerrone was determined to be \$478,890, as approved by the Board of Directors. In settlement of the obligation the Company issued to Mr. Cerrone 159,630 units, consisting of 159,630 shares of the Company's common stock and 159,630 warrants to purchase 159,630 shares of common stock of the Company, calculated by dividing the obligation by \$3.00 per share, as approved by the Board of Directors. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovogene has determined that the warrants issued in connection with these warrants should not be recorded as derivative liabilities.

In April 2009, pursuant to a written consent of the majority of the shareholders, Thomas Adams was appointed as Chairman of the Board and was given delegated duties as the most senior executive officer of the Company until a Chief Executive Officer was appointed. Mr. Adams was granted 800,000 ten year options to purchase shares of the Company's stock at \$3.00 a share which vest in three equal annual installments on April 6, 2010, 2011 and 2012 provided he is still a director, officer or consultant and was retained

Edgar Filing: Trovogene, Inc. - Form 10-K

Table of Contents

as a consultant for a term three years at an annual amount of \$100,000. The fair value of the options at the date of grant was \$427,736 and was expensed over the vesting term in accordance with ASC 505-50. During the year ended December 31, 2011, the Company recorded stock based compensation in the amount of approximately \$48,000.

In March 2010, the Board of Directors in a Unanimous Written Consent agreed to settle the amount of \$100,000 in full due to Thomas Adams by issuing 33,333 units with each unit consisting of one share of common stock and one warrant to purchase shares of common stock at \$3.00 a unit.

On August 10, 2011, the Company and Tom Adams entered into an agreement to: (i) terminate the consulting arrangement and to consider the 33,333 units issued in March 2010 as full payment for his services under the consulting arrangement (ii) amend and restate his April 2009 option agreement by replacing the 800,000 options granted with 303,750 new options with the following terms:

- a) New grant date of August 5, 2011
- b) Exercise price of \$3.18 per share
- c) 133,333 options vested immediately, with the remaining 56,806 to vest on August 5, 2012, 56,806 to vest on August 5, 2013 and 56,805 to vest on August 5, 2014 provided he continues to provide services to the Company.
- d) Ten year option life, expiring August 5, 2021 or within 90 days of termination

The Company recorded stock based compensation through August 10, 2011 and recorded a total amount of \$292,000 under the original option agreement. The Company fair valued the new options on August 10, 2011 using the Black - Scholes valuation method and the fair value of the new options was \$175,000. 133,333 of the options were vested immediately and the Company recorded \$77,000 of stock based compensation on the date of grant and recorded an additional \$5,000 totaling \$82,000 under the new option agreement for the year ended December 31, 2011 in accordance with ASC 505-50. Approximately \$48,000 and \$58,000 of stock based compensation was recorded during the years ended December 31, 2013 and 2012, respectively.

On October 4, 2011, the Company entered into an executive agreement with Antonius Schuh, Ph.D. in which he agreed to serve as Chief Executive Officer. The term of the agreement is effective as of October 4, 2011 and continues until October 4, 2015 and is automatically renewed for successive one year periods at the end to each term. Dr. Schuh's compensation is \$275,000 per year. During 2013, the Compensation Committee approved an increase to \$385,000. Dr. Schuh is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Dr. Schuh was granted 633,333 non-qualified stock options which have an exercise price of \$3.00 per share and vest annually in equal amounts over a period of four years. In addition, during 2013, he received an additional option grant to purchase 250,000 of common stock with a weighted average exercise price of \$5.91. The shares vest ratably over four years. The total fair value of the options on the date of grant totaled approximately \$1.6 million. Total

Edgar Filing: Trovogene, Inc. - Form 10-K

stock based compensation related to his option grants was approximately \$215,000, \$93,000, and \$23,000 during the years ended December 31, 2013, 2012 and 2011, respectively. Dr. Schuh is also eligible to receive a realization bonus upon the occurrence of either of the following events, whichever occurs earlier;

(i) In the event that during the term of the agreement, for a period of 90 consecutive trading days, the market price of the common stock is \$7.50 or more and the value of the common stock daily trading volume is \$125,000 or more, the Company shall pay or issue Dr. Schuh a bonus in an amount of \$3,466,466 in either cash or registered common stock or a combination thereof as mutually agreed by Dr. Schuh the Company; or

(ii) In the event that during the term of the agreement, a change of control occurs where the per share enterprise value of our company equals or exceeds \$7.50 per share, the Company shall pay Dr. Schuh a bonus in an amount determined by multiplying the enterprise value by 4.0%. In the event in a change of control the per share enterprise value exceeds a minimum of \$14.40 per share, \$22.80 per share or \$30.00 per share, Dr. Schuh shall receive a bonus in an amount determined by multiplying the incremental enterprise value by 2.5%, 2.0% or 1.5%, respectively.

If the executive agreement is terminated for cause or as a result of Dr. Schuh's death or permanent disability or if Dr. Schuh terminates his agreement voluntarily, Dr. Schuh shall receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus or realization bonus earned but not yet paid through the date of termination and (iii) all expenses reasonably incurred by Dr. Schuh prior to date of termination. If the executive agreement is terminated without cause Dr. Schuh shall receive a severance payment equal to base compensation for three months if termination occurs ten months after the effective date of the agreement and six months if termination occurs subsequent to ten months from the effective date. If the executive agreement is terminated as a result of a change of control, Dr. Schuh shall receive a severance payment equal to base compensation for

Table of Contents

twelve months and all unvested stock options shall immediately vest and become fully exercisable for a period of six months following the date of termination.

On February 1, 2012, the Company entered into an executive agreement with Steve Zaniboni in which he agreed to serve as Chief Financial Officer. The term of the agreement is effective as of February 1, 2012 and continues until February 1, 2013 and is automatically renewed for successive one year periods at the end to each term. Mr. Zaniboni's compensation is \$200,000 per year. During 2013, the Compensation Committee approved an increase in salary to \$242,000. Mr. Zaniboni is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Mr. Zaniboni was granted 166,667 non-qualified stock options which have an exercise price of \$3.60 per share and vest annually in equal amounts over a period of four years. In addition, during 2013, he received an additional option grants to purchase 110,000 shares of common stock at a weighted average exercise price of \$5.79. The options vest ratably over four years. The total fair value of the options on the date of grant totaled approximately \$609,000. Total stock based compensation related to his option grants was approximately \$74,000 and \$25,000 during the years ended December 31, 2013 and 2012, respectively.

If the executive agreement is terminated by the Company for cause or as a result of Mr. Zaniboni's death or permanent disability or if Mr. Zaniboni terminates his agreement voluntarily, Mr. Zaniboni shall receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus or realization bonus earned but not yet paid through the date of termination and (iii) all expenses reasonably incurred by Mr. Zaniboni prior to date of termination. If the executive agreement is terminated by the Company without cause Mr. Zaniboni shall receive a severance payment equal to base compensation for three months if termination occurs ten months after the effective date of the agreement and six months if termination occurs subsequent to ten months from the effective date. If the executive agreement is terminated as a result of a change of control, Mr. Zaniboni shall receive a severance payment equal to base compensation for twelve months and all unvested stock options shall immediately vest and become fully exercisable for a period of six months following the date of termination.

On December 26, 2005, Trovogene entered into a letter agreement with David Robbins, Ph.D. to serve as Vice President of Product Development for a term of three years. Mr. Robbins received a grant of 16,667 incentive stock options with an exercise price of \$11.16 per share which vested in equal amounts over a period of three years beginning January 3, 2007. The agreement contained a provision pursuant to which all of the unvested stock options would vest in the event there was a change in control of the Company. The above options were fully vested at January 31, 2009.

On October 7, 2011, the Company entered into an employment agreement with Dr. Robbins, Ph.D. in which he agreed to serve as Vice President, Research and Development. The term of the agreement is effective as of October 7, 2011 and continues until October 7, 2012 and is automatically renewed for successive one year periods at the end to each term. Dr. Robbins' salary is \$195,000 per year. Dr. Robbins is eligible to receive a cash bonus of up to 25% of his base salary per year at the discretion of the Compensation Committee. If the employment agreement is terminated without cause, Dr. Robbins shall be entitled to a severance payment equal to three months of base salary. Dr. Robbins employment was terminated without cause in October 2012, and upon receipt of a release and indemnification of the Company, he received the severance in accordance with his employment agreement.

In January 2013, the Company entered into an employment agreement with Mark Erlander, Ph.D. in which he agreed to serve as Chief Scientific Officer. Dr. Erlander's salary is \$200,000 per year. During 2013, the Compensation Committee approved an increase in salary to \$260,000. Dr. Erlander is eligible to receive a cash bonus of up to 50% of his base salary per year at the discretion of the Compensation Committee based on goals mutually agreed upon by Dr. Erlander, the CEO and the Board of Directors. In connection with his employment, Dr. Erlander was granted a stock option to purchase 200,000 shares of common stock at an exercise price of \$7.04. The option vests ratably over a four year period. In addition, during 2013, he received an additional grant to purchase 100,000 shares of common stock at an exercise price of \$5.53. The

Edgar Filing: Trovagene, Inc. - Form 10-K

options vest ratably over four years. The total fair value of the options on the date of grant totaled approximately \$1.1 million. Total stock based compensation related to his option grants was approximately \$185,000 for the year ended December 31, 2013.

Consulting Agreements

In December 2010, the Company entered into an agreement with a consultant to introduce the Company to various technologies that he becomes aware of from time to time. As consideration for his services the Company issued 25,000 units upon the execution of the agreement. Each unit consisted of one share of the Company's common stock and one warrant to purchase one share of the Company's common stock and was immediately vested. In addition, the Company will grant an additional 58,333 units upon the achievement of certain milestones. During the year ended December 31, 2011, the Company issued 8,333 units upon achieving certain milestones which were immediately vested. The Company recorded research and development expense \$25,000 in the year ended December 31, 2011. The warrants have an exercise price of \$3.00 per share expiring on December 31, 2018. The above units were price protected and therefore the warrants were recorded as derivative liabilities and the change in fair value was recorded in the year ended December 31, 2011 in accordance with ASC Topic 815-40. During the year ended December 31, 2012, the change in fair

Table of Contents

value was recorded until completion of the underwritten public offering on May 30, 2012 that removed the price protection clause which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital. See Note 7.

On September 19, 2011 the Company entered into a consulting agreement whereby the Company retained the services of an independent management consultant who will provide consulting and advisory services to the Company. As compensation for the consultant's services, the Company issued 50,000 units during the year ended December 31, 2011 with each unit consisting of one share of the Company's common stock and one warrant to purchase one share of the Company's common stock which vested immediately. The Company recorded general and administrative expense of \$150,000 in the year ended December 31, 2011. The agreement terminates six months from the effective date. The warrants have an exercise price of \$3.00 per share expiring on December 31, 2018. The above units were price protected and therefore the warrants issued were recorded as derivative liabilities and the change in fair value was recorded in the year ended December 31, 2011 in accordance with ASC Topic 815-40. During the year ended December 31, 2012, the change in fair value was recorded until completion of the underwritten public offering on May 30, 2012 that removed the condition which required these warrants to be treated as derivative liabilities. Accordingly, the fair value of these warrants were marked to market through May 30, 2012 and then reclassified from a liability to additional paid in capital. See Note 7.

On February 1, 2012 the Company entered into a consulting agreement whereby the Company retained the services of an independent contractor who will provide business development services for the Company. As compensation for the consultant's services, the Company granted a stock option to purchase up to 166,667 shares of common stock at \$3.00 per share. The stock option vests as follows: 33,333 shares vest ratably over a four year period and 133,334 shares vest upon achievement of various milestones. The Company recorded approximately \$227,000 and \$38,000 of share based compensation in general and administrative expense during the year ended December 31, 2013 and 2012, respectively. See Note 2.

On April 26, 2012 the Company entered into a consulting agreement whereby the Company retained the services of an independent contractor who will provide scientific consulting services as a member of the Company's Scientific Advisory Board (SAB). As compensation for the consultant's services, the Company granted a stock option to purchase up to 100,000 shares of common stock at \$3.66 per share. Options to purchase the shares of common stock vest ratably over a three year period. The Company recorded approximately \$160,000 and \$68,000 of share based compensation in research and development expense during the year ended December 31, 2013 and 2012, respectively. See Note 2.

Deferred Founders Compensation

On August 15, 2000 Dr. Tomei, Mr. Umansky and Mr. Melkonyan (collectively the Founders) entered into employment agreements with the Company pursuant to which each Founder contributed 100% of their time to the Company with payment of their compensation deferred until the Company was sufficiently funded, sold or merged with another company.

In accordance with SAB 107, Topic 5, section T, the value of services performed by the Founders and principal shareholders was recorded as a liability and compensation expense. On April 12, 2004, in contemplation of entering into the Securities Exchange Agreement with Used Kar Parts, Inc. the Founders terminated their agreements, waiving any claims to be paid deferred compensation. On April 12, 2004, \$1,655,031 of deferred Founders' compensation liability, which had accumulated since August 15, 2000, was deemed an equity contribution and converted to additional paid-in-capital.

Lease Agreements

a) On October 28, 2009, the Company entered a three year and two months lease, commencing January 1, 2010, for its current corporate headquarters located in San Diego, California with an average annual rent of approximately \$132,000 through February 28, 2013. A security deposit in the amount of \$65,472 was paid to the landlord.

b) During 2011, the Company entered into two lease amendments. The first amendment commenced October 1, 2011 and added 2,761 square feet of additional space to the corporate headquarters with an average annual rent of approximately \$71,000 through December 2014. The second amendment extended the lease for the original 5,280 square feet from February 2013 through December 2014 with an average annual rent of approximately \$142,000.

c) On October 22, 2012, the Company entered into a lease amendment extending the lease for its entire corporate headquarters from December 2014 through December 28, 2017, with an average annual rent of approximately \$234,000.

Table of Contents

d) On December 2, 2013, the Company entered into a lease amendment revising the square feet from 8,041 to 8,303.

d) During the years ended December 31, 2013, 2012, and 2011, total rent expense was approximately \$294,000, \$270,000, and \$164,000 respectively. The Company is also a party to various operating lease agreements for office equipment.

Total annual commitments under current lease agreements for each of the twelve months ended December 31, are as follows:

2014	\$	227,541
2015		230,584
2016		237,339
2017		250,855
2018		
Total	\$	946,319

12. Employee Benefit Plan

The Company has a retirement savings plan under Section 401(k) of the Internal Revenue Code covering its employees. The plan allows employees to defer, up to the maximum allowed, a percentage of their income on a pre-tax basis through contributions to the plans, plus any employee of the age of 55 can participate in the caught-up dollars as allowed by IRS codes. The Company also has a Roth investment plan that is taken after taxes. The Company does not currently make matching contributions.

13. Related Party Transactions

Gabriele M. Cerrone, the Company's former Co-Chairman, and former member of the Board of Directors, served as a consultant to the Company from June 27, 2005 until June 2008 and is affiliated with Panetta Partners Ltd. Transactions between the Company and Mr. Cerrone and Panetta Partners, Ltd. are disclosed in Note 3, *Merger and Asset Purchase Activities*, Note 5, *Stockholders' Equity (Deficiency)*, Note 6, *Stock Option Plan* and Note 11, *Commitments and Contingencies: Employment and Consulting Agreements*.

Gianluigi Longinotti-Buitoni was appointed Executive Chairman on November 14, 2006 and served without cash compensation. For financial statement reporting purposes, the Company estimated the value of his services for the period from November 14, 2006 through January 31, 2007, for the eleven months ended December 31, 2007 and for the twelve months ended December 31, 2008 to be \$62,500, \$275,000 and \$300,000, respectively, and recorded an expense in the above periods for those amounts with corresponding increases to additional paid in capital. See Note 5, *Stockholders' Equity (Deficiency)*.

Edgar Filing: Trovogene, Inc. - Form 10-K

On July 18, 2011, the Company settled with Stanley Tennant, a director of the company, and a Debenture holder with a principal amount of \$137,500 received 56,354 shares of common stock relating to the Forbearance Agreement, and with R. Merrill Hunter, a principal stockholder of the company, and a Debenture holder in the principal amount of \$550,000 received 225,417 shares of common stock relating to the Forbearance Agreement.

F-46

Table of Contents

See Note 11 relating to Thomas Adams, Chairman of the Board, consulting arrangement.

14. Selected Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations of the Company for years ended December 31, 2013 and 2012:

	March 31	Quarter Ended		December 31
		June 30	September 30	
	(dollars in thousands, except per share data)			
2013				
Revenues	\$ 119	\$ 49	\$ 44	\$ 47
Operating expenses	2,509	2,423	3,121	2,897
Net loss and comprehensive loss attributable to common stockholders	(1,117)	(5,279)	(4,407)	(1,038)
Net loss per share - basic and diluted	\$ (0.07)	\$ (0.34)	\$ (0.25)	\$ (0.05)
Shares used in the calculation of net loss per share- basic and diluted (1)	15,510,340	15,583,957	17,870,703	18,900,781
2012				
Revenues	\$ 34	\$ 42	\$ 212	\$ 163
Operating expenses	1,164	1,287	1,250	1,598
Net loss and comprehensive loss attributable to common stockholders	(1,172)	(3,436)	(660)	(6,336)
Net loss per share - basic and diluted	\$ (0.11)	\$ (0.28)	\$ (0.05)	\$ (0.43)
Shares used in the calculation of net loss per share- basic and diluted (1)	11,001,679	12,086,528	14,178,733	14,715,668

(1) Basic and diluted EPS are computed independently for each of the periods presented. Accordingly, the sum of the quarterly EPS amount may not agree to the total for the year.