TrovaGene Inc. Form S-1/A May 18, 2012

Use these links to rapidly review the document <a href="TABLE OF CONTENTS">TABLE OF CONTENTS</a>
Index to Consolidated Financial Statements

Table of Contents

As filed with the Securities and Exchange Commission on May 18, 2012

Registration No. 333-180810

27-2004382

(I.R.S. Employer

Identification Number)

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

## FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## TROVAGENE, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

2836

(Primary Standard Industrial Classification Code Number)

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

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

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

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

Copies to:

Jeffrey Fessler, Esq. Sichenzia Ross Friedman Ference LLP Yvan-Claude Pierre, Esq. Daniel I. Goldberg, Esq. Reed Smith LLP

61 Broadway, 32nd Floor New York, New York 10006 Telephone: (212) 930-9700 Facsimile: (212) 930-9725 599 Lexington Avenue New York, New York 10022 Telephone: (212) 549-5400 Facsimile: (212) 521-5450

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

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

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

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

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 o

Accelerated filer o

Non-accelerated filer o

Smaller reporting company ý

(Do not check if a smaller reporting company)

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

### **Table of Contents**

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED MAY 18, 2012

## 4,500,000 Shares

## **Common Stock**

We are offering 4,500,000 shares of our common stock pursuant to this prospectus. We expect to effect a 1-for-5 reverse stock split of our outstanding common stock just prior to the date of this prospectus.

Our common stock is presently quoted on the OTC QB under the symbol "TROV.PK". We have applied to list our common stock on The NASDAQ Capital Market under the symbol "TROV". On May 17, 2012, the last reported sale price for our common stock on the OTC QB was \$4.95 per share after giving pro forma effect to the 1-for-5 reverse stock split of our outstanding common stock.

Our business and an investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 11 of this prospectus for a discussion of information that you should consider before investing in our securities.

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

	Per Share	Total
Public offering price	\$	\$
Underwriting discount(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1)

The underwriters will receive compensation in addition to the underwriting discount. See "Underwriting" beginning on page 60 of this prospectus for a description of compensation payable to the underwriters.

The underwriters may also purchase up to an additional 675,000 shares of common stock from us at the public offering price, less the underwriting discount, within 45 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment therefor on or about

, 2012.

# **Aegis Capital Corp**

## **Summer Street Research Partners**

Brean Murray, Carret & Co.

, 2012

### TABLE OF CONTENTS

Prospectus Summary Risk Factors	<b>Page</b> <u>1</u>
	<u>11</u>
Cautionary Note Regarding Forward-Looking Statements and Industry Data	<u>28</u>
<u>Use of Proceeds</u>	<u>29</u>
Price Range of Common Stock	<u>29</u>
Dividend Policy	<u>30</u>
<u>Dilution</u>	<u>30</u>
Capitalization	
Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Business	<u>32</u>
Management	<u>43</u>
Security Ownership of Certain Beneficial Owners and Management	<u>59</u>
Certain Relationships and Related Party Transactions	<u>67</u>
Description of Securities	<u>69</u>
<del>.</del>	<u>71</u>
<u>Underwriting</u>	<u>75</u>
Legal Matters	<u>83</u>
<u>Experts</u>	<u>83</u>
Where You Can Find More Information	<u>83</u>
Index to Financial Statements	F-1
	1,-1

You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell shares of our common stock. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each case included elsewhere in this prospectus. Unless otherwise stated or the context requires otherwise, references in this prospectus to "Trovagene", the "Company", "we", "us", or "our" refer to Trovagene, Inc.

Unless otherwise indicated, except for our consolidated financial statements and the notes thereto, all share amounts and per share amounts in this prospectus have been presented on a pro forma basis as if a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-5 that we expect to effect just prior to the date of this prospectus, has occurred.

#### TROVAGENE, INC.

#### **Business Overview**

We are a development stage molecular diagnostic company that focuses on the development and marketing of urine-based nucleic acid tests for patient/disease screening and monitoring. Our novel tests predominantly use transrenal DNA, or Tr-DNA, and transrenal RNA, or Tr-RNA. Our primary focus is to leverage our urine-based testing platform to facilitate improvements in the management of cancer care and women's healthcare. Tr-DNAs and Tr-RNAs are fragments of nucleic acids derived from dying cells inside the body. The intact DNA is fragmented in dying cells and released into the blood stream. These fragments have been shown to cross the kidney barrier (i.e., are transrenal) and can be detected in urine. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier. These RNA can also be isolated from urine, detected and analyzed. Our technology is applicable to all transrenal nucleic acids, or Tr-NA.

Our patented technology platform uses safe, non-invasive, cost effective and simple urine collection which can be applied to a broad range of testing including: tumor detection and monitoring (e.g., KRAS mutations in pancreatic cancer), prenatal genetic testing, infectious diseases, tissue transplantation, forensic identification, and for patient selection in clinical trials. Our products are developed using commercially available chemicals and biologicals, as well as instrumentation and equipment. The only custom components we use are specific synthetic sequences of nucleic acids (DNA and RNA) synthesized in a sequence to order. We believe that our technology is ideally suited to be used in developing molecular diagnostic assays that will allow physicians to provide simple, non-invasive and convenient screening and monitoring tests for their patients by identifying specific biomarkers involved in a disease process. If we are successful, our novel assays may facilitate improved testing compliance resulting in earlier diagnosis of disease, more targeted treatment which will be more cost-effective, and improvements in the quality of life for the patient.

In order to facilitate early availability and use of our products and technologies, on February 1, 2012, we acquired the CLIA laboratory assets of MultiGEN Diagnostics, Inc., or MultiGEN, which included CLIA (Clinical Laboratory Improvement Amendments of 1998) certification and licensing documentation, laboratory procedures, customer lists and marketing materials. A CLIA lab is a clinical reference laboratory that can perform high complexity diagnostic assays (e.g., those requiring PCR amplification). Through this CLIA laboratory we are able to offer laboratory developed tests, or LDTs, in compliance with CLIA guidelines, and, depending on the diagnostic assay, without the need for Food and Drug Administration, or FDA review. This will make our tests and technology available to physicians to order for their patient management, and in turn generate revenue. We will determine on a case-by-case basis whether an eventual FDA review of a given diagnostic assay is necessary. This decision will, amongst other factors, be based on the desired route of commercialization (e.g., in vitro

1

### Table of Contents

diagnostic product vs. laboratory testing service) and the specific nature of the respective diagnostic test.

### **Market Opportunity**

Estimates of the size of the global molecular diagnostics market vary, however the market was projected to approach \$7.0 billion in 2011 (final data not yet available). 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 19%. The molecular diagnostics market has emerged as the fastest growing segment of the in-vitro diagnostics, or 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). It is noteworthy that the Indian molecular diagnostics market is showing growth, expected to reach 1.0 billion INR (\$220 million) by 2011 (final data not yet available). United States and Europe markets were projected to surpass \$4.0 billion and \$1.0 billion, respectively (final data not yet available). Key drivers for this impressive growth include the exceptional ability to accurately and quickly detect the primary cause of disease and provide a strong tool for quick therapy decisions, need for automated and easier techniques, and the increased availability of tests for monitoring the efficacy of expensive drugs.

We believe transrenal molecular diagnostics will provide relevant diagnostic information that will lead to improvements in personalized patient management. Infectious diseases, cancer diagnosis and monitoring are where most of the use and progress in personalized molecular diagnostic medicine has occurred to date. In addition, new products that facilitate personalized care are emerging in the areas of central nervous system, or CNS, autism, diabetes, and depression, and most major pharmaceutical companies have active pharmacogenomic programs in their clinical studies in anticipation of the need to utilize diagnostic testing to stratify patients for efficacy.

### **Our Technologies**

We believe that our scientists were the first to report the discovery that a portion of cell-free DNA or RNA found in the bloodstream can cross the kidney barrier and be detected in the urine. This genetic material is referred to as Tr-DNA or Tr-RNA, or in aggregate Tr-nucleic acid. Analysis of Tr-DNA or Tr-RNA provides a simple, non-invasive and cost-effective method for molecular diagnostics and a platform for a broad range of diagnostic tests. In comparison with conventional tissue, sputum or plasma-based tests, this urine-based methodology has significant advantages with respect to patient convenience, privacy and compliance, ease of testing by elimination of difficult extraction steps in sample preparation, speed in performing the assay, amount of sample available, and cost effectiveness.

We have a dominant patent position as it relates to transrenal molecular testing. We own issued U.S. and European patents that cover any and all testing for molecular targets that pass through the kidney (i.e., transrenal). In addition to these core patents, we have numerous patent applications pending in the areas of cancer, infectious diseases, transplantation, prenatal and genetic testing.

In order to test the feasibility of testing urine samples for human papillomavirus, or HPV DNA, we engaged in an in-house study of clinical samples from India during January through August 2008. This study was not sanctioned by the FDA nor conducted under the guidance of the FDA. Results from this study may be presented to the FDA in the event of a pre-IND meeting and are not directly applicable to seeking regulatory approval. Samples were collected from high and low risk populations in India including those from staged cancer patients by Simbiosys Biowares Inc. and Metropolis Inc. High risk subjects were recruited either from sexually transmitted disease clinics in hospitals or district brothels in West Bengal in eastern India. The study enrolled 320 patients during January through May, 2008. Pap smears and QIAGEN High-Risk HPV DNA hc2 tests were performed on collected cervical cells by Simbiosys Biowares Inc. and Metropolis Inc. Urine samples were shipped to us for in-house

### **Table of Contents**

PCR amplification and detection. Urine samples which gave results discordant with the cervical specimen-based hc2 assay were further examined by DNA sequencing for resolution. PCR product sequences were examined by the NCBI Blastn algorithm to match specific human papillomavirus strains.

We generated positive clinical study results with our HPV urine-based test to identify women at risk for developing cervical cancer. In this study, 31 out of 38 cervical swab samples that were initially classified as "negative" were subsequently determined to be positive by PCR followed by DNA sequencing of the urine using our urine-based platform. Additionally, 24 out of 34 cervical swab samples initially classified as "positive" were determined to be negative based on DNA sequencing of the urine. Our urine-based test only had 10 false negatives and 7 false positives, which represents 93% sensitivity and 96% specificity. As a result we believe that the sensitivity and specificity of our urine-based test is at least similar to and potentially better than the currently used cervical-cell-based tests. As noted earlier, our urine-based test is non-invasive, more convenient and private for the patient, simpler, less technically demanding in terms of cytology proficiency and potentially cost effective. Our unique primer pair focused on the E1 region of the HPV genome is expected to provide freedom to operate within the HPV patent landscape (i.e., we believe that our HPV patent will issue in the major geographic areas and be enforceable). It should be noted that these studies were research studies, not regulatory studies. These studies resulted in valuable insight that needs further work and validation by us. While the results were encouraging, they were not sufficient to complete the development of, seek approval for and launch a product in the U.S. or ex-U.S. markets. Consequently, we have initiated development of a diagnostic test to determine the presence of high risk HPV subtypes from urine specimens. The proprietary test (U.S. patent application pending) might, once available, be particularly useful for the determination of carrier status in males.

Presently, we are working towards finalizing a clinical study protocol and recruiting study sites in conjunction with key opinion leaders in the field of Ob/Gyn pathologists. We may use the results of this study, anticipated to begin at the earliest in 2012, toward the pursuit of a CE Mark in Europe and all other countries that recognize CE Marks for marketing approval.

In order to test the feasibility of using urine samples in tumor detection and monitoring, we have successfully completed the analytical development of digital PCR assays for the detection of both the most prevalent KRAS mutations and wild type KRAS DNA sequences. KRAS mutations are found in 90% of patients with pancreatic cancer, in 23% of all tumor samples examined by the Sanger Centre, and have been previously detected in the urine of colorectal cancer patients by others. Furthermore, three specific KRAS mutations account for approximately 96% of all KRAS mutations in pancreatic cancer and all three are among those we have established in-house. In order to quickly apply our technology to tumor detection and monitoring we have established protocols for the isolation of DNA from 100ml of urine and the concentration of the DNA for mutation and wild type KRAS analysis using commercial means, and we are in late-stage discussions with two premier cancer centers to procure urine samples from patients with pancreatic cancer.

In addition, our technology can be applied to the development and subsequent commercialization of our fetal medicine assay, initially to screen for Down Syndrome, one of many genetic disorders caused by chromosomal abnormalities. There is a huge unmet market need for a simple, convenient and truly non-invasive screening approach in the maternal arena. Initial studies of our transrenal assays with maternal urine clearly showed that we can detect Y chromosomal sequences which in turn clearly demonstrates the ability to detect transrenal fetal nucleic acids in this maternal urine. Additionally, our novel assays show and incorporate a complete representation of the maternal and most likely fetal genome in maternal urine. The combination of our transrenal nucleic acid platform in combination with next generation sequencing may allow for the development and commercialization of the first truly non-invasive prenatal screening test for these chromosomal-related diseases.

### **Table of Contents**

Our August 2010 acquisition of a highly sensitive molecular detection platform utilizing proprietary probe chemistry and on chip CMOS signal detection expands our reach within the molecular diagnostic arena. This analytical platform is synergistic and complementary to our transrenal nucleic acid technology and will be leveraged in our women's healthcare and other development endeavors by providing unsurpassed analytical and detection capabilities. Patents for this detection platform are pending in the U.S., Europe and Japan. The technology platform consists of several novel inventions: (i) direct attachment of a probe to a CMOS sensor chip, (ii) a proprietary conjugate capture and (iii) a conjugate reporter probe. In combination they enable ultra-sensitive detection of nucleic acids or proteins, without the need for a separate amplification step such as with PCR. As such, no expensive equipment is required to be purchased by labs or hospitals, all of which constantly look for ways to reduce their expenses wherever possible. The chips may be processed using off-the-shelf available liquid handling systems and the results are read with a simple USB to an existing computer running our proprietary software. The demonstrated sensitivity using an engineering prototype is 300 molecules.

Highly complementary to our Tr-DNA and Tr-RNA platform and projects, we have the exclusive worldwide rights to the use of the nucleophosmin protein gene (NPM1) for use in human *in-vitro* diagnostic testing, monitoring, prognostic evaluation and drug therapy selection for patients with acute myeloid leukemia, or AML. These rights and subsequent sublicenses have been crucial in terms of generating a steady incoming cash flow stream. We actively seek sublicense agreements with diagnostic laboratories planning to offer lab testing services to the clinical market based on an LDT for this marker. Two of our early sublicensees, LabCorp and Invivoscribe Technologies, have already announced commercial availability of a validated LDT molecular test for the NPM1 gene either as a standalone test or as part of an AML profile assay. In addition, two companies, Asuragen and Ipsogen, have sublicensed the rights to make and sell tests kits for the NPM1 mutations and are now offering these products as Research Use Only kits to the market. Lastly, we will be seeking drug development partnerships with pharmaceutical companies with active AML drug development initiatives as NPM1 is a valuable biomarker to guide patient selection in clinical trials.

### **Our Business Strategy**

We plan to leverage our transrenal technology to develop and market, either independently or in conjunction with corporate partners, molecular diagnostic products in each of our initial focus markets of women's healthcare, infectious diseases and cancer. Our marketing strategy includes multiple approaches. During the late stages of development of each product, while collecting clinical data for regulatory submissions, we intend to market the products as LDTs through our CLIA laboratory. CLIA laboratories may offer the tests and receive reimbursement under the laboratory developed test, or LDT, regulations and it is our plan to establish a CLIA laboratory market presence and generate revenues for tests not subject to FDA clearance or approval.

While most common laboratory tests are commercial tests, manufactured and marketed to several labs, 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 others, they do not require approval for marketing from the 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 intend to pursue FDA pre-market review and as we receive FDA clearance or approval for our products, we intend to market urine-based test kits through a U.S. commercial organization directly to CLIA medical testing laboratories. We also intend to complete business partnerships (out-license

### **Table of Contents**

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 opportunity. This would provide both short term (license fees) and long term (royalties) revenue streams. These licensees will license and use our platform in clinical development of their products, monitor patients taking their marketed products (i.e. TNF inhibitors) and in certain situations license the rights to develop, test and commercialize our transrenal products in predefined fields of use and geographic territories. We plan to become a fully integrated business in which we develop, test, manufacture, register, market and sell our products.

In comparison with many other genetic tests, our Tr-DNA or Tr-RNA tests are expected to be cost effective. These tests involve a relatively simple process and can easily be automated. Therefore, major advantages of our Tr-DNA or Tr-RNA test, if and when commercially available, will be the ease of sample collection, enhanced sensitivity and specificity, patient convenience (i.e., home-based test), non-invasive and will potentially provide more efficient and effective monitoring protocols (e.g., for opportunistic infections).

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 may be available under the current procedural terminology, or CPT codes, for molecular-based testing. We expect to initially market our tests to independent and hospital-based laboratories at price points that we believe will translate into substantially higher operating margins than has been traditional in the laboratory industry. We believe this will create a strong incentive for laboratories to adopt our transrenal molecular diagnostic tests.

#### Risks

We are a development stage company and have generated minimal revenues to date. Since our inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should carefully consider the following risks, which are discussed more fully in "Risk Factors" beginning on page 9 of this prospectus.

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

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.

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.

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

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.

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.

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

### **Table of Contents**

Our inability to establish strong business relationships with leading clinical reference laboratories to perform Tr-DNA/Tr-RNA tests using our technologies will limit our revenue growth.

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.

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

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

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

If the FDA were to begin regulating our LDTs, 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.

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 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.

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.

In preparing our consolidated financial statements, our management determined that our disclosure controls and procedures were ineffective as of December 31, 2011 which could result in material misstatements in our financial statements.

If we continue to fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

We have not filed any Federal, state or foreign tax returns since inception, except for Delaware franchise tax returns and we do not know the amount of any tax liability, interest and penalties.

Our Series A Convertible Preferred Stock contain certain covenants that limit the way we can conduct business.

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

Because we will have broad discretion and flexibility in how the net proceeds from this offering are used, we may use the net proceeds in ways in which you disagree.

Our stockholders may experience significant dilution as a result of any additional financing using our equity securities and/or debt securities.

6

### **Table of Contents**

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

If our common stock remains subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.

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

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.

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.

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.

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 subject to volatility.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

We intend to effect a 1-for-5 reverse stock split of our outstanding common stock immediately prior to this offering. However, the reverse stock split may not increase our stock price sufficiently and we may not be able to list our common stock on The NASDAQ Capital Market, in which case this offering will not be completed.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of The NASDAQ Capital Market.

Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of The NASDAQ Capital Market.

The reverse stock split may decrease the liquidity of the shares of our common stock.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

### **Recent Developments**

On April 27, 2012, holders of a majority of our common stock voted in favor of the following proposals at a special meeting of our shareholders:

an amendment to our 2004 Stock Option Plan to increase the number of shares issuable thereunder to 22,000,000 from 12,000,000;

an amendment to our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our issued and outstanding common stock at a ratio of not less than one-for-two

### **Table of Contents**

and not greater than one-for-six at any time prior to April, 27, 2013, at the discretion of the Board of Directors; and

an amendment to our Amended and Restated Certificate of Incorporation to effect an increase in our authorized shares of common stock from 100,000,000 to 150,000,000

On May 1, 2012, we announced that Dr. Carlo Croce joined us as a consultant and member of our Scientic Advisory Board. Dr. Croce is the John W. Wolfe Chair in cancer genetics, and Chairman, Department of Molecular Virology, Immunology and Medical Genetics and also Director of the Human Cancer Genetics Program and the Genetics Institute at Ohio State University.

On May 2, 2012, we closed a private placement which raised gross proceeds of \$300,000. We issued 120,000 shares of our common stock and warrants to purchase 120,000 shares of common stock in this transaction. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share.

### **Corporate Information**

We were incorporated in the State of Florida on April 26, 2002 under the name "Used Kar Parts, Inc." Our name was changed to Trovagene, Inc. and we redomesticated our state of incorporation from Florida to Delaware in January 2010. Our principal executive offices are located at 11055 Flintkote Avenue, Suite B, San Diego, CA 92121, and our telephone number is (858) 217-4838. Our website address is www.trovagene.com. The information on our website is not part of this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website.

### The Offering

Securities offered by us 4,500,000 shares of common stock (up to 675,000 shares if the underwriter exercise their

over-allotment option in full).

Common Stock to be outstanding after

OTC Bulletin Board trading symbol

this offering Use of Proceeds 18,336,071 shares. We intend to use the net proceeds received from this offering to fund our research and

development activities and for working capital and general corporate purposes and possibly acquisitions of other companies, products or technologies, though no such acquisitions are

currently contemplated. See "Use of Proceeds" on page 23.

Risk Factors" beginning on page 9 and the other information included in this prospectus

for a discussion of factors you should carefully consider before investing in our securities.

TROV.PK

Proposed Symbol and Listing We have applied for listing of our common stock on The NASDAQ Capital Market under the

symbol "TROV".

Unless we indicate otherwise, all information in this prospectus (i) reflects a 1-for-5 reverse stock split of our issued and outstanding shares of common stock, options and warrants to be effected just prior to the date of this prospectus and the corresponding adjustment of all common stock price per share and stock option and warrant exercise price data, except for the consolidated financial statements and the notes thereto, and have assumed an offering price of \$4.65, the closing price of the Company's common stock on May 4, 2012; (ii) is based on 13,836,071 shares of common stock issued and outstanding as of May 17, 2012; (iii) assumes no exercise by the underwriters of their option to purchase up to an additional 675,000 shares of common stock to cover over-allotments, if any; (iv) excludes 119,500 shares of common stock issuable upon conversion of outstanding Series A Convertible Preferred Stock; (v) excludes 3,674,180 shares of our common stock issuable upon exercise of outstanding stock options under our stock incentive plans at a weighted average exercise price of \$5.30 per share as of May 17, 2012; (vi) excludes 5,178,309 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$2.55 per share as of May 17, 2012; and (vii) excludes 180,000 shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering.

### SUMMARY CONSOLIDATED FINANCIAL DATA

The following table sets forth our (i) summary statement of operations data for the years ended December 31, 2011 and 2010, derived from our audited financial statements and related notes included elsewhere in this prospectus, (ii) summary statement of operations data for the three months ended March 31, 2012 and 2011 derived from our unaudited financial statements included elsewhere in this prospectus, and (iii) summary consolidated balance sheet data as of March 31, 2012 derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The summary consolidated financial data for the three months ended March 31, 2012 and 2011 and as of March 31, 2012 are not indicative of results to be expected for the full year. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	Year ended December 31,		Three months ended March 31,			
	2011		2010	2012		2011
Statement of Operations Data:						
Royalty income	\$ 227,696	\$	255,665	\$ 34,153	\$	89,082
License fees	30,000		10,000			
Total Revenues	257,696		265,665	34,153		89,082
Operating Expenses:						
Research and development	910,685		1,024,159	337,407		258,016
Purchased in-process research and development expenses-related						
party			2,666,869			
General and administrative	2,323,814		1,953,925	826,964		551,044
Operating loss	(2,976,803)		(5,379,288)	(1,130,218)		(719,978)
Other income (expense)	737,591		(69,850)	(32,424)		167,991
Preferred stock dividend	(38,240)		(38,240)	(9,560)		(9,560)
Net loss and Comprehensive loss attributable to common						
stockholders	\$ (2,277,452)	\$	(5,487,378)	\$ 1,172,202	\$	561,547
Weighted average shares of common stock outstanding basic and						
diluted	11,653,823		8,590,550	13,202,015		10,827,579
Net loss per common share basic and diluted	\$ (0.20)	\$	(0.65)	\$ (0.09)	\$	(0.05)
*	` -/		,,	/		/

	As of March 31, 2012			
		Pro Forma, As Actual Adjusted(1)		
Balance Sheet Data:		Terum		rujusteu(1)
Cash and cash equivalents	\$	586,777	\$	20,511,027
Total assets		1,182,155		21,106,405
Total liabilities		5,516,157		5,896,253
Total stockholders' equity (deficiency)		(4,334,002)		15,210,248

Pro forma, as adjusted amounts give effect to (i) the issuance of common stock and warrants from April 1, 2012 through and immediately prior to the date of this prospectus and (ii) the sale of the shares in this offering at the assumed public offering price of \$4.65 per share, the closing price of the Company's common stock on May 4, 2012, and after deducting underwriting discounts and

commissions and other estimated offering expenses payable by us.

#### RISK FACTORS

Any investment in our common stock involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this prospectus before deciding whether to purchase our common stock. Our business, financial condition or results of operations could be materially adversely affected by these risks if any of them actually occur. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this prospectus.

#### **Risks Related to Our Business**

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

We are a development stage company and have incurred losses since we were formed. As of December 31, 2011 and March 31, 2012, we have an accumulated total deficit of \$43,598,431 and \$44,770,633, respectively. For the fiscal year ended December 31, 2011 and the three months ended March 31, 2012, we had net losses attributable to common stockholders of \$2,277,452 and \$1,172,202, respectively. To date, we have experienced negative cash flow from development of our transrenal molecular technology. We currently have no products ready for commercialization, have not generated any revenue from operations except for licensing and royalty income and expect to incur substantial net losses for the foreseeable future to further develop and commercialize the transrenal molecular technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from the transrenal molecular technology or attain profitability, we will not be able to sustain operations.

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

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

In their report dated March 30, 2012 our independent registered public accountants stated that our financial statements for the year ended December 31, 2011 were prepared assuming that we would continue as a going concern. Our ability to continue as a going concern, which may hinder our ability to obtain future financing, is an issue raised as a result of recurring losses from operations. We continue to experience net operating losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities, increasing sales or obtaining loans and grants from various financial institutions where possible. Our continued net operating losses increase the difficulty in meeting such goals and there can be no assurances that such methods will prove successful.

### **Table of Contents**

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 May 15, 2012 our cash balance was \$785,243 and our working capital deficit was \$305,216. Our existing capital resources are not sufficient to fund our operations for the next 12 months. At our current burn rate, we estimate that our existing capital resources will fund our operations for the next four months. We estimate that we will require approximately \$5 million over the next 12 months in order to sustain our operations and implement our business strategy. Consequently, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. The development of our business will require substantial additional capital in the future to conduct research and development and commercialize our transrenal molecular technology. For example, we currently estimate that \$5 million of capital resources will be required over the next 12 months. This amount will be sufficient to launch our products in the marketplace currently under development as LDTs. An additional \$5 to \$10 million will be required in 2013 to implement our business strategy and launch additional products as LDTs. We have historically relied upon private sales of our equity and issuances of notes to fund our operations. We currently have no credit facility or committed sources of capital. During the next 12 months, we will have to raise additional funds to continue the development and commercialization of our transrenal molecular technology. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms.

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

Physicians and patients may decide not to order our products unless third-party payors, such as managed care organizations as well as government payors such as Medicare and Medicaid pay a substantial portion of the test price. Reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that our product candidates are:

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

Market acceptance, sales of products based upon the Tr-DNA or Tr-RNA 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

### **Table of Contents**

we are able to commercialize our products. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement of the test. Since each payor makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals may be a time-consuming and costly process. We cannot be sure that reimbursement in the U.S. or elsewhere will be available for any of our products in the future. If reimbursement is not available or is limited, we may not be able to commercialize our products.

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

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

We believe our scientists were the first to discover Tr-DNA. 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 Tr-DNA or Tr-RNA 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 Tr-DNA or Tr-RNA 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 Tr-DNA tests for their patients and consequently our revenue and profitability will be limited.

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

The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. In each of our potential product areas, we face significant competition from large biotechnology, medical diagnostic and other companies. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain

### **Table of Contents**

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

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

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

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

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

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

Our inability to establish strong business relationships with leading clinical reference laboratories to perform Tr-DNA/Tr-RNA tests using our technologies will limit our revenue growth.

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

### **Table of Contents**

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

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

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

We are a small company with only four full-time employees as of May 16, 2012. 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 Tr-DNA and Tr-RNA 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 Tr-DNA or Tr-RNA 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 Tr-DNA or Tr-RNA technology, we will be unable to sell such products and will not be able to sustain operations.

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

The regulatory review and approval process, which may include evaluation of preclinical studies and clinical trials of products based on the Tr-DNA or Tr-RNA technology, as well as the evaluation of

### Table of Contents

manufacturing processes and contract manufacturers' facilities, is lengthy, expensive and uncertain. Securing regulatory approval for products based upon the transrenal molecular technology may require the submission of extensive preclinical and clinical data and supporting information to regulatory authorities to establish such products' safety and effectiveness for each indication. We have limited experience in filing and pursuing applications necessary to gain regulatory approvals.

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

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

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

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

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

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could

### **Table of Contents**

result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

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

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

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

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

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

Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA under the 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 will need 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 required to report suspected medical device related deaths to both the FDA and the relevant manufacturers of products we purchase and use.

Clinical laboratory tests like our current product offerings are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the FDA. Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation. We expect that, upon the commencement of commercialization, our product candidates will be an LDT and not a diagnostic kit. As a result, we believe that our product candidates should not be subject to regulation under current FDA policies, however there is no assurance that it will not be subject to such regulation in the future. The container we expect to

### **Table of Contents**

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 these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our test, or to become profitable.

### Table of Contents

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

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

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

Third parties may challenge the validity of our patents and other intellectual property rights, resulting in costly litigation or other time-consuming and expensive proceedings, which could deprive us of valuable rights. If we become involved in any intellectual property litigation, interference or other judicial or administrative proceedings, we will incur substantial expenses and the diversion of financial resources and technical and management personnel. An adverse determination may subject us to

### **Table of Contents**

significant liabilities or require us to seek licenses that may not be available from third parties on commercially favorable terms, if at all. Further, if such claims are proven valid, through litigation or otherwise, we may be required to pay substantial financial damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights. In our European patent application that covers mutations in the NPM-1 gene related to acute myeloid leukemia, an anonymous third party has filed "Observations" against the claims prior to allowance of the patent. Observations concern the patentability of the invention to which a European patent application or patent relates and are considered by the examining or opposition division of the European Patent Office.

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

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 Our Common Stock and the Offering

In preparing our consolidated financial statements, our management determined that our disclosure controls and procedures were ineffective as of December 31, 2011 which could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. As of December 31, 2011, our management has determined that our disclosure controls and procedures were ineffective due to weaknesses in our financial closing process.

We intend to implement remedial measures designed to address the ineffectiveness of our disclosure controls and procedures. If these remedial measures are insufficient to address the ineffectiveness of our disclosure controls and procedures, or if material weaknesses or significant deficiencies in our internal control are discovered or occur in the future and the ineffectiveness of our disclosure controls and procedures continues, we may fail to meet our future reporting obligations on a timely basis, our consolidated financial statements may contain material misstatements, we could be required to restate our prior period financial results, our operating results may be harmed, we may be subject to class action litigation, and if we gain a listing on The NASDAQ Capital Market or the NYSE Amex, our common stock could be delisted from that exchange. Any failure to address the ineffectiveness of our disclosure controls and procedures could also adversely affect the results of the

### **Table of Contents**

periodic management evaluations regarding the effectiveness of our internal control over financial reporting and our disclosure controls and procedures that are required to be included in our annual report on Form 10-K. Internal control deficiencies and ineffective disclosure controls and procedures could also cause investors to lose confidence in our reported financial information. We can give no assurance that the measures we plan to take in the future will remediate the ineffectiveness of our disclosure controls and procedures or that any material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or adequate disclosure controls and procedures or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future those controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

If we continue to fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

We have not filed any Federal, state or foreign tax returns since inception, except for Delaware franchise tax returns and we do not know the amount of any tax liability, interest and penalties we may owe.

We have not filed any federal, state or foreign tax returns since inception, except for Delaware franchise tax returns. The amount of any tax liability, interest and penalties that could arise since inception is undetermined as of May 17, 2012. We intend to file all tax returns that are currently due as soon as possible.

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

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

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

Our certificate of incorporation gives our board of directors the right to create new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could 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

### **Table of Contents**

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.

Because we will have broad discretion and flexibility in how the net proceeds from this offering are used, we may use the net proceeds in ways in which you disagree.

We currently intend to use the net proceeds from this offering to fund our research and development activities and for working capital and other general corporate purposes and possibly acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated. See "Use of Proceeds" on page 23 of this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

Our stockholders may experience significant dilution as a result of any additional financing using our equity securities and/or debt securities.

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

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

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

technological innovations or new products and services by us or our competitors;
clinical trial results relating to our tests or those of our competitors;
commercial acceptance of our products, if approved or cleared;
coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
FDA, CMS and comparable ex-U.S. agency regulation and oversight of our products and services;
the establishment of partnerships with clinical reference laboratories;
health care legislation;
intellectual property disputes;

### Table of Contents

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.
In addition, trading in stock traded over the counter on the pink sheets is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with a company's operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to our business or operating performance. Moreover, trading is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like the NYSE Amex. Accordingly, shareholders may have difficulty reselling any of their shares of common stock.
If our common stock remains subject to the SEC's penny stock rules, broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.
Unless our securities are listed on a national securities exchange, or we have net tangible assets of \$5,000,000 or more and our common stock has a market price per share of \$5.00 or more, transactions in our common stock will be subject to the SEC's "penny stock" rules. If our common stock remains subject to the "penny stock" rules promulgated under the Securities Exchange Act of 1934, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected.
Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:
make a special written suitability determination for the purchaser;
receive the purchaser's written agreement to the transaction prior to sale;
provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks'

and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and

obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

As a result, if our common stock becomes or remains subject to the penny stock rules, the market price of our securities may be depressed, and you may find it more difficult to sell our securities.

23

### **Table of Contents**

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

As of May 16, 2012, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 29.0% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

delaying, deferring or preventing a change in corporate control;

impeding a merger, consolidation, takeover or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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

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

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

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

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

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

# **Table of Contents**

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

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

# 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.

You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to 4,500,000 shares offered in this offering at an assumed public offering price of \$4.65 per share, and after deducting the underwriter's discounts and commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$3.84 per share. In addition, in the past, we issued options and warrants to acquire shares of common stock. To the extent these options are ultimately exercised, you will sustain future dilution. We may also acquire

# **Table of Contents**

or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

# Risks Related to Our Reverse Stock Split

We intend to effect a 1-for-5 reverse stock split of our outstanding common stock immediately prior to this offering. However, the reverse stock split may not increase our stock price sufficiently and we may not be able to list our common stock on The NASDAQ Capital Market, in which case this offering will not be completed.

We expect that the 1-for-5 reverse stock split of our outstanding common stock will increase the market price of our common stock so that we will be able to meet the minimum bid price requirement of the Listing Rules of The NASDAQ Capital Market. However, the effect of a reverse stock split upon the market price of our common stock cannot be predicted with certainty, and the results of reverse stock splits by companies in similar circumstances have been varied. It is possible that the market price of our common stock following the reverse stock split will not increase sufficiently for us to be in compliance with the minimum bid price requirement. If we are unable meet the minimum bid price requirement, we may be unable to list our shares on The NASDAQ Capital Market, in which case this offering will not be completed.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be able to continue to comply with the minimum bid price requirement of The NASDAQ Capital Market.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock to be in compliance with the minimum bid price of The NASDAQ Capital Market, there can be no assurance that the market price of our common stock following the reverse stock split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of a reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain The NASDAQ Capital Market's minimum bid price requirement. In addition to specific listing and maintenance standards, The NASDAQ Capital Market has broad discretionary authority over the initial and continued listing of securities, which it could exercise with respect to the listing of our common stock.

Even if the reverse stock split increases the market price of our common stock, there can be no assurance that we will be able to comply with other continued listing standards of The NASDAQ Capital Market.

Even if the market price of our common stock increases sufficiently so that we comply with the minimum bid price requirement, we cannot assure you that we will be able to comply with the other standards that we are required to meet in order to maintain a listing of our common stock on The NASDAQ Capital Market. Our failure to meet these requirements may result in our common stock being delisted from The NASDAQ Capital Market, irrespective of our compliance with the minimum bid price requirement.

The reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots

# Table of Contents

(less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

# CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

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

This prospectus also includes estimates of market size and industry data that we obtained from industry publications and surveys and internal company sources. The industry publications and surveys used by management to determine market size and industry data contained in this prospectus have been obtained from sources believed to be reliable.

#### **USE OF PROCEEDS**

We estimate that our net proceeds from the sale of the common stock offered pursuant to this prospectus will be approximately \$19.0 million, or approximately \$21.9 million if the underwriters exercise in full their option to purchase 675,000 additional shares, assuming a public offering price of \$4.65 per share, the closing price of the Company's common stock on May 4, 2012, and after deducting the underwriting discount and the estimated offering expenses that are payable by us.

We currently intend to use the net proceeds from this offering to fund our research and development activities and for working capital and other general corporate purposes and possibly acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering. Pending any use as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

# PRICE RANGE OF COMMON STOCK

Our common stock currently trades over the counter on the OTC QB under the symbol TROV.PK. Our common stock was quoted on the OTC Bulletin Board under the symbol "XNOM.OB" from July 27, 2004 until June 14, 2007. 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 closing bid quotations per share for our common stock based on information provided by the OTC QB. 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. These prices do not reflect the expected 1-for-5 reverse stock split that we intend to effect in connection with this offering.

Fiscal 2012	I	ligh	Low
Second Quarter (through May 17, 2012)	\$	1.11	\$ 0.61
First Quarter	\$	0.93	\$ 0.425

Fiscal 2011	High Lov		
Fourth Quarter	\$ 0.70	\$ 0.35	
Third Quarter	\$ 0.95	\$ 0.16	
Second Quarter	\$ 0.39	\$ 0.13	
First Ouarter	\$ 0.50	\$ 0.27	

Fiscal 2010	High		1	Low	
Fourth Quarter	\$	0.52	\$	0.19	
Third Quarter	\$	0.50	\$	0.15	
Second Quarter	\$	0.70	\$	0.40	
First Ouarter	\$	0.59	\$	0.52	

The closing price of our common stock on the OTC QB on May 17, 2012 was \$0.99 per share. As of May 17, 2012, we had 146 stockholders of record of our common stock.

# DIVIDEND POLICY

We have never declared dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. In addition, our Series A Convertible Preferred Stock includes various covenants limiting our ability to pay dividends. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

#### DILUTION

If you invest in our common stock, your interest will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after giving effect to this offering.

Our pro forma net tangible book value as of March 31, 2012 was \$(4,092,298) or \$(0.30) per share of common stock, based upon 13,836,071 outstanding, after giving effect to issuances of common stock and warrants from April 1, 2012 through and immediately prior to the date of this offering. After giving effect to the sale of the shares in this offering at the assumed public offering price of \$4.65 per share, the closing price of the Company's common stock on May 4, 2012, at March 31, 2012, and after deducting underwriting discounts and commissions and other estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at March 31, 2012 would have been approximately \$14,917,952, or \$0.81 per share. This represents an immediate increase in pro forma net tangible book value of approximately \$1.11 per share to our existing stockholders, and an immediate dilution of \$3.84 per share to investors purchasing shares in the offering.

Dilution in pro forma net tangible book value per share represents the difference between the amount per share paid by purchasers of our common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after this offering.

The following table illustrates the per share dilution to investors purchasing shares in the offering:

Assumed public offering price per share		\$ 4.65
Pro forma net tangible book value per share as of March 31, 2012	\$ (0.30)	
Increase in net tangible book value per share attributable to this offering	\$ 1.11	
Pro forma as adjusted net tangible book value per share after this offering		\$ 0.81
Dilution in pro forma net tangible book value per share to new investors		\$ 3.84

The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$0.94 per share, representing an immediate increase to existing stockholders of \$1.24 per share and an immediate dilution of \$3.71 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

# **CAPITALIZATION**

The following table sets forth our capitalization as of March 31, 2012:

on an actual basis;

on a pro forma basis to give effect to the issuance of common stock and warrants from April 1, 2012 through and immediately prior to the date of this prospectus; and

on a pro forma, as adjusted basis to give effect to (i) the issuance of common stock and warrants from April 1, 2012 through and immediately prior to the date of this prospectus and (ii) the sale of the shares in this offering at the assumed public offering price of \$4.65 per share, the closing price of the Company's common stock on May 4, 2012, and after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

You should consider this table in conjunction with our financial statements and the notes to those financial statements included elsewhere in this prospectus.

	As of March 31, 2012					
		Actual		Pro Forma		Pro Forma As Adjusted
Stockholders' equity (deficiency)						
Preferred stock, \$0.001 par value, 20,000,000 shares authorized; 95,600 shares						
issued outstanding at March 31, 2012 designated as Series A Convertible Preferred						
Stock with liquidation preference of \$956,000 at March 31, 2012, actual, pro forma						
and pro forma, as adjusted, respectively	\$	96	\$	96	\$	96
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 13,429,371,						
issued and outstanding at March 31, 2012 actual; 13,836,071 and 18,336,071 shares						
issued and outstanding, pro forma and pro forma, as adjusted, respectively		1,343		1,383		1,833
Additional paid-in capital		40,435,192		40,975,527		59,985,327
Deficit accumulated during the development stage		(44,770,633)		(44,777,008)		(44,777,008)
Total stockholders' equity (deficiency)	\$	(4,334,002)	\$	(3,800,002)	\$	15,210,248
		, , ,		, , , ,		, ,
31						

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. All share amounts and per share amounts in Management's Discussion and Analysis of Financial Condition and Results of Operations" have been presented on a pro forma basis as if a reverse stock split of our outstanding shares of common stock at a ratio of 1-for-5 that we expect to effect just prior to the date of this prospectus, has occured.

# Overview

From August 4, 1999 (inception) through March 31, 2012, we have sustained cumulative total deficit of \$44,770,633. From inception through March 31, 2012, we have generated minimal out-licensing revenues and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have commercial products for several years, if at all.

Our product development efforts are thus in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of failing to complete any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical development and testing, successfully demonstratinig specific performance of proposed products under stringent clinical trial protocols subject to regulatory oversight, the extended regulatory review and approval 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 15. Financial Statements Note *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.

# 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.

# **Table of Contents**

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. The Company has not received or recognized milestone payment revenues to date.

#### Allowance for Doubtful Accounts

We review the collectability of accounts receivable based on an assessment of historic experience, current economic conditions, and other collection indicators. At December 31, 2011 and 2010 and March 31, 2012, we have 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. Accounts receivable of \$99,140, \$75,000 and \$76,533 at December 31, 2011 and 2010 and March 31, 2012, respectively, represent the minimum royalty payments due as of those dates.

#### 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, 2011 and 2010 and March 31, 2012, the fair value of such warrants was \$994,627, \$609,155 and \$1,045,967, respectively, which are included in the derivative financial instruments' liability on our balance sheet.

We have issued units that were price protected during the years ended December 31, 2011 and 2010 and the three months ended March 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 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, 2011 and 2010 and the three months ended March 31, 2012, the fair value of such price protected units was \$2,846,017, \$1,476,783 and \$2,937,464, respectively, which are included in the derivative financial instruments' liability on our balance sheet.

# Table of Contents

At December 31, 2011 and 2010 and March 31, 2012, the total fair value of all warrants and price protection, valued using the Black-Scholes option-pricing model and the Binomial option pricing model was \$3,840,644, \$2,085,938 and \$3,983,430, 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, as well as contract research, insurance and FDA consultants, 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 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,			For the three months ended March 31,					ngust 4, 1999 nception) to March 31,
	2011		2010		2012		2011		2012
Salaries and staff costs	\$ 468,893	\$	656,740	\$	169,893		174,111	\$	9,946,466
Outside services, consultants and lab									
supplies	283,350		180,429		86,802		37,963		2,734,962
Facilities	137,793		157,467		78,678		33,588		2,677,377
Other	20,649		29,523		2,033		12,353		507,761
Total Research and development	\$ 910,685	\$	1,024,159	\$	337,407	\$	258,016	\$	15,866,566

We do not currently have any commercial molecular diagnostic products, and we do not expect to have such for several years if at all. Accordingly our research and development costs are expensed as incurred. 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.

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.

# 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.

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 estimated fair value of employee options on the date of

# Table of Contents

grant was determined by using the Black-Scholes option valuation model which requires management to make certain assumptions with respect to selected model inputs. The risk-free interest rate assumption is based upon observed U.S. Treasury interest rates appropriate for the expected term of the individual stock options. We have not paid any dividends on common stock since its inception and do not anticipate paying dividends on our common stock in the foreseeable future. The computation of the expected option term is based on expectations regarding future exercises of options which generally vest over three years and have a ten year life. The expected volatility is based on the historical volatility of our stock. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate future unvested option forfeitures based upon its historical experience and has incorporated this rate in determining the fair value of employee option grants. The expense is to be 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 we account for non-employee stock-based compensation. We continue to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the shares of stock and for the stock option or warrant, using the Black-Scholes options pricing model, if that value is more reliably measurable than the fair value of the consideration or services received. We account for equity instruments granted to non-employees in accordance with ASC Topic 505-50 "Equity-Based Payment to Non-Employees" whereas the value of the stock 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.

In accordance with ASC Topic 718 stock-based compensation expense related to our share-based compensation arrangements attributable to employees and non-employees is being recorded as a component of general and administrative expense and research and development expense in accordance with the guidance of Staff Accounting Bulletin 107, Topic 14, paragraph F, Classification of Compensation Expense Associated with Share-Based Payment Arrangements ("SAB 107").

#### Fair value of financial instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, debentures 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.

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.

# Table of Contents

# Convertible Debentures

We initially had \$2,225,500 of 6% convertible debentures initially due November 14, 2008 (the "Debenture" or "Debentures"). The Debentures accrued interest at the rate of 6% per annum, payable semi-annually on April 1 and November 1 of each year beginning November 1, 2007. We could, in our discretion, elect to pay interest on the Debentures in cash or in shares of our common stock, subject to certain conditions related to the market for shares of our 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 our common stock at an initial price of \$2.75 per share, subject to adjustment for certain dilutive issuances. During the year ended December 31, 2009, we entered into a Forbearance Agreement that resulted in the issuance of 1,087,494 shares of common stock in full settlement of amounts claimed for interest, penalties, late fees and liquidated damages related to the Debentures totaling \$2,042,205. Under the terms of the Forbearance Agreement the maturity date was extended to December 31, 2010 and the interest rate increased to 11%. A total of 1,216,753 shares of common stock purchase warrants, expiring November 14, 2012, continued to be outstanding. We accounted for the forbearance agreement and subsequent modifications and eventual extinguishment of these convertible debentures in accordance with ASC 470-50 "Debt Modifications and Extinguishments".

The fair value of the 1,087,494 shares on January 30, 2009 was \$1.60 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 in the year ended December 31, 2009.

The aggregate initial principal amount of \$2,170,500 plus two additional issuances of an aggregate principal amount 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 our Board of Directors;

conditions regarding the determination of compensation to be paid to our officers and directors; and

a total of 1,216,753 shares of common stock purchase warrants, expiring November 14, 2012, continued to be outstanding.

The carrying value of the debenture 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 reduction of other forbearance agreement settlement costs in the statement of operations in the year ended December 31, 2009.

During the years ended December 31, 2011 and 2010, we incurred interest expense of \$128,421 and \$256,856, respectively, that was paid in 154,114 shares. The Debenture Holders were entitled to interest expense at 11%. The total value of the shares issued for interest expense incurred during the years ended December 31, 2011 and 2010 was \$172,222 based on the stock price allocation in the fair value of the price protected units issued. The difference in the fair value of the consideration given and the amounts due to the debt holder was \$71,791, and \$141,271 for the years ended December 31, 2011 and 2010, respectively and was recorded as a reduction of the interest expense in our Consolidated Statements of Operations.

# Table of Contents

On July 18, 2011 we settled with the holders of the Debentures by converting the amounts outstanding by issuing 934,020 shares of common stock pursuant to a note and warrant agreement and we issued an additional 93,402 shares of common stock to the Debenture Holders as consideration for their agreement to extinguish the debt. This resulted in a \$1.2 million gain on extinguishment based on the fair value of the stock being \$1.10 a share as of the date of the transaction. In addition, the 1,216,753 warrants, originally issued in 2006 with the debentures with an expiration date of November 14, 2012, were exchanged for 1,216,753 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 the year ended December 31, 2011 on the Consolidated Statements of Operations.

The 1,216,753 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, 2011, 2010 and inception (August 4, 1999) to December 31, 2011 was a gain of \$35,127, a loss of \$31,999, and a gain of \$494,714, respectively. The losses for year ended December 31, 2011 and the gain from inception (August 4, 1999) to December 31, 2011 exclude the \$581,503 charge for the modification in the change in fair value of the derivative liability on the Consolidated Statements of Operations.

# **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.

# **Recent Accounting Pronouncements**

In June 2011 and December 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* and ASU No. 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-5. As a result of ASU 2011-05, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU 2011-05 and ASU 2011-12 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of these standards did not have a material impact on our consolidated financial position or results of operations.

In 2011, FASB ASU No. 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in US GAAP and International Financial Reporting Standards (Topic 820) Fair Value Measurement". The new guidance relates to fair value measurements, related disclosures and consistent meaning of the term "fair value" in US GAAP and International Financial Reporting Standards. The amendment clarifies how to apply the existing fair value measurements and disclosures.

# Table of Contents

For fair value measurements classified within Level 3, an entity is required to disclose quantitative information about the unobservable inputs. A reporting entity is also required to disclose additional information like valuation processes, a narrative description of the sensitivity of the fair value measurements to changes in unobservable inputs and the interrelationships between those unobservable inputs. The amendments specified in ASU 2011-04 were effective upon issuance. The adoption of this standard did not have a material effect on our results of operations or our financial position.

In 2010, the FASB issued an ASU related to Revenue Recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The adoption of this standard did not have a material effect on our results of operations or our financial position.

In 2010, the FASB issued ASU 2010-06 Fair Value Measurements and Disclosures (Topic 820) that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB also clarified existing fair-value measurement disclosure guidance about the level of disaggregation, inputs, and valuation techniques. The new and revised disclosures are required to be implemented in interim or annual periods beginning after December 15, 2009, except for the gross presentation of the Level 3 rollforward, which is required for annual reporting periods beginning after December 15, 2010. The adoption of this standard did not have any effect on our financial position and results of operations.

# **Results of Operations**

#### Three Months Ended March 31, 2012 and 2011

#### Revenues

Our total revenues were \$34,153 and \$89,082 for the three months ended March 31, 2012 and 2011, respectively, and consisted of the following:

#### Three months ended March 31,

	2012	2011	Inc	rease/(Decrease)
Royalty income	\$ 34,153	\$ 69,082	\$	(34,929)
License fees		20,000	\$	(20,000)
Total revenues	\$ 34,153	\$ 89,082	\$	(54,929)

Royalty income decreased by \$34,929 in the three months ended March 31, 2012 substantially due to an October 2011 termination of an agreement that provided \$24,657 of royalties during the three month period ended March 31, 2011. License fees decreased by \$20,000 in the three month period ended March 31, 2012 as no new license agreements were signed in the period, while in the three month period ended March 31, 2011, there was one license signed with a fee of \$20,000.

# Research and Development Expenses

Research and development expenses consisted of the following:

#### For the three months ended March 31,

	2012	2011	Inc	rease/(Decrease)
Salaries and staff costs	\$ 169,893	\$ 174,111	\$	(4,218)
Outside services, consultants and lab supplies	86,802	37,963		48,839
Facilities	78,678	33,588		45,090
Other	2,033	12,353		(10,320)
Total research and development	\$ 337,407	\$ 258,016	\$	79,391

Research and development expenses increased by \$79,391 to \$337,407 for the three months ended March 31, 2012 from \$258,016 for the same period in 2011. This overall increase is due to the start-up of our CLIA lab operations in February 2012 as a result of the purchase of the CLIA license from MultiGen Diagnostics, Inc.

# General and Administrative Expenses

General and administrative expenses consisted of the following:

#### For the three months ended March 31,

	2012	2011	Increase	(Decrease)
Salaries and staff costs	\$ 129,948	\$ 230,444	\$	(100,496)
Outside services and Board of Director fees	291,543	80,264		211,279
Legal and accounting fees	328,856	176,992		151,864
Facilities	24,123	29,902		(5,779)
Insurance	17,548	22,224		(4,676)
Other	34,946	11,218		23,728
	\$ 826,964	\$ 551,044	\$	275,920

General and administrative expenses increased by \$275,920 to \$826,964 for the three months ended March 31, 2012 from \$551,044 for the same period in 2011. This overall increase was primarily due to a decrease in salaries and staff costs, more than offset by increases in outside services, legal and accounting fees. The decrease in salaries and staff costs occurred primarily because the three month period ended March 31, 2011 included \$100,000 related to the settlement of employment lawsuits with Mr. Umansky and the estate of the late Mr. Melkonyan. The increase in outside services resulted primarily from the addition of a Chief Executive Officer and Chief Financial Officer, as well as services provided by outside financial personnel related to the preparation of the Form 10 and Form 10-K in March 2012. Legal and accounting fees also increased in the three month period ended March 31, 2012 as a result of the preparation, review, audit and filing of the Form 10 and Form 10-K in March 2012.

# Interest Expense

There was no interest expense in the three months ended March 31, 2012 compared to \$28,511 in the three months ended March 31, 2011. The interest expense in the three months ended March 31, 2011 related to convertible debentures which were extinguished in July 2011.

# Change in Fair Value of Derivative Instruments

We issued securities that are accounted for as derivative liabilities during the three months ended March 31, 2012 and during prior periods as well. As of March 31, 2012, the derivative liabilities related

# Table of Contents

to securities issued prior to the three months ended March 31, 2012 were revalued to \$3,598,102, resulting in a net increase in value of \$32,424 from December 31, 2011, based primarily upon changes in the expected term and risk free interest rates for the expected term. The increase in value was recorded as non-operating loss for the three months ended March 31, 2012.

# Years Ended December 31, 2011 and 2010

#### Revenues

Our total revenues were \$257,696 and \$265,665 for the years ended December 31, 2011 and 2010, respectively. Total revenues consisted of the following:

	Year ended December 31,					
	2011 2010					
Royalty income	\$ 227,696	\$	255,665			
License fees	30,000		10,000			
Total revenues	\$ 257,696	\$	265,665			

Royalty income increased in the year ended December 31, 2011 as the total number of agreements resulting in royalty income increased by one from the prior year. License fees increased during the year ended December 31, 2011 as in 2011 there were license fees received from more agreements than in 2010.

# Research and Development Expenses

Research and development expenses were as follows:

	Year ended December 31,				
		2011		2010	
Salaries and staff costs	\$	468,893	\$	656,740	
Outside services, consultants and lab supplies		283,350		180,429	
Facilities		137,793		157,467	
Other		20,649		29,523	
Total Research and development	\$	910,685	\$	1,024,159	

Salaries and staff costs decreased by \$187,847 during the year ended December 31, 2011 as compared to the year ended December 31, 2010 due to the departure of our Chief Medical Officer. Outside services, consultant and lab supplies increased by \$102,921 during the year ended December 31, 2011 as compared to the year ended December 31, 2010, primarily due to an increase in the use of outside consultants. Facilities expenses decreased by \$19,674 during the year ended December 31, 2011 as compared to the year ended December 31, 2010, as the year ended December 31, 2010 included the costs to relocate laboratory items from New Jersey to our current location in San Diego, California.

# Purchased In-Process Research and Development Expense

There was no purchased in-process research and development expense for the year ended December 31, 2011 as compared to \$2,666,869 in the year ended December 31, 2010. The amount recorded during the year ended December 31, 2010 was in connection with the Etherogen Inc., merger.

# Table of Contents

# General and Administrative Expenses

General and administrative expenses increased by \$369,889, or 19%, to \$2,323,814 for the year ended December 31, 2011 from \$1,953,925 for the year ended December 31, 2010. This increase was primarily due to (i) an increase of approximately \$264,000 in accounting fees related to the preparation of our Form 10, (ii) an increase in outside consultants' expense of approximately \$160,000, (iii) an increase in legal fees of approximately \$28,000, (iv) an increase in fees owed to board members of approximately \$28,000 and (v) a \$47,000 increase in printer expenses related to the filing of our Form 10. These increases were partially offset by a decrease in employee expenses of approximately \$194,000.

#### Net Loss

Net loss for the year ended December 31, 2011 was \$2,239,212 compared to a net loss of \$5,449,138 incurred for the year ended December 31, 2010. This decrease in our net loss of \$3,209,926, or 59%, was a result primarily of (i) the decrease in research and development expenses discussed above, (ii) the net gain on extinguishment of debt of \$623,383 in the year ended December 31, 2011, and (iii) the decrease in gain in fair value of derivative instruments-warrants of approximately \$96,000 from a gain of approximately \$267,000 in the year ended December 31, 2010. This was due to a decline in the stock price of \$.01, an increase in the risk free interest rate of 1.41% to 2.80% and a decrease in the volatility from 100% to 90%. The above changes were offset by an increase in general and administrative expenses and purchased in-process research and development expense as discussed above.

# **Liquidity and Capital Resources**

As of May 15, 2012, our cash balance was \$785,243 and our working capital deficit was \$305,216. As of March 31, 2012, we had \$586,777 in cash and cash equivalents. Net cash used in operating activities for the three months ended March 31, 2012 was \$905,088, compared to \$568,653 for the three months ended March 31, 2011. Our use of cash was primarily a result of the net loss of \$1,164,642 for the three months ended March 31, 2012, adjusted for non-cash items related to stock-based compensation of \$102,830, depreciation and amortization of \$6,190 and the change in fair value of derivatives of \$32,424. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses and a decrease in accounts receivable and prepaid expenses. 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 and intangible assets that used \$98,009 in cash during the three months ended March 31, 2012, compared to \$1,528 for the same period in 2011.

Net cash provided by financing activities was \$889,500 during the three months ended March 31, 2012, compared to \$600,000 in 2011. Financing activities during the three months ended March 31, 2012 and 2011 were from proceeds received related to the sale of common stock.

As of March 31, 2012, and December 31, 2011, we had working capital deficits of \$826,997 and \$587,712, respectively.

On July 18, 2011, we settled with the holders of the Debentures by converting the amounts outstanding by issuing 934,020 shares of common stock pursuant to a note and warrant agreement and we issued an additional 93,402 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 \$1.10 a share as of the date of the transaction. In addition, the 1,216,753 warrants, originally issued in 2006 with the debentures with an expiration date of November 12, 2012, were exchanged for 1,216,753 new warrants with a new expiration date of December 31, 2017. The additional

# Table of Contents

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 the year ended December 31, 2011 on the Consolidated Statements of Operations.

On February 10, 2012, we closed a private placement which raised gross proceeds of \$800,000. We issued 320,000 shares of our common stock and warrants to purchase 320,000 shares of common stock in this transaction. In addition, we issued 14,940 shares of common stock and warrants to purchase 14,940 shares of common stock as a finder's fee. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share.

On February 14, 2012, we closed a private placement which raised gross proceeds of \$150,000. We issued 60,000 shares of our common stock and warrants to purchase 60,000 shares of common stock in this transaction. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share.

On April 13, 2012, we closed a private placement which raised gross proceeds of \$650,000. We issued 260,000 shares of our common stock and warrants to purchase 260,000 shares of common stock in this transaction. In addition, we issued 10,800 shares of common stock and warrants to purchase 10,800 shares of common stock as a finder's fee, as well as a cash payment for finder's fees in the amount of \$18,000. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share.

On May 2, 2012, we closed a private placement which raised gross proceeds of \$300,000. We issued 120,000 shares of our common stock and warrants to purchase 120,000 shares of common stock in this transaction. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share. In connection with the financing, 10,800 shares of common stock and warrants to purchase 10,800 shares of common stock were issued for finder's fees, as well as a cash payment for finder's fees in the amount of \$18,000.

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 will be required to raise additional capital within the next twelve months to complete the development and commercialization of current product candidates, to fund the existing working capital deficit and to continue to fund operations at our current cash expenditure levels. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures. We cannot be certain that additional funding will be available on acceptable terms, or at 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, 2011 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, 2011 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.

# **BUSINESS**

We are a development stage molecular diagnostic company that focuses on the development and marketing of urine-based nucleic acid tests for patient/disease screening and monitoring. Our novel tests predominantly use transrenal DNA, or Tr-DNA, and transrenal RNA, or Tr-RNA. Our primary focuses are to leverage our urine-based testing platform to facilitate improvements in the management of cancer care and women's healthcare. Tr-DNAs and Tr-RNAs are fragments of nucleic acids derived from dying cells inside the body. The intact DNA is fragmented in dying cells and released into the blood stream. These fragments have been shown to cross the kidney barrier (i.e., are transrenal) and can be detected in urine. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier. These RNA can also be isolated from urine, detected and analyzed. Our technology is applicable to all transrenal nucleic acids, or Tr-NA.

Our patented technology platform uses safe, non-invasive, cost effective and simple urine collection and can be applied to a broad range of testing including: tumor detection and monitoring (e.g., KRAS mutations in pancreatic cancer), prenatal genetic testing, infectious diseases, tissue transplantation, forensic identification, and for patient selection in clinical trials. We believe that our technology is ideally suited to be used in developing molecular diagnostic assays that will allow physicians to provide simple, non-invasive and convenient screening and monitoring tests for their patients by identifying specific biomarkers involved in a disease process. If we are successful, our novel assays may facilitate improved testing compliance resulting in earlier diagnosis of disease, more targeted treatment which will be more cost-effective, and improvements in the quality of life for the patient.

Our products are developed using commercially available chemicals and biologicals, as well as instrumentation and equipment. The only custom components we use are specific synthetic sequences of nucleic acids (DNA and RNA) synthesized in a sequence to order. Raw materials are commercially available, often from multiple vendors. Vendors of biological and chemical components include QIAGEN, GE Healthcare, Life Technologies Corporation, and Sigma-Aldrich Corporation. Synthetic DNA and RNA are available from multiple vendors, including Integrated DNA Technologies, Inc. Special chemical modifications of synthetic DNA and RNA are available from Applied Biosystems (now part of Life Technologies Corporation) and licensed providers. These vendors either have worldwide distribution or alternative vendors are available.

As relates to our urine-based testing platform and focuses on improving women's healthcare and cancer care, one of our corporate priorities may include to pursue and receive a European Conformity, or CE mark, and thus marketing approval, for our human papillomavirus (HPV) HPV urine-based test to identify women at increased risk for cervical cancer. The CE mark is obtained through a self-certification, performed by a qualified European marketing and manufacturing partner. We may pursue this strategy in all countries that recognize and accept CE marks for regulatory marketing approval. During 2012 we intend to commence a pilot clinical study of our HPV urine-based test. We anticipate that this study will be led by key opinion leaders in clinical Obstetrics and Gynecology (OB/Gyn), as well as leaders in Ob/Gyn pathology. Positive results from this study would be used for publication purposes and to file for marketing approval in all countries that recognize CE Marks. Our HPV test would be the first urine-based HPV test approved for commercial use. It would provide key advantages versus current tests which are all based on cervical samples. These advantages include patient convenience and privacy, use of non-invasive sample collection, potentially increased sensitivity, and other benefits.

Another key priority within our women's healthcare testing pipeline falls within the fetal medicine arena. We plan to develop a urine-based prenatal screening test to detect pregnancies at increased risk for various chromosomal disorders, with an initial emphasis on Down Syndrome, or T21. Such a test would address a huge unmet need for an accurate, reliable and truly non-invasive screening modality.

# Table of Contents

In August 2010, we acquired a highly sensitive complementary metal-oxide-semiconductor, or CMOS, detection technology for DNA, RNA as well as proteins through our merger with Etherogen, Inc. A key advantage of this technology is that it is extremely sensitive and doesn't require amplification of nucleic acids. Therefore, it reduces the complexity and cost of molecular diagnostics as it does not require significant equipment purchases or amplification training. Our CMOS detection technology may also open up new markets for molecular diagnostics such as hospitals and independent labs that currently do not perform high complexity assays such as those requiring use of a polymerase chain reaction, or PCR. We believe that this detection technology is highly complementary and synergistic with our transrenal technology, and can also be positioned in certain situations as a standalone molecular diagnostic device. In this regard, we plan to leverage this novel CMOS technology toward the development of Women's Healthcare and cancer diagnostics. We are finalizing the system architecture, operating procedure and software specifications for this platform and will commence system development pending resource availability.

During 2006 we in-licensed a new DNA-based biomarker, NPM1, specific for a subtype of acute myeloid leukemia, or AML from Brunangelo Falini and Cristina Mecucci. This NPM1 marker provides valuable information and insights as to disease prognosis and monitoring for minimal residual disease. Testing for NPM1 mutations has been added to AML practice guidelines by the National Comprehensive Cancer Network (NCCN). Pursuant to the license agreement we are responsible for preparing, filing, prosecuting, obtaining and maintaining the NPM1 patent rights. We are obligated to pay a royalty in the single digits based on net sales, in the teens on sublicense income received and in the single digits on all sublicense royalties received. The term of the license ends on October 28, 2025. The license can terminate at our option for a commercially reasonable reason or in the event of a material breach. In the event that the licensor decides to sell or convey the licensed rights, we shall have an option to acquire such property. Since 2006 we have executed out-licenses incorporating this biomarker with Sequenom, Inc. (subsequently terminated in March of 2011), and with Ipsogen S.A. (Europe) and Asuragen Inc. (U.S.), both of whom have developed and are manufacturing test kits for sale to labs from which we earn a royalty. We have also signed non-exclusive royalty bearing licenses with various labs including LabCorp (U.S.), Invivoscribe Technologies, Inc. (U.S.), Skyline Diagnostics B.V. (Europe), MLL Munich Leukemia Laboratory GmbH (Europe) and Warnex Inc. (Canada), who will all be providing lab testing services for this marker. We are actively seeking to sign additional royalty bearing non-exclusive license agreements with labs that wish to provide this testing service.

The material terms of the sublicense agreements we have entered into are as follows:

*Ipsogen S.A.* On August 27, 2007, we entered into a Co-Exclusive Sublicense Agreement with Ipsogen S.A, or Ipsogen. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. Ipsogen is obligated to develop, seek registration and sell licensed products derived from the NPM1 patent rights. Ipsogen is obligated to pay a royalty in the teens with annual minimum royalties of \$10,000 for the first year, \$25,000 for the second year, \$40,000 for the third and fourth year and \$50,000 thereafter and milestone payments with a potential aggregate of \$230,000. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. Through March 31, 2012, the amount paid to us under the agreement totals \$254,571. The license terminates if Ipsogen fails to pay, or upon 60 day written notice to us. If we determine that Ipsogen is not developing or selling products or services, we may notify Ipsogen. If resolution is not achieved within 3 months, we may terminate the agreement.

Asuragen, Inc. On October 22, 2007, we entered into a Co-Exclusive Sublicensing Agreement with Asuragen, Inc., or Asuragen. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights. Asuragen is obligated to develop, seek registration and sell licensed products derived from the NPM1 patent rights.

# Table of Contents

Asuragen is obligated to pay a single digit royalty on a sliding scale based on sales volume with annual minimum royalties of \$10,000 for the first year, \$25,000 for the second year and \$50,000 thereafter and milestone payments with a potential aggregate of \$300,000. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. Through March 31, 2012, the amount paid to date to us under the agreement is \$334,211. The license terminates if Asuragen fails to pay us after 45 days written notice, or upon 30 days written notice to us. If we determine that Asuragen is not developing or selling products or services, we may notify Asuragen. If resolution is not achieved within 3 months, we may terminate the agreement.

Laboratory Corporation of America Holdings. On August 25, 2008, we entered into a sublicense agreement with Laboratory Corporation of America Holdings, or LabCorp. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. LabCorp is obligated to pay a royalty in the teens with annual minimum royalties of \$10,000 for the first and second year, \$15,000 for the third year, \$20,000 for the fourth year and \$25,000 thereafter. Through March 31, 2012, the amount paid under the agreement is \$43,085. The term of the license ends August 25, 2018. The license terminates if LabCorp fails to pay, or upon 90 day written notice to us.

*InVivoScribe Technologies, Inc.* On December 1, 2008, we entered into a sublicense agreement with InVivoScribe Technologies, Inc., or IVS. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. IVS is obligated to pay a royalty in the teens with annual minimum royalties of \$5,000 for the first year, \$20,000 for the second year and \$25,000 thereafter. Through March 31, 2012, the amount paid to us under the agreement is \$27,653. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. The license terminates if IVS fails to pay, or upon 90 day written notice to us.

Warnex Medical Laboratories. On January 8, 2008, we entered into a sublicense agreement with Warnex Medical Laboratories, or Warnex. The Warnex sublicense agreement is limited to the territory of Canada. Pursuant to the agreement we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. Warnex is obligated to pay a royalty in the teens. No amount has been paid through March 31, 2012. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. The license terminates if Warnex fails to pay, or upon 60 days written notice to us.

Skyline Diagnostics BV. On June 15, 2010, we entered into a sublicense agreement with Skyline Diagnostics BV, or Skyline. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. Skyline is obligated to pay the greater of a royalty of 1% or \$20 per reported test on a leukemia panel test with annual minimum royalties of \$10,000 for the first year, \$15,000 for the second year and \$20,000 thereafter and milestone payments with a potential aggregate of \$70,000. Through March 31, 2012, the amount paid to us under the agreement is \$27,500. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. The license terminates if Skyline fails to pay, or upon 60 days written notice to us.

MLL Münchner Leukämielabor. On February 8, 2011, we entered into a sublicense agreement with MLL Münchner Leukämielabor, or MLL. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. MLL is obligated to use diligent effort to develop and sell laboratory services

# Table of Contents

as soon as practicable. MLL is obligated to pay a royalty in the teens with annual minimum of \$15,000 for the first year and \$20,000 thereafter. Through March 31, 2012, the amount paid to us under the agreement is \$16,250. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. The license terminates if MLL fails to pay, or upon 90 days written notice to us.

On January 18, 2011, we entered into an asset purchase agreement pursuant to which we acquired a hybridoma able to produce a monoclonal antibody targeting the NPM1 biomarker for an upfront fee of \$10,000. In addition we have 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 the aggregate amount of 10% of all royalties received by us from licensees pursuant to any licenses of rights to the antibody which has not occurred as of the date hereof. In addition, we agreed to pay (i) 10% of all cash consideration received by us from licensees as an upfront license fee pursuant to any licenses of the product and (ii) 7% of all cash consideration received by us from licensees as milestone payments. The agreement may be terminated at any time by either us or the seller in case of non-fulfillment of the obligations of the agreement or by seller in case of non-compliance of us with respect to the royalty payments.

In July 2011, we entered into a sublicense agreement with Fairview Health Services ("Fairview") for NPM1 patent rights. We are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights. Fairview is obligated to pay royalties in the teens with annual minimum and milestone payments with a potential aggregate of \$10,000. The term of the license ends upon expiration or abandonment of all patent rights. The patent expires on October 25, 2025. The license terminates if Fairview fails to pay, or upon 90 day written notice to us. 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. Through March 31, 2012, the amount paid to us under the agreement is \$10,000.

In October 2011, we entered into an exclusive license agreement pursuant to which we licensed the patent rights to a specific gene mutation with respect to chronic lymphoblastic leukemia. In consideration of the license, we 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 us or a single digit royalty on sublicense income received by us if sales are made by sublicensees. This has not occurred as of the date hereof. We have 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 us if we determine that it is not commercially or scientifically appropriate to further develop the license product rights.

On December 12, 2011, we entered into an exclusive license agreement, subject to certain retained academic research rights, pursuant to which we licensed 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 in the single digits on net sales if sales are made by us or a single digit royalty on sublicense income received by us if sales are made by sublicensees which has not occurred as of the date hereof. 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 with 90 days prior notice or by us if we determine that it is not commercially or scientifically appropriate to further develop the license product rights.

In order to facilitate early availability and use of our products and technologies, on February 1, 2012, we acquired the CLIA laboratory assets of MultiGEN Diagnostics, Inc., or MultiGEN, which included CLIA (Clinical Laboratory Improvement Amendments of 1998) certification and state

# Table of Contents

licensing documentation, laboratory procedures, customer lists and marketing materials. A CLIA lab is a clinical reference laboratory that can perform high complexity diagnostic assays (e.g., those requiring PCR amplification). Through this CLIA laboratory we are able to offer laboratory developed tests, or LDTs, in compliance with CLIA guidelines, and, depending on the diagnostic assay, without the need for FDA review. This will make our tests and technology available to physicians to order for their patient management, and in-turn generate revenue. We will determine on a case-by-case basis whether an eventual FDA review of a given diagnostic assay is necessary. This decision will, amongst other factors, be based on the desired route of commercialization (e.g., in vitro diagnostic product vs. laboratory testing service) and the specific nature of the respective diagnostic test. In connection with the acquisition, we issued 150,000 shares of our restricted common stock to MultiGEN. In addition, up to an additional \$3.7 million in common stock and cash may be paid to MultiGEN upon the achievement of specific sales and earnings targets. In addition, in connection with the acquisition, we entered into a Reagent Supply Agreement dated as of February 1, 2012 pursuant to which MultiGEN will supply and deliver to us reagents to be used in connection with our CLIA lab. The reagents will be sold to us in an amount equal to cost per unit plus 20%. The Reagent Supply Agreement shall be in effect for a period of three years but can be terminated by either party upon a breach of the agreement and we can terminate the agreement for any reason upon 1 year prior written notice.

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

# History

We were incorporated in the State of Florida on April 26, 2002 as Used Kar Parts, Inc. and planned to develop an on-line marketplace for used car parts. In an effort to develop that business, we entered into a contract with a web hosting service on a month to month basis to provide storage for website development and transaction processing. Our temporary website arrangement was suspended to preserve cash and pending new management's evaluation of the business. On February 24, 2004, Jeannine Karklins, our former President, Treasurer, Secretary, principal shareholder and control person entered into a Capital Stock Purchase Agreement with Panetta Partners Ltd., a limited partnership affiliated with our former Co-Chairman and current director, Gabriele M. Cerrone, pursuant to which Panetta purchased an aggregate of 400,000 restricted shares of our common stock from Ms. Karklins for \$386,400 which represented approximately 97% of our outstanding shares of common stock at the time. Pursuant to the agreement, Ms. Karklins resigned as an officer and director of our company.

On July 2, 2004, we acquired Xenomics, a California corporation, which was developing and commercializing our Tr-DNA technology. As part of the acquisition, we changed our corporate name to Xenomics, Inc. ("Xenomics").

In 2007, we changed our fiscal year end from January 31 to December 31. In January 2010, we redomesticated our state of incorporation from Florida to Delaware and changed our name to TrovaGene, Inc.

# **Our Technologies**

We believe that our scientists were the first to report the discovery that a portion of cell-free DNA or RNA found in the bloodstream can cross the kidney barrier and be detected in the urine. This

# Table of Contents

genetic material is referred to as Tr-DNA or Tr-RNA, or in aggregate Tr-nucleic acid. Analysis of Tr-DNA or Tr-RNA provides a simple, non-invasive and cost-effective method for molecular diagnostics and a platform for a broad range of diagnostic tests. In comparison with conventional tissue, sputum or plasma-based tests, this urine-based methodology has significant advantages with respect to patient convenience, privacy and compliance, ease of testing by elimination of difficult extraction steps in sample preparation, speed in performing the assay, amount of sample available, and cost effectiveness.

We have a dominant patent position as it relates to transrenal molecular testing. We own issued U.S. and European patents that cover any and all testing for molecular targets that pass through the kidney (i.e., transrenal). In addition to these core patents, we have numerous patent applications pending in the areas of cancer, infectious diseases, transplantation, prenatal and genetic testing.

In order to test the feasibility of testing urine samples for HPV DNA, we engaged in an in-house study of clinical samples from India during January through August 2008. This study was not sanctioned by the FDA nor conducted under the guidance of the FDA. Results from this study may be presented to the FDA in the event of a pre-IND meeting and are not directly applicable to seeking regulatory approval. Samples were collected from high and low risk populations in India including those from staged cancer patients by Simbiosys Biowares Inc. and Metropolis Inc. High risk subjects were recruited either from sexually transmitted disease clinics in hospitals or district brothels in West Bengal in eastern India. The study enrolled 320 patients during January through May, 2008. Pap smears and QIAGEN High-Risk HPV DNA hc2 tests were performed on collected cervical cells by Simbiosys Biowares Inc. and Metropolis Inc. Urine samples were shipped to us for in-house PCR amplification and detection. Urine samples which gave results discordant with the cervical specimen-based hc2 assay were further examined by DNA sequencing for resolution. PCR product sequences were examined by the NCBI Blastn algorithm to match specific human papillomavirus strains.

We generated positive clinical study results with our HPV urine-based test to identify women at risk for developing cervical cancer. In this study, 31 out of 38 cervical swab samples that were initially classified as "negative" were subsequently determined to be positive by PCR followed by DNA sequencing of the urine using our urine-based platform. Additionally, 24 out of 34 cervical swab samples initially classified as "positive" were determined to be negative based on DNA sequencing of the urine. Our urine-based test only had 10 false negatives and 7 false positives, which represents 93% sensitivity and 96% specificity. As a result we believe that the sensitivity and specificity of our urine-based test is at least similar to and potentially better than the currently used cervical-cell-based tests. As noted earlier, our urine-based test is non-invasive, more convenient and private for the patient, simpler, less technically demanding in terms of cytology proficiency and potentially cost effective. Our unique primer pair focused on the E1 region of the HPV genome is expected to provide freedom to operate within the HPV patent landscape (i.e., we believe that our HPV patent will issue in the major geographic areas and be enforceable). It should be noted that these studies were research studies, not regulatory studies. These studies resulted in valuable insight that needs further work and validation by us. While the results were encouraging, they were not sufficient to complete the development of, seek approval for and launch a product in the U.S. or ex-U.S. markets. Consequently, we have initiated development of a diagnostic test to determine the presence of high risk HPV subtypes from urine specimens. The proprietary test (U.S. patent application pending) might, once available, be particularly useful for the determination of carrier status in males.

Presently, we are working towards finalizing a clinical study protocol and recruiting study sites in conjunction with key opinion leaders in the field of Ob/Gyn pathologists. We may use the results of this study, anticipated to begin at the earliest in 2012, toward the pursuit of a CE Mark in Europe and all other countries that recognize CE Marks for marketing approval.

In order to test the feasibility of using urine samples in tumor detection and monitoring, we have successfully completed the analytical development of digital PCR assays for the detection of both the

# Table of Contents

most prevalent KRAS mutations and wild type KRAS DNA sequences. KRAS mutations are found in 90% of patients with pancreatic cancer, in 23% of all tumor samples examined by the Sanger Center, and have been previously detected in the urine of colorectal cancer patients by others. Furthermore, three specific KRAS mutations account for approximately 96% of all KRAS mutations in pancreatic cancer and all three are among those we have established in-house. In order to quickly apply our technology to tumor detection and monitoring we have established protocols for the isolation of DNA from 100ml of urine and the concentration of the DNA for mutation and wild type KRAS analysis using commercial means, and we are in late-stage discussions with two premier cancer centers to procure urine samples from patients with pancreatic cancer.

In addition, our technology can be applied to the development and subsequent commercialization of our fetal medicine assay, initially to screen for Down Syndrome, one of many genetic disorders caused by chromosomal abnormalities. There is a huge unmet market need for a simple, convenient and truly non-invasive screening approach in the maternal arena. Initial studies of our transrenal assays with maternal urine clearly showed that we can detect Y chromosomal sequences which in turn clearly demonstrates the ability to detect transrenal fetal nucleic acids in this maternal urine. Additionally, our novel assays show and incorporate a complete representation of the maternal and most likely fetal genome in maternal urine. The combination of our unique transrenal nucleic acid platform in combination with next generation sequencing may allow for the development and commercialization of the first truly non-invasive prenatal screening test for these chromosomal-related diseases.

Our recent acquisition of a highly sensitive molecular detection platform utilizing proprietary probe chemistry and on chip CMOS signal detection expands our reach within the molecular diagnostic arena. This analytical platform is synergistic and complementary to our transrenal nucleic acid technology and will be leveraged in our women's healthcare and other development endeavors by providing unsurpassed analytical and detection capabilities. Patents for this detection platform are pending in the U.S., Europe and Japan. The technology platform consists of several novel inventions: (i) direct attachment of a probe to a CMOS sensor chip, (ii) a proprietary conjugate capture and (iii) a conjugate reporter probe. In combination they enable ultra-sensitive detection of nucleic acids or proteins, without the need for a separate amplification step such as with PCR. As such, no expensive equipment is required to be purchased by labs or hospitals, all of which constantly look for ways to reduce their expenses wherever possible. The chips may be processed using off-the-shelf available liquid handling systems and the results are read with a simple USB to an existing computer running our proprietary software. The demonstrated sensitivity using an engineering prototype is 300 molecules.

Highly complementary to our Tr-DNA and Tr-RNA platform and projects, we have the exclusive worldwide rights to the use of the nucleophosmin protein gene (NPM1) for use in human *in-vitro* diagnostic testing, monitoring, prognostic evaluation and drug therapy selection for patients with AML. These rights and subsequent sublicenses have been crucial in terms of generating a steady incoming cash flow stream. We actively seek sublicense agreements with diagnostic laboratories planning to offer lab testing services to the clinical market based on an LDT for this marker. Two of our early sublicensees, LabCorp and Invivoscribe Technologies, have already announced commercial availability of a validated LDT molecular test for the NPM1 gene either as a standalone test or as part of an AML profile assay. In addition, two companies, Asuragen and Ipsogen, have sublicensed the rights to make and sell tests kits for the NPM1 mutations and are now offering these products as Research Use Only kits to the market. Lastly, we will be seeking drug development partnerships with pharmaceutical companies with active AML drug development initiatives as NPM1 is a valuable biomarker to guide patient selection in clinical trials.

#### The Market

Estimates of the size of the global molecular diagnostics market vary, however the market was projected to approach \$7.0 billion in 2011 (final data not yet available). The market is poised to deliver

# Table of Contents

strong double-digit annual growth during the next 5 years, with one industry source quoting a compound annual growth rate (CAGR) of 19%. The molecular diagnostics market has emerged as the fastest growing segment of the in-vitro diagnostics, or 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). It is noteworthy that the Indian molecular diagnostics market is showing growth, expected to reach 1.0 billion INR (\$220 million) by 2011 (final data not yet available). United States and Europe markets were projected to surpass \$4.0 billion and \$1.0 billion, respectively (final data not yet available). Key drivers for this impressive growth include the exceptional ability to accurately and quickly detect the primary cause of disease and provide a strong tool for quick therapy decisions, need for automated and easier techniques, and the increased availability of tests for monitoring the efficacy of expensive drugs.

Transrenal molecular diagnostics will provide relevant diagnostic information that will lead to improvements in personalized patient management. Infectious diseases, cancer diagnosis and monitoring are where most of the use and progress in personalized molecular diagnostic medicine has occurred to-date. In addition, new products that facilitate personalized care are emerging in the areas of CNS, autism, diabetes, and depression, and most major pharmaceutical companies have active pharmacogenomic programs in their clinical studies in anticipation of the need to utilize diagnostic testing to stratify patients for efficacy.

We believe that we are very well positioned, with our very broad IP portfolio, to develop and market transrenal molecular diagnostic products, all of which we expect would address the huge unmet market needs of simplicity, patient convenience and privacy, accuracy, and cost effectiveness, and 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 target present in the sample leading to greater sensitivity. These modified screening practices will most likely meet with wide physician and patient acceptance in women's healthcare, the management of cancer care and beyond.

Women's Healthcare Human Papilloma Virus (HPV) HPV Screening and Monitoring is one of our key priority areas. This specifically relates to our development-stage urine-based HPV test. The rationale for screening HPV is that high-risk subtypes cause virtually all cases 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 still a huge global problem, especially in the developing world where screening practices are far from ideal. More than 85% of these cases and deaths occur in developing countries, which typically have poor screening practices. India alone accounts for 27% (77,100) of the total cervical cancer deaths. A recent clinical trial in rural India found that a single round of HPV DNA testing was associated with about a 50% reduction in risk of developing advanced cervical cancer and associated deaths. In the United States, where there is much better patient compliance and screening guidelines, there will be an estimated 12,710 cases in 2011, resulting in only 4,290 deaths. The major drivers for poor screening in these developing regions are cultural, limited resources/economics and poor cytology proficiency. Further exacerbating the compliance hurdles is the fact that the primary screening mechanism involves an invasive cervical scraping (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.

The bottom line is that there is a tremendous unmet need for a new non-invasive, simple, private and cost effective test to simplify the screening process for patients, and in turn improve compliance. We believe our urine-based test will address these market needs.

Women's Healthcare Fetal Medicine i.e, Down Syndrome This is a second core area within our women's healthcare screening pipeline. Of the roughly 4.1 million live births annually in the U.S.,

# Table of Contents

approximately 580,000 (1 in 7) are born to women over the age of 35 a population where screening for Down Syndrome is highly recommended due to increasingly higher risk. The key risk driver is age of the mother (e.g., pregnant women age 20 have a 1 in 1068 risk compared to 1 in 38 for women at age 42). However, it is noteworthy that a huge proportion of babies with Down Syndrome are born to mothers < 35 years of age primarily because this is the predominant maternal age. As such, it is paramount that these younger expectant women be screened. Our urine-based test would represent an ideal screening option as it will be totally non-invasive (unlike amniocentesis) and likely be more robust (improved specificity, sensitivity and positive predictive value) compared to the Triple Marker Screen or Quad Marker Screen blood tests. The annual U.S. market opportunity for such a convenient non-invasive urine-based screening test, assuming all pregnant women are tested, totals upwards of \$2.1-\$3.15 billion (4.1MM tests at \$500 to \$750 each, as estimated by us).

Infectious Diseases Viruses, bacteria, fungi, and parasites cause most infectious diseases. Tr-DNA and Tr-RNA assays that detect molecular targets in such organisms provide a quick, accurate, simple and cost effective method for screening and monitoring. Specific areas of interest for us, in addition to the aforementioned HPV infection, 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 a considerable problem in immune compromised patients such as patients with HIV, patients who are undergoing cancer treatments, etc. A test for these fungal infections by targeting Tr-DNA specific to Aspergillus species in a urine sample will provide a much easier and faster way to diagnose and treat these patients. With these patients, getting fast test results is paramount and can mean the difference between survival and death. Our urine-based test addresses this need for speed, as well as simplicity, patient convenience and accuracy.

An 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 test). The goal of such a test will be to detect active infection prior to the onset of symptoms, to allow for proactive intervention (i.e., drug holiday).

One problematic organism of particular interest to us is Borrelia, the cause of Lyme disease. Lyme disease is the most common tick-borne disease in the Northern Hemisphere and is caused by at least three species of Borrelia. The number of reported annual cases in the U.S. in 2009 was nearly 30,000, although total annual incidence could be higher due to reporting and recognition issues. Borrelia is transmitted to humans by the bite of infected ticks belonging to a few species of the genus Ixodes ("hard ticks"). Early symptoms may include fever, headache, fatigue, depression, and a characteristic circular skin rash called erythema migrans. Left untreated, later symptoms may involve the joints, heart, and central nervous system. In most cases, antibiotics eliminate the infection and its symptons, especially if the illness is treated early. Late, delayed, or inadequate treatment can lead to the more serious symptoms, which can be disabling and difficult to treat. The challenge with Lyme disease is that the early symptoms are often vague and subtle, making differential diagnoses difficult. Occasionally, symptoms such as arthritis persist after the infection has been eliminated by antibiotics, prompting

# Table of Contents

suggestions that Borrelia causes autoimmunity. A Tr-DNA assay for Borrelia would provide a much needed mechanism for early and quick detection of Lyme disease.

JC Virus is a virus that commonly causes infections of no consequence in individuals with normal immune systems. However, in immunosuppressed individuals, JC Virus is responsible for a life-threatening infection of the brain and spinal cord called progressive multifocal leukoencephalopathy, or PML. JC Virus is also the primary cause of nephropathy (kidney disease) in people who have received a kidney transplant and are on immunosuppressive therapy. Patients with multiple sclerosis (MS) who are being treated with the drug, natalizumab (Tysabri), are at risk for developing PML. This prompted the FDA to require a "black box" warning on Tysabri labeling. By monitoring these patients with a test for JC Virus, a physician would be able to routinely check patients to determine if and when the early signs of PML are present and to discontinue Tysabri therapy prior to the onset of full-blown PML. Multiple sclerosis currently affects about 2.5 million patients worldwide with more than 350,000 in the U.S. Tysabri is widely thought of as the most effective treatment for MS, although its use is somewhat restricted due to the "black box" warning. Another commonly used drug (for rheumatoid arthritis, or RA, and numerous hematologic cancers) associated with a high risk of JCV/PML is Genentech's immunomodulator rituximab (Rituxan). Our very quick and simple urine-based test to monitor for PML would allow many more patients to receive these two highly effective treatments with much less concern about PML.

Cancer Testing It is anticipated that Tr-DNA and Tr-RNA analysis may be useful for detecting and monitoring various primary cancers. Such testing could serve to help the physician choose a treatment regimen offering the highest likelihood of a successful outcome and monitor response to these treatments and check for disease recurrence. By testing Tr-DNA for the appropriate genetic markers, it may also be possible to carry out pre-cancerous screening. As a case in point, Tr-DNA technology was evaluated in a cancer clinical study at Thomas Jefferson University, funded jointly by the National Institute of Health (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 are a mainstay in 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 will most likely not respond to EGFR drugs. By first testing for these KRAS mutations, the physician will be able to better manage their patients and avoid costly treatments that are not likely 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, quick, cost effective and convenient (i.e., at home test) testing alternative for physicians and patients. The number of patients that could potentially benefit from such a simple urine-based testing approach is enormous, as there are roughly 141,000 and 44,000 new cases of colorectal and pancreatic cancer in the United States per year, respectively, all of whom are at risk for KRAS mutations. Tr-DNA testing could also be applicable in lung cancer (221,000 new cases per year) and breast cancer (230,000 new cases per year) where the screening and monitoring for mutations is also crucial. 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 leading to an improved quality of life for the patients,

In 2006, we in-licensed a new DNA-based biomarker (the nucleophosmin gene known as NPM1) for a subtype of AML. AML remains a complex cancer with poor outcomes in elderly patients. During 2010 there were 12,330 new cases of AML diagnosed, and approximately 9,000 deaths from AML within the U.S. According to the Leukemia and Lymphoma Society, in 2009 there were approximately 27,000 patients with AML in the U.S. AML is generally a disease of older adults, and the median age

# Table of Contents

of a patient diagnosed with AML is about 67 years. AML patients with relapsed or refractory disease, and newly diagnosed AML patients over 60 years of age with poor prognostic risk factors, typically die within one year. There is a definite need for new treatment options for these patients. Overall, AML has the lowest 5 year survival rate (<17%) of any of the adult leukemias. There are significant efforts in the pharmaceutical industry for the development of new drugs targeting AML. Of the patients with AML, 48% lack any cytogenetic abnormalities and the monitoring of those patients for minimal residual disease and tumor relapse is a topic of high interest within the medical community. Currently, there is a growing body of evidence released from clinical and academic studies showing that mutations of the nucleophosmin gene (NPM1) correlate with the prognosis of AML and can be used for monitoring of minimal residual disease. We have sublicensed to two companies co-exclusive rights to develop and manufacture test kits for this mutation and have sublicensed non-exclusive rights to several laboratories that wish to develop their own LDTs and provide this NPM1 testing service to the market. We plan to continue to license the rights to this cancer marker to interested companies, including antibody applications.

**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 early death of the 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 a key to administration and monitoring of the immunosuppressive therapies used to fend off tissue 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/year. Transplantation 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 to maximize shareholder value.

Drug Development and Monitoring of Therapeutic Outcomes The Tr-DNA and Tr-RNA technology has significant potential as a very simple, quick, home-based and non-invasive way of monitoring clinical responses to new 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 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, monitoring of transplantation patients on immunosuppressive drugs, and the monitoring MS patients for JC virus while on Tysabri.

In cancer treatment today, there is no reliable way to determine if a particular patient is responding to their current chemotherapy regimen. Generally, patients are reexamined after a sixty day interval to determine if the 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. If the tumor has grown in size, or remained the same, the chemotherapy may be adjusted. By measuring and monitoring tumor specific genetic markers in the patient's urine pre, peri and post chemotherapy, it may be possible to determine whether a patient is responding to chemotherapy within 48 hours after administration, instead of the current sixty day cycle. Our Tr-DNA or Tr-RNA technology may permit much quicker therapeutic decisions on a patient-specific basis (i.e., personalized medicine). About 1.6 million new cancer cases are diagnosed annually and there are several hundred companies developing chemotherapeutic agents in the United States alone. This defines the tremendous potential for applications of Tr-DNA and Tr-RNA technology in both drug development and monitoring therapeutic outcomes.

# Table of Contents

One of the largest costs associated with development of a new drug is the size of human clinical trials required to identify the cohort of responders to the drug, 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 drug, and restrict patient recruitment to this subset. This would significantly reduce the cost to develop the drug and improve timelines. Having our urine-based nucleic acid tests incorporated into these clinical trial protocols, and ultimately the post-approval patient identification protocols, represents significant commercial potential for our platform.

Ultra-sensitive Analytical and Detection System As it relates to detection platforms which are required for the final assay analysis, we will be developing a new instrument that provides features that will be synergistic and complementary to our transrenal technology and Women's Healthcare assays. In this regard, in August 2010 we acquired Etherogen, Inc. which owns the CMOS Sensor Detection Platform, and we will be designing 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. Such a platform would undoubtedly expand the user base for molecular diagnostics. Currently, the cost of adding these new testing modalities at 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 will address cost efficiencies and potentially help overcome these adoption hurdles. Many of these facilities may adopt our simple, ultra-sensitive, cost effective platform. We are finalizing the system architecture, operating procedure and software specifications for this platform and will commence system development pending resource availability.

Technologies for the collection, shipment and storage of urine specimens, and transrenal nucleic acid extraction Successful implementation of Tr-DNA or Tr-RNA technology in molecular testing is tightly linked to the availability of techniques and procedures for Tr-DNA and Tr-RNA 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 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 technology to develop and market, either independently or in conjunction with corporate partners, molecular diagnostic products in each of our initial focus markets of women's healthcare, infectious diseases and cancer. Our marketing strategy includes multiple approaches. In the U.S. market, we have acquired a Clinical Laboratory Improvement Amendments of 1988, or CLIA laboratory. During the late stages of development of each product, while collecting clinical data for regulatory submissions, we intend to market the products as LDTs (laboratory developed tests) through our CLIA laboratory. CLIA laboratories may offer the tests and receive reimbursement under the laboratory developed test, or LDT, regulations and it is our plan to establish a CLIA laboratory presence and generate revenues for tests not subject to FDA clearance or approval.

# Table of Contents

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) 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 several labs, 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 these LDTs are not marketed to others, 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 intend to pursue FDA pre-market review and as we receive FDA clearance or approval for our products, we intend to market urine-based test kits through a U.S. commercial organization directly to 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 opportunity. This would provide both short term (license fees) and long term (royalties) revenue streams. These licensees will license and use our platform in clinical development of their products, monitor patients taking their marketed products (i.e., TNF inhibitors) and in certain situations license the rights to develop, test and commercialize our transrenal products in predefined fields of use and geographic territories. We plan to become a fully integrated business in which we develop, test, manufacture, register, market and sell our products.

In comparison with many other genetic tests, our Tr-DNA or Tr-RNA tests are expected to be cost effective. These tests involve relatively simple process and can easily be automated. Therefore, major advantages of our Tr-DNA or Tr-RNA test, if and when commercially available, will be the ease of sample collection, enhanced sensitivity and specificity, patient convenience (i.e., home-based test), non-invasive and will potentially provide more efficient and effective monitoring protocols (e.g., for opportunistic infections).

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 may be available under the current procedural terminology, or CPT codes, for molecular-based testing. Following FDA approval or clearance, we expect to initially market our tests to independent and hospital-based laboratories at price points that we believe will translate into substantially higher operating margins than has been traditional in the laboratory industry. We believe this will create a strong incentive for laboratories to adopt our transrenal molecular diagnostic tests.

# **Research and Development**

We have three dedicated scientists who are located in our office in San Diego, CA. We plan to continue to grow this organization to 10 to 15 talented 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. It is our goal to have at least two self-funded development projects ongoing at all times. Starting in 2012 we plan to conduct two projects every 12 to 15 months which will allow us to introduce new products to the market that could be used as lab developed tests to the CLIA labs and to simultaneously continue with the necessary clinical trials and regulatory submissions for marketing approval or clearance depending upon the nature of the

# Table of Contents

product. We currently do not have sufficient resources to complete these projects in 2012. Additional funding will be required. 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.

# **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 May 4, 2012, we had six issued U.S. patents and one issued European patent. The six issued patents expire between 2018 and 2027. All patents are directed at the detection of nucleic acid sequences and nucleic acid modifications and alterations in urine. One of the U.S. patents consists of claims directed to analysis of fetal DNA and determining the sex of a fetus and detecting diseases such as Down Syndrome caused by genetic alterations. Another of the U.S. patents consists of claims directed to detecting and monitoring cancer through urine-based testing. A broad reissued U.S. patent covers a number of nucleic acid screening and monitoring applications including cancer, transplantation, infectious diseases and fetal medicine. The European patent covers the use of our proprietary transrenal nucleic acid technology in the area of potential diagnostics and genetic testing. We have filed a number of patent applications with claims directed to methods of detection and monitoring specific diseases caused by pathogens and viruses and methods of using urine-based microRNA for detection purposes. In addition to pursuing patents and patent applications relating to our platform technology, we have and may enter into other license arrangements to obtain rights to third-party intellectual property where appropriate. Specifically, we have licensed from the inventors a patent application with claims directed to the detection of nucleophosmin ("NPM1") protein gene mutations, corresponding gene sequences, and use of same for diagnosing, monitoring, and treating AML. We have also licensed a provisional patent application for hairy cell leukemia biomarkers, We have additionally licensed a provisional patent application for a specific gene mutation with respect to chronic lymphoblastic leukemia.

Wherever possible, we seek to protect our inventions through filing U.S. patents and 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 these licenses is foreclosed.

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 confidentiality agreements with our employees and 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 2012 we plan to introduce assays into the marketplace through ASR or LDTs in CLIA licensed laboratories. We may also begin the process of filing a 510(k) statement of equivalency with the FDA,

# Table of Contents

the filing of a pre-market approval ("PMA") application with the FDA as appropriate, or the pursuit of a CE Mark in countries that recognize this as a means toward garnering marketing approval. The preferred option would be determined on a case-by-case basis and would be determined by such factors as cost, quantity requirements, etc. We have begun talks with potential partners to accomplish these goals but we have not developed specific manufacturing project plans at this time. Our first priority will be selling LDTs through our own CLIA laboratory. Assays may be introduced in partnership arrangements with labs or as test kits to be manufactured and sold to labs. In some cases, the test may be made available under ASR guidelines during the regulatory submission process. Because testing of some diseases under consideration are of great international interest, we may explore manufacturing and licensing partnerships overseas. We expect it will take approximately 2 years for our first kit to be broadly commercialized based on normal regulatory approval (i.e., not based on an LDT). We may rely on third party manufacturers, or set up internal manufacturing. For internal manufacturing we would also set up all required quality systems to assure regulatory compliance and the production of a quality product. At the present time our products are still in development and we have not yet entered into manufacturing or distribution agreements. We plan to establish international partnerships that could expand the global availability of our products, and these partners may have manufacturing and distribution networks that can be leveraged.

# Reimbursement

Medicare and other third-party payers will independently evaluate our technologies by, among other things, an efficacy and clinical utility analysis, assessing other available options and reviewing the published literature with respect to the results obtained from our clinical studies. Currently, CPT codes 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 applicability to our tests will help facilitate Medicare's reimbursement process as well as that for third party insurance providers. Reimbusement regulations are updated on an annual basis, as are CPT codes, and thus subject to change.

# **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. ASR's 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

# Table of Contents

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 the product labeling, promotion, 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 comply 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 or make our technology obsolete. Academic institutions, governmental 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 products developed.

# **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.

# **Properties**

We lease approximately 5,300 square feet of laboratory and office space in our headquarters in San Diego, California under a lease that expires in February 2013. 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.

# **Employees**

As of May 17, 2012 we had four full-time employees. We believe our relationship with our employees are good.

58

#### MANAGEMENT

# 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 May 17, 2012.

Name	Age	Position
Thomas H. Adams, PhD	68	Chairman of the Board
Antonius Schuh, Ph.D	48	Chief Executive Officer and Director
Steve Zaniboni	54	Chief Financial Officer
John Brancaccio	63	Director
Gary S. Jacob	64	Director
Gabriele M. Cerrone	39	Director
Dr. Stanley Tennant	60	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**

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, Dr. Adams has served as a director of IRIS International, Inc., a diagnostics company, and as Chief Technology Officer of IRIS since April 2006. 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. Before founding Gen-Probe, Dr. Adams held management positions at Technicon Instruments and the Hyland Division of Baxter Travenol. He has significant public-company experience serving as a director of Biosite Diagnostics, Inc., a publicly held medical research firm, from 1989 to 1998 and as a director of Invitrogen, a publicly held company that develops, manufactures and markets research tools and products, from 2000 to 2002. 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. Adam's 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. Dr. Schuh co-founded Sorrento Therapeutics, Inc., a biopharmaceutical company developing monoclonal antibodies, in January 2006. From such time until April 2011, he served as Chairman of the Board and Chief Executive Officer from November 2008 to April 2011. From April 2006 to September 2008, Dr. Schuh served as Chief Executive Officer of AviaraDx (now bioTheranostics, Inc., a bioMerieux company), a molecular diagnostic testing company that is focused on clinical applications in oncology. From March 2005 to April 2006, Dr. Schuh was Chief Executive Officer of Arcturus Bioscience Inc., a developer of laser capture microdissection and reagent systems for microgenomics. From December 1996 to February 2005, Dr. Schuh was employed by Sequenom Inc., a publicly traded diagnostic testing and genetics analysis company. He started with Sequenom as a Managing Director and was promoted to Executive Vice President, Business

# Table of Contents

Development and Marketing, and from May 2000 to February 2005, served as Sequenom's President and Chief Executive Officer. He also previously served as the Head of Business Development at Helm AG, an international trading and distribution corporation for chemical and pharmaceutical products, and in medical and regulatory affairs positions with Fisons Pharmaceuticals (now part of Sanofi-Aventis). Since March 2009, Dr. Schuh has been appointed to the board of directors 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. 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 AviaraDx (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. From October 2005 to April 2006, Mr. Zaniboni was Chief Financial Officer of Arcturus Bioscience (acquired by Molecular Devices Corp., now MDS). He joined Arcturus from Sequenom, Inc., a publicly traded diagnostic testing and genetics analysis company, where he served as Chief Financial Officer from May 1997 to September 2005. 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. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. 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 as Chairman of a subsidiary of Synergy from October 2003 until July 2008. Dr. Jacob currently serves as Chief Executive Officer and a director of Callisto Pharmaceuticals, Inc. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. 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 also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England. 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.

#### Table of Contents

Gabriele M. Cerrone. Gabriele M. Cerrone has served as a director of our company since February 2010. Since July 2008, Mr. Cerrone has served as Chairman of the Board of Directors and a consultant with Synergy Pharmaceuticals, Inc., a biotechnology company. From March 1999 to January 2005 Mr. Cerrone served as a Senior Vice President of Investments of Oppenheimer & Co. Inc., a financial services firm. In May 2001, Mr. Cerrone led the restructuring of SIGA Technologies, Inc., a biotechnology company, and served on its board of directors from May 2001 to May 2003. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc., a biotechnology company, and served as Chairman from August 2005 to September 2007, when the company was acquired by Inhibitex, Inc., a biotechnology company. Mr. Cerrone served as a director of Inhibitex, Inc. from September 2007 until February 2012 when it was acquired by Bristol-Myers Squibb Company. Since 2003, Mr. Cerrone has been Chairman of Callisto Pharmaceuticals, Inc., a biotechnology company, and a consultant to Callisto since 2005. Mr. Cerrone is the managing partner of Panetta Partners Ltd., a limited partnership that is a private investor in both public and private venture capital in the life sciences and technology arena as well as real estate. Mr. Cerrone's experience in finance and investment banking allows him to contribute broad financial and strategic planning expertise and led to the Board's conclusion that he should serve as a director of the 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 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.

#### **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 reverse, 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.

#### Table of Contents

#### 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. 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.

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, Tennant 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

62

#### **Table of Contents**

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.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or 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 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.

#### Table of Contents

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.

#### 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 other highest paid executive officer whose total annual salary and bonus exceeded \$100,000 (collectively, the "named executive officers") for fiscal year 2011.

			Option	
Name & Principal Position	Year	Salary (\$)	Awards (\$)(1)	Total (\$)
Dr. Antonius Schuh, CEO(2)	2011	57,291	23,254	80,545
Dr. Andreas Braun Former Acting CEO(3)	2011	105,347		105,347
	2010	199,038(4)	56,744	255,782

- (1)
  Amount represents aggregate grant date fair value in accordance with FASB ASC Topic 718. See Note 7 to the Consolidated Financial Statements.
- (2) Dr. Schuh was issued 760,000 non-qualified stock options upon his appointment as CEO in October 2011.
- Dr. Braun resigned from our company effective August 5, 2011.
- (4) Includes his salary as Vice President and Chief Medical Officer for the period January 1, 2010 December 31, 2010

#### 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, 2011.

	Number of	Number of		
	Securities	Securities		
	Underlying	Underlying		
	Unexercised	Unexercised	Option	Option
	Options (#)	Options (#)	Exercise	Expiration
Name	exercisable	Unexercisable	Price	Date
Dr. Antonius Schuh		570,000(1)	2.50	October 4, 2021

(1) The unexercisable options of 570,000 vest as follows: 190,000 each on October 4, 2012, 2013 and 2014.

#### DIRECTOR COMPENSATION

The following table sets forth summary information concerning the total compensation paid to our non-employee directors in 2011 for services to our company.

Name	Fees Earned or Paid in Cash			Total		
Thomas H. Adams(2)	\$ 27,500	\$	175,431	\$	202,931	
John P. Brancaccio(3)	\$ 33,500	\$		\$	33,500	
Gary S. Jacob(4)	\$ 23,000	\$		\$	23,000	
Gabriel M. Cerrone(5)	\$ 20,500	\$		\$	20,500	
Stanley Tennant(6)	\$ 24,504	\$	5,187	\$	29,691	

- (1)
  Amounts represent the aggregate grant date fair value for fiscal year 2011 of stock options granted in 2011 under ASC Topic 718 as discussed in Item 15. Financial Statements Note 7 Stock Option Plan.
- (2) As of December 31, 2011, 364,500 stock options were outstanding, of which 160,000 were exercisable.
- (3) As of December 31, 2011, 43,149 stock options were outstanding, of which 36,483 were exercisable.
- (4) As of December 31, 2011, 81,000 stock options were outstanding, of which 74,333 were exercisable.
- (5) As of December 31, 2011, 518,714 stock options were outstanding, of which 512,048 were exercisable.
- (6) As of December 31, 2011, 10,000 stock options were outstanding, of which 3,333 were exercisable.

#### **Employment Agreements**

On October 4, 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. 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 760,000 non-qualified stock options which have an exercise price of \$2.50 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 \$6.25 or more and the volume of the common stock daily trading volume is 25,000 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
- (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 \$6.25 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 \$12.00 per share, \$19.00 per share or \$25.00 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.

#### **Table of Contents**

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.

On February 1, 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. 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 200,000 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.

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.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth, as of May 17, 2012, the number of and percent of our common stock beneficially owned by:

each of our directors;

each of our named executive officers;

our directors and executive officers as a group; and

persons or groups known by us to own beneficially 5% or more of our common stock.

Unless otherwise specified, we believe that all persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned by them.

A person is deemed to be the beneficial owner of securities that can be acquired by him within 60 days from May 17, 2012 upon the exercise of options, warrants or convertible securities. Each beneficial owner's percentage ownership is determined by assuming that options, warrants or convertible securities that are held by him, but not those held by any other person, and which are exercisable within 60 days of May 17, 2012 have been exercised and converted.

	Amount and nature of	
Name and Address of Beneficial Owner	beneficial ownership(1)	Percent of class(2)
Thomas Adams	630,647(3)	4.5
Antonius Schuh		
Andreas Braun		
Gabriele Cerrone	1,616,352(4)	11.0
Gary Jacob	240,067(5)	1.7
John Brancaccio	92,416(6)	*
Stanley Tennant	259,583(7)	1.9
All Directors and Officers as a group (7 persons)	2,839,064(8)	18.6
5% or greater stockholder		
R. Merrill Hunter	1,813,001(9)	12.4

Less than 1%

- (1)
  The address of each person is c/o Trovagene, Inc., 11055 Flintkote Avenue, Suite B, San Diego, CA 92121 unless otherwise indicated herein.
- The calculation in this column is based upon 13,836,071 shares of common stock outstanding on May 17, 2012. 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 May 17, 2012 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) 160,000 shares of common stock issuable upon exercise of stock options and (ii) 55,823 shares of common stock issuable upon exercise of warrants.

Consists of (i) 788,071 shares of common stock held by Panetta Partners, Ltd., (ii) 7,500 shares of common stock held by Mr. Cerrone, (iii) 516,381 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, (iv) 296,900 shares of common stock issuable upon exercise of warrants held by Panetta and (v) 7,500 shares of common stock issuable upon exercise of warrants held by Mr. Cerrone. Mr. Cerrone is

67

### Table of Contents

the managing partner 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.

- (5) Includes (i) 79,867 shares of common stock issuable upon exercise of stock options and (ii) 12,600 shares of common stock issuable upon exercise of warrants.
- (6) Includes (i) 59,216 shares of common stock issuable upon exercise of stock options and (ii) 16,600 shares of common stock issuable upon exercise of warrants.
- (7) Includes (i) 6,333 shares of common stock issuable upon exercise of stock options and (ii) 90,000 shares of common stock issuable upon exercise of warrants.
- (8) Includes (i) 914,431 shares of common stock issuable upon exercise of stock options and (ii) 478,423 shares of common stock issuable upon exercise of warrants.
- (9) Includes 800,000 shares of common stock issuable upon exercise of warrants.

68

#### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

On August 6, 2010, we entered into an Agreement and Plan of Merger with E Acq Corp., our wholly-owned subsidiary, and Etherogen, Inc. pursuant to which we acquired all of the outstanding common stock of Etherogen, Inc. by issuing 2,452,556 shares of our common stock to the shareholders of Etherogen. Thomas Adams, our Chairman, Gary Jacob, a director of our company and Panetta Partners, Ltd., each were stockholders in Etherogen. Gabriele Cerrone, a director of our company, is the managing partner 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.

Dr. Adams, Dr. Jacob and Panetta received 360,000, 120,000 and 360,000 shares of our common stock in the merger. The disinterested members of our board of directors determined that the terms of the merger and the merger agreement were fair to, and in the best interests of, the company and our stockholders and the merger was approved by the disinterested board. The fair value of the shares issued to effect the merger was \$2,771,389, based on the fair value of our 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 de minimus property, plant and equipment, patents, trademarks and other intellectual property, and in-process research and development. In addition, we assumed a note in the amount of \$104,700 which was converted in to shares on the date of acquisition. In accordance with ASC Topic 805, Business Combinations, we recorded the total fair value of an intangible asset related to the patent of \$104,700 on our 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 notes was recorded as purchased in process research and development expense-related party on our consolidated statement of operations.

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 our most senior executive officer until a Chief Executive Officer was appointed. Mr. Adams was granted 960,000 ten year options to purchase shares of the Company's stock at \$2.50 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 as a consultant for a term of three years at an annual amount of \$100,000.

In March 2010, the Board of Directors agreed to settle the amount of \$100,000 in full due to Thomas Adams by issuing 40,000 units with each unit consisting of one share of common stock and one warrant to purchase shares of common stock at \$2.50 a unit.

On August 10, 2011, we entered into an agreement with Thomas Adams to: (i) terminate the consulting arrangement and to consider the 40,000 units issued in March 2010 as full payment for his services under the consulting arrangement; and (ii) amend and restate his April 2009 option agreement by replacing the 960,000 options granted with 364,500 new options with the following terms:

- a) new grant date of August 5, 2011;
- b) exercise price of \$2.65 per share;
- c)
  160,000 options vested immediately, with the balance to vest as follows: 68,167 on August 5, 2012, 68,167 on August 5, 2013 and 68,166 on August 5, 2014 provided he continues to provide services to the Company; and
- d) ten year option life, expiring August 5, 2021 or within 90 days of termination

Stanley Tennant, a director of our company, and a Debenture Holder in the principal amount of \$137,500 received 67,625 shares of common stock relating to the Forbearance Agreement. R. Merrill

### Table of Contents

Hunter, a principal stockholder of our company, and a Debenture Holder in the principal amount of \$550,000 received 270,501 shares of common stock relating to the Forbearance Agreement.

On April 24, 2012, we issued a warrant to purchase 60,000 shares of common stock to Panetta Partners, Ltd. for consulting services, Gabriele Cerrone, a director of our company, is the managing partner 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.

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

70

#### **DESCRIPTION OF SECURITIES**

#### General

As of May 17, 2012, our authorized capital stock consisted of 150,000,000 shares of common stock, \$0.0001 par value per share, and 20,000,000 shares of preferred stock, \$0.001 par value per share. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of May 17, 2012, there are 13,836,071 shares of our common stock issued and outstanding and 95,600 shares of Series A convertible preferred stock are issued and outstanding.

#### Common Stock

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

#### **Preferred Stock**

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

the designation of the series, which may be by distinguishing number, letter or title;

the number of shares of the series, which number the board of directors may thereafter (except where otherwise provided in the Preferred Stock Designation) increase or decrease (but not below the number of shares thereof then outstanding);

whether dividends, if any, shall be paid, and, if paid, the date or dates upon which, or other times at which, such dividends shall be payable, whether such dividends shall be cumulative or noncumulative, the rate of such dividends (which may be variable) and the relative preference in payment of dividends of such series;

the redemption provisions and price or prices, if any, for shares of the series;

the terms and amounts of any sinking fund or similar fund provided for the purchase or redemption of shares of the series;

the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of our corporation;

whether the shares of the series shall be convertible into shares of any other class or series, or any other security, of our corporation or any other corporation, and, if so, the specification of such other class or series of such other security, the conversion price or prices, or rate or rates,

#### **Table of Contents**

any adjustments thereto, the date or dates on which such shares shall be convertible and all other terms and conditions upon which such conversion may be made;

restrictions on the issuance of shares of the same series or of any other class or series; and

the voting rights, if any, of the holders of shares of the series.

On July 13, 2005, we closed a private placement of 277,100 shares of Series A Convertible Preferred Stock (the "Series A Convertible Preferred Stock") and 77,330 warrants to certain investors for aggregate gross proceeds of \$2,771,000 pursuant to a Securities Purchase Agreement dated as of July 13, 2005. The warrants sold to the investors were immediately exercisable at \$16.25 per share and were exercisable at any time within five years from the date of issuance. These investor warrants had a fair value of \$567,085 on the date of issuance using a market price of \$12.00 on that date. In addition we paid an aggregate \$277,102 and issued an aggregate 21,086 warrants to purchase common stock to certain selling agents. The warrants issued to the selling agents are immediately exercisable at \$12.50 per share and will expire five years after issuance. The material terms of the Series A Convertible Preferred Stock consist of:

- 1) *Dividends*. Holders of the Series A Convertible Preferred Stock shall be entitled to receive cumulative dividends at the rate per share of 4% per annum, payable quarterly on March 31, June 30, September 30 and December 31, beginning with September 30, 2005. Dividends shall be payable, at our sole election, in cash or shares of common stock. As of December 31, 2011 and 2010, we had recorded \$152,960 and \$114,720, respectively, in accrued cumulative unpaid preferred stock dividends, included in Accrued Expenses in our consolidated balance sheets, and \$38,240 was recorded for each of the years ended December 31, 2011 and 2010.
- 2) Voting Rights. Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of the shares of Series A Convertible Preferred Stock then outstanding, (a) adversely change the powers, preferences or rights given to the Series A Convertible Preferred Stock, (b) authorize or create any class of stock senior or equal to the Series A Convertible Preferred Stock, (c) amend our articles of incorporation or other charter documents, so as to affect adversely any rights of the holders of Series A Convertible Preferred Stock, or (d) increase the authorized number of shares of Series A Convertible Preferred Stock.
- 3) Liquidation. Upon any liquidation, dissolution or winding-up of our company, the holders of the Series A Convertible Preferred Stock shall be entitled to receive an amount equal to the Stated Value per share, which is equal to \$10 per share plus any accrued and unpaid dividends.
- 4) Conversion Rights. Each share of Series A Convertible Preferred Stock shall be convertible at the option of the holder into that number of shares of common stock determined by dividing the Stated Value, currently \$10 per share, by the conversion price, originally \$10.75 per share.
- 5) Automatic Conversion. Beginning July 13, 2006, if the price of the common stock equals \$21.50 per share for 20 consecutive trading days, and an average of 10,000 shares of common stock per day shall have been traded during the 20 trading days, we shall have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, to convert any portion of the shares of Series A Convertible Preferred Stock into shares of Common Stock at the conversion price.

#### **Table of Contents**

#### **Stock Options**

As of May 17, 2012 we had 18,370,901 stock options issued and outstanding, of which 9,550,404 are exercisable, with a weighted average exercise price of \$1.06 per share.

#### Warrants

As of May 17, 2012 we had 25,891,543 warrants outstanding, all of which are exercisable, with a weighted average exercise price of \$0.51 per share.

#### **Anti-Takeover Provisions**

#### Delaware Law

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

prior to such date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by persons who are directors and also officers and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to such date, the business combination is approved by the board of directors and authorized at an annual meeting or special meeting of stockholders and not by written consent, by the affirmative vote of at least  $66^2/3\%$  of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

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

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

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

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

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

#### Table of Contents

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

#### Amended and Restated Certificate of Incorporation and Bylaw Provisions

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

provide our board of directors with the ability to alter its bylaws without stockholder approval; and

provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum.

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

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

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

#### Listing

The shares of our common stock are currently quoted on the OTC QB. We have applied for the listing of our common stock on the The NASDAQ Capital Market under the symbol "TROV."

#### UNDERWRITING

Aegis Capital Corp. is acting as the representative of the underwriters of the offering. We have entered into an underwriting agreement dated , 2012 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

N CT. I 4	Number of
Name of Underwriter	Shares
Aegis Capital Corp.	
Summer Street Research Partners	
Brean Murray, Carret & Co., LLC	

#### Total

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if it purchases any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of 675,000 additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to the public will be \$24,063,750 and the total net proceeds, before expenses, to us will be \$22,379,288.

*Discounts and Commissions.* The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

		Total				
		Without	With			
	Per Share	Over-Allotment	Over-Allotment			
Public offering price	\$	\$	\$			
Underwriting discount (7%)	\$	\$	\$			
Proceeds, before expenses, to us	\$	\$	\$			

The underwriters propose to offer the shares offered by us to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the

#### **Table of Contents**

shares to other securities dealers at such price less a concession of \$ per share. If all of the shares offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a further supplement to this prospectus supplement.

We have paid an expense deposit of \$10,000 to the representative, which will be applied against the accountable expenses that will be paid by us to the underwriters in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, the \$10,000 expense deposit paid to the representative will be returned to the extent offering expenses are not actually incurred.

We have also agreed to pay the underwriters' expenses relating to the offering, including (a) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$5,000 per individual, but no more than \$15,000 in the aggregate; (b) all fees incurred in clearing this offering with FINRA; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (d) upon successfully completing this offering, \$20,000 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; and (e) upon successfully completing this offering, \$20,000 of the representative's actual accountable road show expenses for the offering (less the \$10,000 deposit).

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount, will be approximately \$

*Discretionary Accounts.* The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements. Pursuant to certain "lock-up" agreements, we, our executive officers and directors, and certain of our stockholders have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the underwriter, for a period of ninety (90) days after the date of this prospectus.

Representative's Warrants. We have agreed to issue to the representative warrants to purchase up to a total of shares of common stock (4% of the shares of common stock sold in this offering). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the offering, which period shall not extend further than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants are exercisable at a per share price equal to 125% of the public offering price per share in the offering. The warrants have been deemed compensation by FINRA and are therefore subject to a one-year lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the date of this prospectus. In addition, the warrants provide for registration rights upon request, in certain cases. In addition, the warrants provide for registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable

#### **Table of Contents**

on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

Right of First Refusal. Until six months after the closing date of the offering, the representative shall have a right of first refusal to purchase for its account or to sell for our account, or any subsidiary or successor, any securities of our company or any such subsidiary or successor which we or any subsidiary or successor may seek to sell in public or private equity and public debt offerings during such six (6)-month period.

We may, however, in lieu of granting a right of first refusal, designate the representative as lead underwriter or co-manager of any underwriting group or co-placement agent of any proposed financing, and the representative shall be entitled to receive as its compensation 50% of the compensation payable to the underwriting or placement agent group when serving as co-manager or co-placement agent, and 33% of the compensation payable to the underwriting or placement agent group when serving as co-manager or co-placement agent with respect to a proposed financing in which there are three co-managing or lead underwriters or co-placement agents.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Stabilization. In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the

#### **Table of Contents**

underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive market making. In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The NASDAQ Capital Market or on the OTC QB in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships. Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. Aegis Capital Corp. has provided certain financial advisory services to us for which they received a payment of \$10,000 on or about December 20, 2011. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

#### Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

#### **Table of Contents**

#### Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the common stock under this prospectus is only made to persons to whom it is lawful to offer the common stock without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the common stock sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

#### China

The information in this document does not constitute a public offer of the common stock, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The common stock may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

#### European Economic Area Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of common stock will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of common stock has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- (a)
   to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- (c)
  to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the
  Prospectus Directive) subject to obtaining the prior consent of Trovagene, Inc. or any underwriter for any such offer; or
- (d)
  in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of common stock shall result in a requirement for the publication by Trovagene, Inc. of a prospectus pursuant to Article 3 of the Prospectus Directive.

#### France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French

#### **Table of Contents**

Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 *et seq.* of the General Regulation of the French Autorité des marchés financiers ("AMF"). The common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the common stock have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D. 744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the common stock cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

#### Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The common stock have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

#### Israel

The common stock offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such common stock been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

#### Italy

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societ--\$\$--Aga e la Borsa, "CONSOB" pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy

80

#### **Table of Contents**

in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 11971") as amended ("Qualified Investors"); and

in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

#### Japan

The common stock have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the common stock may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires common stock may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of common stock is conditional upon the execution of an agreement to that effect.

#### **Portugal**

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### Table of Contents

#### Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of common stock in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

#### Switzerland

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

#### **United Arab Emirates**

Neither this document nor the common stock have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has Trovagene, Inc. received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by Trovagene, Inc.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.

#### **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the common stock. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

#### Table of Contents

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In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

#### LEGAL MATTERS

The validity of the securities being offered by this prospectus has been passed upon for us by Sichenzia Ross Friedman Ference LLP, New York, New York. Sichenzia Ross Friedman Ference LLP owns an aggregate of 14,000 shares of our common stock and 14,000 of our warrants. Certain legal matters in connection with this offering will be passed upon for the underwriters by Reed Smith LLP, New York, New York.

### **EXPERTS**

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

### WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and special reports, and other information with the Securities and Exchange Commission. Copies of the reports and other information may be read and copied at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. You can request copies of such documents by writing to the SEC and paying a fee for the copying cost. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules and regulations of the SEC. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus. For further information you may:

read a copy of the registration statement, including the exhibits and schedules, without charge at the SEC's Public Reference Room; or

obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

# TROVAGENE, INC. (A Development Stage Company)

## **Index to Consolidated Financial Statements**

Report of Independent Registered Public Accounting Firm	<u>F-2</u>
Consolidated Balance Sheets as of December 31, 2011 and 2010	
	<u>F-3</u>
Consolidated Statements of Operations and Comprehensive Loss for each of the two years in the period ended December 31, 2011	
and for the period from August 4, 1999 (Inception) to December 31, 2011	<u>F-4</u>
Consolidated Statements of Stockholders' Equity (Deficiency) for the period from August 4, 1999 (Inception) to December 31, 2011	
	<u>F-5</u>
Consolidated Statements of Cash Flows for each of the two years in the period ended December 31, 2011, and for the period from	
August 4, 1999 (Inception) to December 31, 2011	<u>F-12</u>
Notes to Consolidated Financial Statements	
	<u>F-14</u>
Condensed Consolidated Balance Sheets as of March 31, 2012 (unaudited) and December 31, 2011	
	<u>F-58</u>
Condensed Consolidated Statements of Operations and Comprehensive Net Loss for the Three Months Ended March 31, 2012 and	
2011 (unaudited) and the period August 4, 1999 (Inception) to March 31, 2012 (unaudited)	<u>F-59</u>
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the period August 4, 1999 (Inception) to	
March 31, 2012 (unaudited)	<u>F-60</u>
Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2012 and 2011 (unaudited) and the	
period August 4, 1999 (Inception) to March 31, 2012 (unaudited)	<u>F-67</u>
Notes to Condensed Consolidated Financial Statements (unaudited)	
	<u>F-68</u>
F-1	

#### Table of Contents

#### Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders TrovaGene, Inc. San Diego, CA

We have audited the accompanying consolidated balance sheets of TrovaGene, Inc. and Subsidiaries (a development stage company) as of December 31, 2011 and 2010 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficiency), and cash flows for each of the two years in the period ended December 31, 2011 and for the period from August 4, 1999 (inception) to December 31, 2011. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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 TrovaGene, Inc. and Subsidiaries at December 31, 2011 and 2010, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2011 and the period from August 4, 1999 (inception) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP	
New York, New York	
March 30, 2012	
	F-2

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Consolidated Balance Sheets**

	Ι	December 31, 2011	Г	December 31, 2010
Assets				
Current assets:				
Cash and cash equivalents	\$	700,374	\$	58,703
Accounts receivable		99,140		75,000
Prepaid expenses		42,658		151,032
Total current assets		842,172		284,735
Property and equipment, net		22,504		31,260
Other assets		174,581		196,229
Total Assets	\$	1,039,257	\$	512,224
		, ,		ĺ
Liabilities and Stockholders' Deficency				
Current liabilities:				
Accounts payable	\$	928,364	\$	637,863
Interest payable		,.		28,639
Accrued expenses		501,517		420,099
Convertible debentures		,		2,335,050
				, ,
Total current liabilities		1,429,881		3,421,651
Derivative financial instruments		3,840,644		2,085,938
		2,010,011		_,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Total Liabilities		5,270,525		5,507,589
Commitments and contingencies (Note 11)		3,270,323		3,307,309
Stockholders' deficiency				
Preferred stock, \$0.001 par value, 20,000,000 shares authorized, 95,600 shares outstanding at				
December 31, 2011 and December 31, 2010, designated as Series A Convertible Preferred Stock with				
liquidation preference of \$956,000 at December 31, 2011 and December 31, 2010		96		96
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 64,422,157 and 52,610,713 issued		, ,		
and outstanding at December 31, 2011 and December 31, 2010, respectively		6,442		5,261
, , , , , , , , , , , , , , , , , , ,		-,		-, -
Additional paid-in capital		39,360,625		36,320,257
Deficit accumulated during development stage		(43,598,431)		(41,320,979)
Total stockholders' deficiency		(4,231,268)		(4,995,365)
,		(.,_51,_50)		(1,22,000)
	\$	1,039,257	\$	512,224

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Consolidated Statements of Operations and Comprehensive Loss**

		For the ye Decemb			For the period August 4, 1999 (Inception) to		
		2011		2010	December 31, 2011		
Royalty income	\$	227,696	\$	255,665	\$ 645,070		
License fees		30,000		10,000	1,363,175		
Revenues		257,696		265,665	2,008,245		
Operating synances		,		,	,,		
Operating expenses: Research and development		010 695		1.024.150	15 520 152		
		910,685		1,024,159 2,666,869	15,529,153 2,666,869		
Purchased in-process research and development expense-related party General and administrative		2 222 914					
General and administrative		2,323,814		1,953,925	22,540,855		
Total operating expenses		3,234,499		5,644,953	40,736,877		
Operating loss		(2,976,803)		(5,379,288)	(38,728,631)		
Other income (expense):		(=,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(0,017,200)	(23, 23, 32 3)		
Interest income		171		182	266,883		
Interest expense		(56,636)		(115,585)	(1,325,372)		
Amortization of deferred debt costs and original issue discount		(30,030)		(221,373)	(2,346,330)		
Change in fair value of derivative instruments		170,673		266,926	1,226,006		
Gain on extinguishment of debt		623,383		200,720	623,383		
Liquidated damages and other forbearance agreement settlement costs		025,505			(1,758,111)		
Enquired damages and other respondence agreement sectionent costs					(1,730,111)		
Net loss and Comprehensive loss		(2,239,212)		(5,449,138)	(42,042,172)		
1100 1000 4110 Comprehensia (Citation		(2,20),212)		(0,115,100)	(12,012,112)		
Preferred stock dividend		(38,240)		(38,240)	(307,918)		
Cumulative effect of early adoption of ASC 815-40 on November 1,		(0 0,2 10)		(0 0,= 10)	(50.,500)		
2006					(455,385)		
Series A convertible preferred stock beneficial conversion feature							
accreted as a dividend					(792,956)		
					, ,		
Net loss and Comprehensive loss attributable to common stockholders	\$	(2,277,452)	\$	(5,487,378)	\$ (43,598,431)		
The rest and comprehensive rest and comment stocking to	Ψ	(2,277,102)	Ψ	(2,107,270)	(15,505, 151)		
Weighted average shares of common stock outstanding:							
Basic and diluted		58,269,113		42,952,748			
Duste and anated		50,207,115		12,732,740			
Nat loss per common share:							
Net loss per common share: Basic and diluted	\$	(.04)	\$	(0.13)			
Dasic and diluted	φ	(.04)	φ	(0.13)			

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency)

	C	\4I_	T	. Charre	Additional	Deferred Stock	Deficit Accumulated During	Total Stockholders'
	Common S Shares	Amount	Treasury Shares		Paid-In	Based Compensation	Development Stage	
Balance, August 4, 1999 (Inception)		\$ 0						\$ 0
Issuance of common stock to		•			•			
founders for cash at \$0.0002 per								
share	222,000,000	22,200			19,800			42,000
Net loss							(14,760)	(14,760)
							( ), )	( ), /
D.1 1 21 2000	222 000 000	22 200	0	0	10.000	0	(14.7(0)	27.240
Balance, January 31, 2000	222,000,000	22,200	0	0	19,800	0	(14,760)	
Net loss							(267,599)	(267,599)
Balance, January 31, 2001	222,000,000	22,200	0	0	19,800	0	(282,359)	(240,359)
Capital contribution of cash					45,188			45,188
Net loss							(524,224)	(524,224)
Balance, January 31, 2002	222,000,000	22,200	0	0	64,988	0	(806,583)	(719,395)
Issuance of common stock for cash	222,000,000	22,200	· ·	Ü	01,700	· ·	(000,505)	(11),5)5)
at \$0.0005 per share	7,548,000	755			2.645			3,400
Capital contribution of cash	*	755			2,500			2,500
Net loss					2,300		(481,609)	
1101 1055							(101,00))	(101,00))
D 1	220 540 000	22.055	0	0	70.122	0	(1.000.100)	(1.107.104)
Balance, January 31, 2003	229,548,000	22,955	0	0	70,133	0	(1,288,192)	
Net loss							(383,021)	(383,021)
Balance, January 31, 2004	229,548,000	22,955	0	0	70,133	0	(1,671,213)	(1,578,125)
Waiver of founders' deferred								
compensation					1,655,031			1,655,031
Private placement of common stock	2,645,210	265			2,512,685			2,512,950
Redemption of shares held by								
Panetta Partners, Inc.	(218,862,474)	(21,886)			(478,114)			(500,000)
Costs associated with								
recapitalization					(301,499)			(301,499)
Share exchange with founders	2,258,001	226			(226)			0
Issuance of treasury shares			350,000	35	(35)			0
Issuance of treasury shares to escrow	350,000	35	(350,000	) (35)	0			0
Issuance of common stock and								
warrants for cash at \$1.95 per share	1,368,154	136			2,667,764			2,667,900
Issuance of 123,659 warrants to								
selling agents					403,038			403,038
Finders warrants charged to cost of								
capital					(403,038)			(403,038)
Deferred stock-based compensation					1,937,500	(1,937,500)		0
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	17,306,891	\$ 1,731	0	\$ 0	\$11,923,247	\$ (1,691,803)	\$ (7.042.240)	\$ 3,190,935
Danielo, Januar J 31, 2000	17,500,071	Ψ 1,/31	U	Ψ	Ψ 11,723,2-T1	Ψ (1,071,003)	Ψ (7,0±2,2±0)	4 3,170,733

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

							Deficit	
	Preferred Stock	Common		Treasury Shar	Paid-In	Deferred Stock Based	Development	Total Stockholders' Equity
D-1 1 21 2005	Shares Amount	<b>Shares</b> 17,306,891	Amount			Compensation		(Deficiency)
Balance, January 31, 2005	0 \$ 0		\$ 1,/31	0 \$	0 \$11,923,247 199,990	\$ (1,691,803)	\$ (7,042,240)	
Private placement of common stock Payment of selling agents fees and		102,564	10		199,990			200,000
expenses in cash					(179,600	`		(179,600)
Common stock issued to selling					(179,000)	)		(179,000)
agents		24,461	2		(2)	`		0
Private placement of common stock		1,515,384	152		2,954,847	,		2,954,999
Payment of selling agents fees and		1,515,564	132		2,754,047			2,754,777
expenses in cash					(298,000	)		(298,000)
Issuance of 121,231 warrants issued					(270,000)	,		(270,000)
to selling agents					222,188			222,188
Selling agents warrants charged to					222,100			222,100
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)	0
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 105,432 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		(350,000)	) (35)	,	35			0
Retirement of treasury shares				(350,000) (	35) 35			0
Common stock issued for services		5,000	0		16,500			16,500
Stock-based compensation expense								
for non-employees					2,928,298			2,928,298
Amortization of deferred stock-based						61#.C==		647.055
compensation						645,832		645,832
Preferred stock dividend							(60,741)	
Net loss							(7,844,326)	(7,844,326)
Balance, January 31, 2006	277,100 \$ 277	18,604,300	\$ 1,860	0 \$	0 \$20,264,807	\$ (1,045,971)	\$ (15,740,263)	\$ 3,480,710

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

	Preferred Stock	Common Stock		Additional Paid-In	Deferred Stock Based	Deficit Accumulated During Someone	Total tockholders' Equity	Temporary Equity Unregistered Common Stock	
	Shares Amount	Shares	Amount		Compensation		Deficiency)	Shares	Amount
Balance, January 31, 2006	277,100 \$ 277	18,604,300	\$ 1,860			\$ (15,740,263)			\$
Conversion of Series A preferred									
stock and issuance of common									
stock	(174,000) (174)	826,431	83	91					
Implementation of ASC 718				(1,045,971)	1,045,971		0		
Private placement of common									
stock		754,721	75	943,326			943,401		
Payment of selling agents fees and									
expenses in cash				(118,341)	)		(118,341)		
Issuance of 94,672 warrants to									
selling agents				55,568			55,568		
Selling agents warrants charged to									
cost of apital				(55,568)	)		(55,568)		
Issuance of common stock and									
warrants for cash at \$1.00 per									
share								1,000,000	1,000,000
Payment of finders fees and									
expenses in cash									(80,000)
Value of warrants classified as									
derivative financial instrument									
liability									(15,000)
Issuance of 164,550 units to finder				167,856			167,856		
Common Stock issued for services		8,696	1	9,565			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 ASC 815-40				567,085		(455,385)	111,700		
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	20 104 149	\$ 2.010	\$24 516 416	\$ 0	\$ (23,388,879) \$	t 1 120 650	1 000 000	\$ 905,000
Dalance, January 31, 2007	103,100 \$ 103	20,194,140	φ 4,019	φ 44,310,410	φ 0	φ (43,300,019) 3	1,149,039	1,000,000	φ 905,000

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

	Preferred	referred Stock Common Stock		Additional Paid-In	Deficit Accumulated During Development	Total Stockholders' Equity	Temporary Equity Unregistered Common Stock		
	Shares A	mount	Shares	Amount	Capital	Stage	(Deficiency)	Shares	Amount
Balance, January 31, 2007	103,100	\$ 103	20,194,148	\$ 2,019	\$24,516,416	\$ (23,388,879)	1,129,659	1,000,000	\$ 905,000
Conversion of preferred stock to									
common stock	(7,500)	(7)	46,875	5	2				
Private placement of common stock			1,700,000	170	849,830		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					714,047	(35,054)	(35,054)		
Net loss						(4,683,141)	(4,683,141)		
Balance, December 31, 2007 Reclassification of common stock	95,600	\$ 96	21,941,023	\$ 2,194	\$26,458,991	\$ (28,107,074)	(1,645,793)	1,000,000	\$ 905,000
initially recorded as temporary equity			1,000,000	100	904,900		905,000	(1,000,000)	(905,000)
Private placement of common					,		,	(1,000,000)	(202,000)
stock Payment of selling agents fees and			1,984,091	198	1,144,802		1,145,000		
expenses					(74,500)		(74,500)		
Conversion of debenture to common stock			187,282	19	93,622		93,641		
Derivative liability warrants at issuance					(201,122)		(201,122)		
Donated services					390,750		390,750		
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	25,112,396	\$ 2,511	\$29,261,140	\$ (33,311,554)	\$ (4,047,807)	0	\$ 0

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

								Deficit Accumulated	Total	
	Preferred Stock		Common Stock		Additional Paid-In	During Development	Stockholders' Equity			
	Shares	Am	ount	Shares	A	mount	Capital	Stage	(Deficiency)	
Balance December, 31, 2008	95,600	\$	96	25,112,396	\$	2,511	\$ 29,261,140	\$ (33,311,554)	\$ (4,047,807)	
Issuance of shares of common stock in connection with convertible debenture forbearance agreement				5,437,472		544	1,739,415		1,739,959	
Issuance of shares of common stock in payment of										
convertible debenture interest				360,881		36	112,255		112,291	
Private placements of common stock				2,930,000		293	1,464,707		1,465,000	
Issuance of common stock pursuant to a non-exclusive										
selling agent's agreement				413,379		41	306,696		306,737	
Issuance of shares of common stock re settlement for										
consulting services rendered				957,780		96	478,794		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	35,211,908	\$	3,521	\$ 32,043,275	\$ (35,833,601)	\$ (3,786,709)	

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

								Accumulated	
	Preferre	d St	ock	Common	Sto	nck	Additional	Deficit During	Total Stockholders'
					-		Paid-In	Development	Equity
Polomos Docombos 21, 2000	Shares			Shares		mount	Capital	Stage (25, 822, 601)	( <b>Deficiency</b> ) \$ (3.786.709)
Balance, December 31, 2009 Issuance of shares of common stock in payment	95,600	Ф	96	35,211,908	Ф	3,521	32,043,275	(35,833,601)	\$ (3,786,709)
1 3				512 712		<i>-</i> 1	115 020		115.071
of convertible debenture interest				513,712		51	115,920		115,971
Issuance of common stock to selling agents				476,000		48	(48)		
Private placement of units				3,469,400		347	1,734,353		1,734,700
Derivative liability price protected units upon									
issuance							(1,010,114)		(1,010,114)
Consulting services settled via issuance of stock				425,000		43	212,457		212,500
Shares issued in settlement of legal fees				175,439		17	99,983		100,000
Stock issued in payment of deferred salary to									
former CEO				76,472		8	28,338		28,346
Shares issued in connection with Agreement &				ĺ			Ź		ŕ
Plan of Merger with Etherogen, Inc,				12,262,782		1,226	2,770,163		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	52,610,713	\$	5,261	36,320,257	\$ (41,320,979)	\$ (4,995,365)

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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## $Consolidated\ Statements\ of\ Stockholders'\ Equity\ (Deficiency)\ (Continued)$

	Preferred Preferred Stock Stock Shares Amount		Common Stock Shares	Common Stock Amount		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders' Deficiency	
Balance, December 31, 2010	95,600	\$	96	52,610,713	\$	5,261	\$ 36,320,257	\$ (41,320,979)	\$ (4,995,365)
Issuance of shares of common stock in payment of convertible									
debenture interest in accordance with Forbearance Agreement				385,284		38	85,237		85,275
Private placement of units				5,147,000		515	2,572,985		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				250,500		25	125,225		125,250
Issuance of common stock to shareholder as finder's fees				541,550		54	(54)		
Issuance of common stock in connection with consulting									
services				350,000		35	174,965		175,000
Stock issued in connection with conversion of convertible									
debentures				5,137,110		514	1,129,650		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	64,422,157	\$	6,442	\$ 39,360,625	\$ (43,598,431)	\$ (4,231,268)

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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Consolidated Statements of Cash Flows**

	Year ended December 31, 2011	Year ended December 31, 2010	For the period August 4, 1999 (Inception) to December 31, 2011
Operating activities			
Net loss	\$ (2,239,212)	\$ (5,449,138)	\$ (42,042,172)
Adjustments to reconcile net loss to net cash used in operating activities:	10.202	0.200	221 700
Depreciation and amortization	10,285	8,388	221,799
Stock based compensation expense	250,978	325,930	11,480,325
Founders compensation contributed to equity			1,655,031
Donated services contributed to equity			829,381
Sattlement of consulting convices in steels			479 900
Settlement of consulting services in stock Amortization of deferred debt costs and original issue discount		221,373	478,890 2,346,330
		221,373	2,340,330
Liquidated damages and other forbearance agreement settlement costs paid in stock			1,758,111
Interest expense on convertible debentures paid in stock	56,636	115,585	757,198
Change in fair value of financial instruments	(170,673)	(266,926)	(1,226,002)
Change in ran value of intanetta instruments	(170,073)	(200,720)	(1,220,002)
Gain on extinguishment of debt	(623,383)		(623,383)
Purchased In Process Research and Development expense-related party		2,666,869	2,666,869
Stock issued in connection with payment of deferred salary		28,346	28,346
Stock issued in connection with settlement of legal fees		100,000	100,000
Stock issued in connection with consulting services	175,000	112,500	287,500
Changes in operating assets and liabilities:			
Decrease (increase) in other assets	21,648	9,768	(69,881)
Increase in accounts receivable	(24,140)	(47,035)	(99,141)
Decrease (increase) in prepaid expenses	108,374	(75,501)	(42,658)
Increase (decrease) in accounts payable, accrued expenses and other	504,186	161,125	1,416,365
Net cash used in operating activities	(1,930,301)	(2,088,716)	(20,077,092)
Investing activities:			
Assets acquired in Etherogen, Inc. merger		(104,700)	(104,700)
Capital expenditures	(1,528)	(27,747)	(244,303)
Net cash used in investing activities	(1,528)	(132,447)	(349,003)
The case does in in footing act facts	(1,020)	(102,)	(5.5,000)
Financing activities  Proceeds from sale of 60's convertible deheature			2 225 050
Proceeds from sale of 6% convertible debenture  Debt issuance costs			2,335,050
Proceeds from sale of common stock, net of expenses	2,573,500	1,734,700	(297,104) 17,432,005
Proceeds from a non-exclusive selling agent's agreement	2,373,300	1,734,700	142,187
Note (repayment)			142,107
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	2,573,500	1,734,700	21,126,469
The cash provided by illianeing activities	2,373,300	1,734,700	21,120,409

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Net change in cash and equivalent-increase(decrease)	641,671	(486,463)	700,374
Cash and cash equivalents Beginning of period	58,703	545,166	
Cash and cash equivalents End of period	\$ 700,374 \$	58,703 \$	700,374

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

F-12

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Consolidated Statements of Cash Flows (Continued)**

 			Au (I	or the period ngust 4, 1999 nception) to ember 31, 2011
\$	\$		\$	
\$	\$			
\$	\$		\$	(1,740,000)
			\$	1,740,000
\$ 125,250	\$		\$	125,250
\$ 1,130,164	\$		\$	1,130,164
\$	\$		\$	792,956
\$ 38,240	\$	38,240	\$	152,960
\$ 56,636	\$	115,585	\$	1,325,372
ended \$	\$ \$ \$ \$ 125,250 \$ 1,130,164 \$ \$ 38,240	s \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	ended December 31, 2010  \$	Twelve months ended December 31, 2011         Twelve months ended December 31, 2010         At (I December 31)           \$         \$         \$           \$         \$

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

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

#### **Notes to Consolidated Financial Statements**

#### 1. Business Overview

TrovaGene, Inc. ("TrovaGene" or the "Company") (formerly known as Xenomics, Inc. until its name was changed in January 2010), is a development stage molecular diagnostic company that focuses on the development and marketing of urine-based nucleic acid tests for patient/disease screening and monitoring. The Company's novel tests predominantly use transrenal DNA (Tr-DNA) and transrenal RNA (Tr-RNA). TrovaGene's primary focuses are to leverage its urine-based (i.e., transrenal) testing platform to facilitate improvements in the management of Cancer Care and Women's Healthcare. Tr-DNAs and Tr-RNAs are fragments of nucleic acids derived from dying cells inside the body. The intact DNA is fragmented in dying cells and released in the blood stream. These fragments have been shown to cross the kidney barrier and are detected in urine. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier. These RNA can also be isolated from urine, detected and analyzed. The Company's technology is applicable to all transrenal nucleic acids (Tr-NA). TrovaGene's patented technology uses safe, non-invasive, cost effective and simple urine collection and can be applied to a broad range of testing including: prenatal genetic testing, infectious diseases, tumor detection and monitoring, tissue transplantation, forensic identification and for patient selection in clinical trials. TrovaGene believes that its 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 the disease process. The Company's novel assays will facilitate much improved testing compliance resulting in earlier diagnosis of disease, more targeted treatment which will be more cost effective, and improvements in the quality of life for the patient.

In 2010, TrovaGene acquired a highly sensitive CMOS detection technology for DNA, RNA as well as proteins (See Note 4). A key advantage of this technology is that it is extremely sensitive and does not require amplification (i.e., use of PCR Polymerase Chain Reaction) of nucleic acids. Therefore, it reduces the complexity and cost of molecular diagnostics as it will not require significant equipment purchases or amplification training, and as such may open up new markets for molecular diagnostics such as hospitals and independent labs that currently do not perform high complexity assays such as those requiring PCR. TrovaGene feels that this detection technology is highly complementary and synergistic with its transrenal technology, and may eventually be positioned in certain situations as a standalone molecular diagnostic device. In this regard, TrovaGene plans to leverage this novel CMOS technology toward the development of unique diagnostics for Women's Healthcare and the management of Cancer Care. We are finalizing the system architecture, operating procedure and software specifications for this platform and will commence system development pending resource availability.

As a mechanism to generate steady annual cash flow, in 2006 TrovaGene licensed a new DNA-based biomarker (NPM1) specific for a subtype of acute myeloid leukemia (AML); this marker provides valuable information and insights as to disease prognosis and monitoring for minimal residual disease (MRD). Testing for NPM1 mutations has been added to AML practice guidelines by the National Comprehensive Cancer Network (NCCN). TrovaGene has signed licenses incorporating this biomarker with Sequenom, Inc. which was terminated in March 2011 and with Ipsogen (Europe) and Asuragen (US), who have developed and are manufacturing test kits for sale to labs from which TrovaGene earns a royalty. TrovaGene has also signed non-exclusive royalty bearing licenses with various labs including LabCorp (US), InVivo Scribe (US), Skyline (Europe), MLL (Europe) and Warnex (Canada), who will be providing lab testing services for this marker. TrovaGene is actively

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 1. Business Overview (Continued)

seeking to sign additional royalty bearing non-exclusive license agreements with additional labs to provide this testing service.

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, 2011, the Company has sustained cumulative net losses attributed to common stockholders of \$43,598,431. 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, 2011, the Company has generated only limited licensing revenue from operations and expects to incur additional losses to perform further research and development activities.

TrovaGene's product development efforts are in their early stages and the Company cannot make estimates of the costs or the time they will take to complete. The risk of non-completion of any program is high because of the many uncertainties involved in bringing new tests to market including the long duration of clinical testing, the specific performance of proposed products under stringent protocols, the applicable regulatory approval and review cycles, the nature and timing of costs, and competing technologies being developed by organizations with significantly greater resources.

## 2. Basis of Presentation and Going Concern

The accompanying consolidated financial statements of TrovaGene, which include its wholly owned subsidiary Xenomics, Inc., a California corporation ("Xenomics Sub") 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.

Going Concern

TrovaGene's consolidated financial statements as of December 31, 2011 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 required to raise additional capital within the next two 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 \$1,930,301 and \$2,088,716, for the years ended December 31, 2011and 2010, respectively. During the years ended December 31, 2011 and 2010, the Company incurred net losses attributable to common stockholders of \$2,277,452 and \$5,487,378, respectively.

To date, TrovaGene's sources of cash have been primarily limited to the sale of debt and equity securities. Net cash provided by financing activities for the years ended December 31, 2011 and 2010 was \$2,573,500 and \$1,734,700, respectively. The Company cannot be certain that additional funding

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

#### **Notes to Consolidated Financial Statements (Continued)**

#### 2. Basis of Presentation and Going Concern (Continued)

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.

The Company has approximately \$582,000 of cash in the bank at March 29, 2012. Based on the Company's projections of future ordinary expenses and expected receipts the Company has enough cash to pay expenses through May of 2012.

TrovaGene will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. TrovaGene cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that TrovaGene raises additional funds by issuing equity securities, TrovaGene's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact TrovaGene's ability to conduct business. If TrovaGene is unable to raise additional capital when required or on acceptable terms, TrovaGene may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more 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 TrovaGene would otherwise seek to develop or commercialize ourselves on unfavorable terms.

## 3. Summary of Significant Accounting Policies

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 checking accounts and money market funds as of December 31, 2011 and 2010 on deposit with U.S. commercial banks, which at any point in time, may exceed federally insured limits. The FDIC has increased insured limits per depositor per insured bank.

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 3. Summary of Significant Accounting Policies (Continued)

The Company regularly monitors the financial condition of the institutions at which it has depositary accounts. The risk of loss is nominal.

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. The Company has not received or recognized milestone payment revenues 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, 2011 and 2010, 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 our 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, 2011 and 2010, the fair value of such warrants were \$994,627 and \$609,155, respectively, and are included in the derivative financial instruments liability on the balance sheet.

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

#### **Notes to Consolidated Financial Statements (Continued)**

#### 3. Summary of Significant Accounting Policies (Continued)

The Company has issued units that were price protected during the years ended December 31, 2011 and 2010, respectively. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, 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 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, 2011 and 2010, the fair value of such warrants were \$2,846,017 and \$1,476,783, respectively, and are included in the derivative financial instruments liability on the balance sheet.

At December 31, 2011 and 2010, the total fair value of the above warrants, valued using the Black-Scholes option-pricing model and the Binomial option pricing model was \$3,840,644 and \$2,085,938, respectively, and are classified as derivative financial instruments' liability on the balance sheet.

#### Stock-Based Compensation

The Company relies 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 is designed to provide long-term incentives, develop and maintain an ownership stake and conserve cash during our development stage.

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 which requires management to make certain assumptions with respect to selected model inputs. The expense is to be 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 TrovaGene accounts for non-employee stock-based compensation. TrovaGene continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock option or warrant, using the Black-Scholes options pricing model, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for equity instruments granted to non-employees in accordance with ASC Topic 505-50 "Equity-Based Payment to Non-Employees" whereas the value of the stock 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.

In accordance with ASC Topic 718 stock-based compensation expense related to TrovaGene's share-based compensation arrangements attributable to employees and non-employees is being recorded as a component of general and administrative expense and research and development expense in accordance with the guidance of Staff Accounting Bulletin 107, Topic 14, paragraph F, *Classification of Compensation Expense Associated with Share-Based Payment Arrangements* ("SAB 107").

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 3. Summary of Significant Accounting Policies (Continued)

The estimated fair value of employee options on the date of grant was determined by using the Black-Scholes option valuation model which requires management to make certain assumptions with respect to selected model inputs. The risk-free interest rate assumption is based upon observed U.S. Treasury interest rates appropriate for the expected term of the individual stock options. The Company 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. The computation of the expected option term is based on expectations regarding future exercises of options which generally vest over three years and have a ten year life. The expected volatility is based on the historical volatility of the Company's stock. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimated future unvested option forfeitures based upon its historical experience and has incorporated this rate in determining the fair value of employee option grants.

## Fair value of financial instruments

The Company has adopted FASB ASC 820 Fair Value Measurements ("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. Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and debentures. These financial instruments are stated at their respective historical carrying amounts which approximate fair value due to their short term nature.

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.

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 3. Summary of Significant Accounting Policies (Continued)

Income Taxes

TrovaGene has not filed any Federal tax returns since inception. The amount of any tax liability that could arise since inception is undetermined at this time, however, the Company believes that because it has sustained losses since inception, the amount of any tax liability, if any, that could arise would be immaterial to the Company's Consolidated Financial Statements. The Company intends to record a valuation allowance against any deferred tax assets upon the filing of its tax returns to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. As a result there are no income tax benefits reflected in the consolidated statements of operations to offset pre-tax losses.

## Contingencies

In the normal course of business, TrovaGene 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*, TrovaGene records such loss contingencies when it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. TrovaGene, 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, application and filing for regulatory approval of proposed products, purchased in-process research and development, regulatory and scientific consulting fees, as well as contract research, insurance and FDA consultants, 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.

TrovaGene does not currently have any commercial molecular diagnostic products, and does not expect to have such for several years if at all. Accordingly our research and development costs are expensed as incurred. 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 TrovaGene 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.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 3. Summary of Significant Accounting Policies (Continued)

Net Loss Per Share

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 guide, 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. Diluted weighted-average shares are the same as basic weighted-average shares because shares issuable pursuant to the exercise of stock options would have been antidilutive. For the years ended December 31, 2011 and December 31, 2010 the following outstanding stock options and other common stock equivalents were excluded from the calculation of diluted loss per share because the effect was antidilutive.

	12/31/11	12/31/10
Stock options	14,557,151	14,457,651
Warrants	21,608,843	15,774,338
Conversion of preferred stock	597,500	597,500
Conversion of debentures		4,670,100
Total dilutive instruments	36,763,494	35,499,589
Pacent Accounting Pronouncements		

Recent Accounting Pronouncements

In June 2011 and December 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, Comprehensive Income (Topic 220): *Presentation of Comprehensive Income* and ASU No. 2011-12, Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-5. As a result of ASU 2011-05, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. ASU 2011-05 and ASU 2011-12 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of these standards did not have a material impact on its consolidated financial position or results of operations.

In 2011, FASB issued Accounting Standards Update (ASU) No. 2011-04, "Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in US GAAP and International Financial Reporting Standards (Topic 820) Fair Value Measurement". The new guidance relates to fair value measurements, related disclosures and consistent meaning of the term "fair value" in US GAAP and International Financial Reporting Standards. The amendment clarifies how to apply the existing fair value measurements and disclosures. For fair value measurements classified within Level 3, an entity is required to disclose quantitative information about the unobservable inputs. A reporting

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

## **Notes to Consolidated Financial Statements (Continued)**

## 3. Summary of Significant Accounting Policies (Continued)

entity is also required to disclose additional information like valuation processes, a narrative description of the sensitivity of the fair value measurements to changes in unobservable inputs and the interrelationships between those unobservable inputs. The amendments specified in ASU 2011-04 were effective upon issuance. The adoption of this standard did not have a material effect on the Company's results of operations or its financial position.

In 2010, the Financial Accounting Standards Board (FASB) issued an Accounting Standards Update (ASU) related to Revenue Recognition that applies to arrangements with milestones relating to research or development deliverables. This guidance provides criteria that must be met to recognize consideration that is contingent upon achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The adoption of this standard did not have a material effect on the Company's results of operations or its financial position.

In 2010, the FASB issued ASU 2010-06 Fair Value Measurements and Disclosures (Topic 820) that requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements including significant transfers into and out of Level 1 and Level 2 fair-value measurements and information on purchases, sales, issuances, and settlements on a gross basis in the reconciliation of Level 3 fair-value measurements. The FASB also clarified existing fair-value measurement disclosure guidance about the level of disaggregation, inputs, and valuation techniques. The new and revised disclosures are required to be implemented in interim or annual periods beginning after December 15, 2009, except for the gross presentation of the Level 3 rollforward, which is required for annual reporting periods beginning after December 15, 2010. The adoption of this standard did not have any effect on our financial position and results of operations.

## 4. Merger 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, we were 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 2,258,001 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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 4. Merger Activities (Continued)

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 1,971,734 shares (218,862,474 shares post-split shares) from Panetta Partners Ltd., a principal shareholder, for \$500,000 or \$0.0023 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.
- 4)
  Entered into a Voting Agreement with certain investors, the former Xenomics Sub shareholders and certain principal shareholders.
- 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.
- Issued and transferred 350,000 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, TrovaGene acquired all of the outstanding common stock of Etherogen, Inc. ("Etherogen"), a related party, in exchange for 12,262,782 shares of TrovaGene common stock pursuant to the terms of the Agreement and Plan of Merger dated August 10, 2010 among TrovaGene, 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 TrovaGene'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 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 intangible 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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## 4. Merger Activities (Continued)

process research and development expense-related party on the Company's consolidated statement of operations.

#### 5. 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, 2011 and 2010 and for the period August 4, 1999 (inception) to December 31, 2011 was \$10,285, \$8,388, and \$221,799, respectively. Property and equipment consisted of the following:

	As of				
	Dec	ember 31, 2011	De	cember 31, 2010	
Furniture and fixtures	\$	28,763	\$	28,763	
Leasehold Improvements		11,207		11,207	
Laboratory equipment		204,333		202,804	
		244,303		242,774	
Less accumulated depreciation and amortization		(221,799)		(211,514)	
Property and equipment, net	\$	22,504	\$	31,260	

## 6. Stockholders' Equity (Deficiency)

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 4.

## (A) Common Stock

On July 2, 2004, the Company completed a private placement of 2,645,210 shares of its common stock for aggregate proceeds of \$2,512,950, or \$0.95 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, TrovaGene 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, TrovaGene issued warrants to Trilogy to purchase 1,000,000 shares of Common Stock of TrovaGene at an exercise price of \$2.95 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 price \$4.20 per share, (ii) no dividend, (iii) risk free interest rate 4.5% and (iv) volatility of 80%. This service agreement was terminated by TrovaGene on June 12, 2006.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

On January 28, 2005, the Company closed the first tranche of a private placement selling 1,368,154 shares of common stock and 342,039 warrants to certain investors (the "Investors"). The securities were sold as a unit at a price of \$1.95 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 \$2.95 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 \$4.20 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 123,659 warrants to purchase common stock to various selling agents, which were immediately exercisable at \$2.15 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 102,564 shares of common stock and 25,642 warrants to the Investors at a price of \$1.95 per unit for aggregate proceeds of \$200,000. In addition, the Company paid an aggregate \$179,600 in cash and issued 24,461 shares of common stock to certain selling agents, in lieu of cash, which had a fair value of \$47,699 capitalized at \$1.95 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 1,515,384 shares of common stock and 378,846 warrants to certain additional Investors. The securities were sold as a unit at a price of \$1.95 per unit for aggregate proceeds of \$2,954,999. The warrants issued to the selling agents were immediately exercisable at \$2.15 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 \$2.95 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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

market price of \$2.61 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.

The Company paid an aggregate \$298,000 and issued an aggregate 121,231 warrants to purchase common stock to a selling agent. The warrants issued to the selling agent were immediately exercisable at \$2.15 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 640,000 shares of common stock and 320,000 warrants at \$1.25 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 \$2.00 per share and expired on July 20, 2008. In connection with this transaction, the Company paid \$104,000 and issued 83,200 warrants to a selling agent. The warrants issued to selling agents have the same terms as those issued to the purchasers of common stock.

On August 14, 2006, the Company issued 114,721 shares of common stock and 57,361 warrants at \$1.25 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 \$2.00 per share and expired on August 14, 2008. In connection with this transaction, the Company paid \$14,341 and issued 11,472 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.

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 6. Stockholders' Equity (Deficiency) (Continued)

On December 21, 2006, the Company closed a private placement of 1,000,000 shares of common stock and 500,000 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 \$1.25 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.

On October 12, 2007 and October 16, 2007, the Company closed private placements of 1,400,000 shares and 300,000 shares of common stock, respectively, for aggregate gross proceeds of \$850,000. The Company issued a five year warrant to purchase 100,000 shares of common stock at an exercise price of \$0.50 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 100,000 shares of common stock at an exercise price of \$0.50 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 fair value of \$45,403 on the date of issuance and this amount was charged

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

#### **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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 1,075,000 shares of common stock and 322,500 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 \$0.75 per share in the first year and \$1.50 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 909,091 shares was \$.55 per share, and the investor received warrants to purchase up to 454,545 shares of the Company's common stock at a price of \$.75 per share. The warrants have a three-year term and are exercisable at a price of \$0.75 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.

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 550,000 shares of its common stock and warrants to purchase 550,000 shares of common stock. The purchase price paid by the investors was \$.50 for each unit. The warrants expire after five years and are exercisable at \$.70 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 2,380,000 shares of its common stock and warrants to purchase 2,380,000 shares of common stock. The purchase price paid by the investor was \$.50 for each unit. The warrants expire after six to nine years and are exercisable at \$.50 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 957,780 units consisting of 957,780 shares of common stock and warrants to purchase 957,780 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 \$.50 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.

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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) 413,379 shares of common stock, b) warrants to purchase 418,854 shares of common stock and c) \$164,550 principal amount of 6% convertible debenture. The warrants expire in three years and are exercisable at \$.50 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 \$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, 476,000 shares of common stock and warrants to purchase 476,000 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 12,262,782 shares of common stock, which shares had a fair value of \$2,711,389 at issuance (see Note 4). A total of 262,782 warrants to purchase 262,782 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 3,469,400 shares of its common stock and warrants to purchase 3,469,400 shares of common stock in these transactions. The purchase price paid by the investors was \$.50 for each unit. The warrants expire after eight years and are exercisable at \$.50 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 425,000 shares and warrants to purchase 425,000 shares of common stock in connection with consulting agreements. The fair value used to measure compensation expense was \$.50 for each unit, based on recent private placement transactions, totaling \$212,500. The warrants expire after eight to nine years and are exercisable at \$.50 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, 2009.

In July 2010, 76,472 shares of common stock and warrants to purchase 76,472 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 175,439 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, 541,550 shares of common stock and warrants to purchase 541,550 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.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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 5,147,000 shares of its common stock and warrants to purchase 5,147,000 shares of common stock in these transactions. The purchase price paid by the investors was \$.50 for each unit. The warrants expire after seven years and are exercisable at \$.50 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 the reporting period.

During the year ended December 31, 2011, the Company issued 350,000 shares and warrants to purchase 350,000 shares of common stock in connection with consulting agreements. The fair value used to measure compensation expense for the stock issued was \$0.50 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 \$0.50 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 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 the reporting period.

During the year ended December 31, 2011, 250,500 shares of common stock and warrants to purchase 250,500 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.

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

#### 6. Stockholders' Equity (Deficiency) (Continued)

## (B) Warrants

During the years ended December 31, 2011 and 2010, the Company issued the following warrants to purchase shares of common stock:

	Number of	Weighted Average Exercise		
	Warrants	p	rice	Term
Warrants Outstanding 12/31/2009	12,678,377	\$	0.79	3 - 9 years
Granted	4,709,654	\$	0.50	8 years
Expired	(1,613,693)	\$	2.25	
Warrants Outstanding 12/31/2010	15,774,338			3 - 9 years
Granted	6,289,050	\$	0.50	7 - 8 years
Expired	(454,545)	\$	0.75	·
Warrants Outstanding 12/31/2011	21,608,843	\$	0.53	1 - 8 years

On May 10, 2006, the Company entered into a license agreement wherein it obtained the exclusive rights for the genetic marker for Acute Myeloid Leukemia and intends to utilize these rights for the development of new diagnostic tools. In connection with this agreement, the Company paid \$70,000 to the licensor and agreed to pay an additional \$100,000 upon FDA approval of a commercial product based upon this technology and royalties of 3% of net sales and/or 10% of any sublicense income. Additionally, the Company paid a selling agent fee of \$100,000 and issued warrants for the purchase of 100,000 shares of common stock at \$1.80 per share. These warrants expire June 29, 2014. The value of these warrants was determined to be \$101,131 utilizing the Black Scholes model. The value of these warrants combined with the cash payments aggregated \$271,131 and was immediately expensed and classified as a research and development expense.

On November 30, 2006, the Compensation Committee, in recognition of the technical assistance to be provided by Dr. Sidransky, granted warrants to purchase 300,000 shares of common stock at an exercise price of \$0.65 for a period of ten years. Such warrants vest in equal amounts on the first and second anniversary dates of the grant. The Company has estimated the fair value of these warrants as of the grant date to be \$172,505. This fair value was fully expensed by December 31, 2008. On November 19, 2008, Dr. Sidransky resigned his position as a member of the Board of Directors. All previously unvested options, of 150,000, were terminated on this date.

On December 20, 2006, the Compensation Committee, in connection with services provided pursuant to a consulting agreement with Mr. Cerrone, granted him warrants which vested immediately to purchase 353,570 shares of common stock at an exercise price of \$0.70 for a period of ten years. The Company has estimated the fair value of these warrants as of the grant date to be \$182,271 based on the Black-Scholes option pricing model. The assumptions used were as follows: (i) stock price at date of grant \$.70, (ii) term 10 years, (iii) volatility 100% and (iv) risk free interest rate 4.57%. This fair value was fully expensed as stock based compensation by January 31, 2007.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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 438,956 shares of the Company's common stock at an exercise price of \$.75 per share. The warrant expires 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 \$.31, (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. The amounts charged to general and administrative expense in the years ended December 31, 2011 and 2010 and from August 4, 1999 (Inception) to December 31, 2011 were gains of \$100,243, \$60,586 and \$39,485, respectively. See Note 11.

The Company granted 6,289,050 and 4,709,654 warrants that were price protected during the years ended December 31, 2011 and 2010. These warrants had an exercise price of \$.50 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. See Note 8.

## (C) 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 386,651 warrants to certain investors for aggregate gross proceeds of \$2,771,000 pursuant to a Securities Purchase Agreement dated as of July 13, 2005. The warrants sold to the Investors were immediately exercisable at \$3.25 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 \$2.40 on that date. In addition the Company paid an aggregate of \$277,102 and issued an aggregate of 105,432 warrants to purchase common stock to certain selling agents. The warrants issued to the selling agents were immediately exercisable at \$2.50 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, 2011 and 2010, the Company had recorded \$152,960 and \$114,720, respectively, in accrued cumulative unpaid preferred stock dividends, included in Accrued Expenses in the

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

Company's consolidated balance sheets, and \$38,240 was recorded for each of the years ended December 31, 2011 and 2010.

- 2) Voting Rights. Shares of the Series A Convertible Preferred Stock shall have no voting rights. However, so long as any shares of Series A Convertible Preferred Stock are outstanding, 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.
- 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 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 \$1.60 per share.

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 6. Stockholders' Equity (Deficiency) (Continued)

7) Automatic Conversion. Beginning July 13, 2006, if the price of the common stock equals \$4.30 per share for 20 consecutive trading days, and an average of 50,000 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. During the twelve months ending January 31, 2007 and 2006 and inception to date, the Company recorded a net benefit for the change in fair value of this derivative financial instrument of \$293,929, \$161,456 and \$455,385, respectively.

During the twelve months ended January 31, 2007, 174,000 shares of Series A Convertible Preferred Stock were converted into 826,431 shares of common stock. During the eleven months ended December 31, 2007, an additional 7,500 shares of preferred stock were converted into 46,875 shares of common stock. As of December 31, 2011 and 2010 there remained 95,600 shares of Series A Convertible Preferred Stock outstanding.

#### (D) 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 4,046,364 shares of the Company's common stock at an exercise price of \$0.70 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

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

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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 \$0.55 per share, subject to adjustment for certain dilutive issuances. As a result of the October 2007 private placements the anti-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 \$0.50 per share and the number of common shares issuable upon conversion of the debentures and exercise of the warrants increased to 4,451,000 and 5,664,910, 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 15 th 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 164,550 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 \$0.70 per share, subject to certain adjustments. The initial exercise price of the warrant was \$0.55 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

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## 6. Stockholders' Equity (Deficiency) (Continued)

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 5,437,472 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 \$0.32 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.

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 6,083,763 shares of common stock purchase warrants, expiring November 14, 2012, continued to be outstanding.

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 4,670,100 shares of common stock pursuant to a note and warrant agreement and the Company issued an additional 467,010 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 \$0.22 a share as of the date of the transaction. In addition, the 6,083,763 warrants, originally issued in 2006 with the Debentures with an expiration date of November 12, 2012, were exchanged for 6,083,763 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, 2011, 2010 and inception through December 31, 2011, the Company incurred interest expense of \$128,421, \$256,856, and \$1,325,372, respectively, that was paid in 1,259,877 shares. 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, \$141,271 and \$316,402 for the years ended December 31, 2011, 2010, and from inception

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

#### **Notes to Consolidated Financial Statements (Continued)**

#### 6. Stockholders' Equity (Deficiency) (Continued)

(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 6,083,763 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, 2011, 2010 and inception (August 4, 1999) to December 31, 2011 was a gain of \$35,127, a loss of \$31,999, and a gain of \$494,714, respectively. The losses for year ended December 31, 2011 and the gain from inception (August 4, 1999) to December 31, 2011 exclude the \$581,503 charge for the modification in the change in fair value of the derivative liability on the Consolidated Statements of Operations.

## (E) 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 3,500,000 units, containing one share of its common stock and one warrant, at an initial purchase price of \$0.55 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 6,363,636 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$0.55 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 \$0.70 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.

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 2,727,272 additional units as described above until December 31, 2007, at an initial purchase price of \$0.55 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

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 6. Stockholders' Equity (Deficiency) (Continued)

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 Amendment extended the date the holder of the warrant has the right to purchase up to an aggregate 2,727,272 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$0.55 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 6,363,636 units, each containing one share of common stock and one common stock purchase warrant, at an initial purchase price of \$0.55 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 \$.55 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 13, Related Party Transactions.

Concurrent with completing the Forbearance Agreement, See Note (D) 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.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 7. 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 determined at the time of grant, 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 5,000,000 to 12,000,000. 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 12,000,000 to 22,000,000. 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.

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 1,050,000, 1,012,500, 1,012,500 and 675,000, 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 240,000, 255,000, 225,000 and 75,000, 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 \$2.50 per share with 33½% of the options granted to each officer vesting on each of the first three anniversaries of the date of grant. The options pertaining to Messer's Umansky and Melkonyan remain valid and exercisable until their expiration date of May 2015 as stipulated in the 2010 settlement agreement (see Note 12). The options for Messrs. Cerrone and Tomei were fully vested by May of 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 1,000,000 and 640,000 shares, respectively, of common stock at an exercise price of \$0.79 per

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 7. Stock Option Plan (Continued)

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 666,667 and 426,667 for Mr. Buitoni and Dr. Sidransky, respectively, were terminated on this date.

In November 2010, Mr. Umansky, the estate of the late Mr. Melkonyan and Kira Scheinerman settled their employment lawsuits against the Company which included the issuance of stock options. See Note 12.

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

	Years ended December 31,				
		2011		2010	
In research and development expenses	\$	10,828	\$	86,040	
In general and administrative expenses		240,150		239,890	
Total stock based compensation		250,978		325,930	

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 weighted-average assumptions during the years indicated below:

	Years ended	December 31,
	2011	2010
Risk-free interest rate	.85% - 2.48%	1.46% - 2.30%
Dividend yield		
Expected volatility	90%	100%
Expected term (in years)	5.0 yrs	5.0 yrs
Stock price	\$.22	\$.22 - \$.23

*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.

Dividend yield TrovaGene 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 TrovaGene's stock.

Expected term TrovaGene has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the

F-40

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Consolidated Financial Statements (Continued)**

## 7. Stock Option Plan (Continued)

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. TrovaGene estimated future unvested option forfeitures based on historical experience of 20%.

The weighted-average fair value per share of all options granted during the years ended December 31, 2011 and 2010 estimated as of the grant date using the Black-Scholes option valuation model was \$.12 and \$.28 per share, respectively.

The unrecognized compensation cost related to non-vested employee stock options outstanding at December 31, 2011 and December 31, 2010 was \$653,495 and \$363,455, respectively. The weighted-average remaining contractual term at December 31, 2011 for options outstanding and vested options is 6.8 and 5.5 years, respectively.

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

			A E	eighted verage xercise	
	Number of Options	Exercise Price Per Share		rice Per Share	Intrinsic Value
Balance outstanding, December 31, 2009	14,762,651	\$ 0.50 to \$2.50	\$	.89	\$ 2,197,679
Granted	2,160,000	\$ .50 - \$.75	\$	.57	
Exercised					
Forfeited	(2,465,000)	\$ .50	\$	.50	
Balance outstanding, December 31, 2010	14,457,651	\$ 0.50 to 2.50	\$	.90	\$ 143,500
Granted	4,427,000	\$ 0.50	\$	.50	
Exercised					
Forfeited	(4,327,500)	\$ .50	\$	.50	
Balance outstanding, December 31, 2011	14,557,151	\$ 0.50 to 2.50	\$	.87	\$
Exercisable at December 31, 2011	9,774,818	\$ 0.50 to 2.50	\$	1.04	\$

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 TrovaGene's accumulated deficit position, no tax benefits have been recognized in the cash flow statement.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 8. Derivative Financial Instruments

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 certain warrants issued in connection with the private placements must be recorded as derivative liabilities with a charge to additional paid in capital. 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 changes 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.

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	Year ended
	December 31, 2011	December 31, 2010
Estimated fair value of warrant	\$0.50 to \$2.50	\$0.50 to \$2.50
Expected warrant term	5 years	5 years
Risk-free interest rate	1.07 - 1.23%	.19 - 1.02%
Expected volatility	90%	100%
Dividend yield	0%	0%

Expected volatility is based on historical volatility of TrovaGene's common stock. The warrants have a transferability provision and based on guidance provided in SAB 107 for instruments issued with such a provision, TrovaGene 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.

# TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## **8. Derivative Financial Instruments (Continued)**

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	Warrants	In	Derivative Istrument Liability
12/31/2009	Balance of derivative financial instruments liability	7,399,405	\$	740,617
3/31/2010	Change in fair value of warrants during the quarter recognized as income in the statement of operations	7,577, 105	\$	(266,632)
3/31/2010	Balance of derivative financial instruments liability	7,399,405	\$	473,985
6/30/2010	Warrants expiration	(322,500)		,
6/30/2010	Change in fair value of warrants during the quarter recognized as income in the statement of operations		\$	(168,439)
6/30/2010	Balance of derivative financial instruments liability	7,076,905	\$	305,546
9/30/2010	Change in fair value of warrants during the quarter recognized as a loss in the statement of operations		\$	347,425
9/30/2010	Balance of derivative financial instruments liability	7,076,905	\$	652,971
12/31/2010	Change in fair value of warrants during the quarter recognized as income in the statement of operations		\$	(43,816)
12/31/2010	Balance of derivative financial instruments liability	7,076,905	\$	609,155
3/31/2011	Change in fair value of warrants during the quarter recognized as income in the statement of operations		\$	(141,193)
3/31/2011	Balance of derivative financial instruments liability	7,076,905	\$	467,962
6/30/2011	Change in fair value of warrants during the quarter recognized as income in the statement of operations		\$	(143,555)
6/30/2011	Balance of derivative financial instruments liability	7,076,905	\$	324,407
9/30/2011	Change in fair value of warrants during the quarter recognized as a loss in the statement of operations		\$	555,730
9/30/2011	Balance of derivative financial instruments liability	7,076,905	\$	880,137
12/31/2011	Change in fair value of warrants during the quarter recognized as a loss in the statement of operations		\$	114,490
12/31/2011	Balance of derivative financial instruments liability	7,076,905	\$	994,627
	F-43			

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

## **Notes to Consolidated Financial Statements (Continued)**

## **8. Derivative Financial Instruments (Continued)**

During the years ended December 31, 2011 and 2010, the Company issued 6,289,050 and 4,709,654 units at \$.50 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 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 \$.50 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.

The fair value of the warrants granted during the two years ended December 31, 2011 was estimated using the following weighted average assumptions:

	2011	2010
Range of risk-free interest rates	1.35% to 2.80%	.29% to 1.39%
Range of expected volatility	90%	60 to 100%
Expected fair value of the stock	\$.23 - \$.25	\$.23 - \$.33
Weighted average remaining contractual life	7 years	8 years
Expected warrant term	5 years	5 years

The weighted average remaining contractual term of all of the Company's warrants outstanding at December 31, 2011 and 2010 was seven and five years, respectively.

## TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

#### **8. Derivative Financial Instruments (Continued)**

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:

Ouarter	Number of Price Protected Units at Issuance	L	Derivative iability For ssued Units	Change In Fair value of Derivative Liability For Previously Outstanding Price Protected Units	Ending Balance Derivative Liability
Total at 12/31/2009	2,930,000	\$	613,291	(11,158)	602,133
Quarter ended 3/31/2010	863,000		188,331	(20,716)	769,748
Quarter ended 6/30/2010	993,000		214,186	(29,485)	954,449
Quarter ended 9/30/2010	2,628,654		559,862	(37,247)	1,477,064
Quarter ended 12/31/2010	225,000		47,736	(48,017)	1,476,783
Total at 12/31/10	7,639,654		1,623,406	(146,623)	1,476,783
Ouarter ended 3/31/2011	1,522,500		320,791	(55,139)	1,742,435
Quarter ended 6/30/2011	775,000		161,260	(82,862)	1,820,833
Quarter ended 9/30/2011	1,829,550		374,843	(92,267)	2,103,409
Quarter ended 12/31/2011	2,162,000		486,983	255,625	2,846,017
Total at 12/31/11	13,928,704	\$	2,967,283	\$ (121,266)	\$ 2,846,017

The total derivative liability for the Company at December 31, 2011 and 2010 was \$3,840,644 and \$2,085,938, respectively.

During the fourth quarter of the fiscal year ended December 31, 2011, the Company recorded an adjustment of approximately \$278,000 to derivative liabilities based on a correction of an assumption in the binomial valuation of the derivative liabilities. The effect of this fourth quarter adjustment resulted in an increase of approximately \$45,000 to the change in the fair value of derivative instruments on the statement of operations for the three months ended December 31, 2011.

## 9. Fair Value Measurements

The following table presents the Company's 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, 2011 and 2010:

	<b>Quoted Prices</b>			
	in Active	Significant		
	Markets for	Other	Significant	
	Identical Assets Observable Unobserv		Unobservable	Balance as of
	and Liabilities	Inputs	Inputs	December 31,
Description	(Level 1)	(Level 2)	(Level 3)	2011
Derivative liabilities related to Warrants	\$	\$	\$ 3,840,644	\$ 3,840,644

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

## **Notes to Consolidated Financial Statements (Continued)**

### 9. Fair Value Measurements (Continued)

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2010
Derivative liabilities related to Warrants	\$	\$	\$ 2.085,938	\$ 2.085,938

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, 2011 and 2010:

	Balance at		Fa	Fair Value of		nrealized	Bala	ance as of
	De	ecember 31,	mber 31, warrants upon		(	(gains) or I		ember 31,
Description		2010 issuance		issuance		losses		2011
Derivative liabilities related to Warrants	\$	2,085,938	\$	1,343,876	\$	410,830(1) \$	\$	3,840,644

	Balance at December 31,		Fair Value of warrants upon			Inrealized (gains) or	 alance as of ecember 31,
Description	2009		issuance		issuance losses		2010
Derivative liabilities related to Warrants	\$	1,342,750	\$	1,010,114	\$	(266,926)	\$ 2,085,938

(1) Includes \$581,503 of loss on modification of the debt as a result of the warrant expiration extension. Without this loss, the gain on the change in fair value for the year ended December 31, 2011 totaled \$170,673. See Note 6 (D).

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.

#### 10. Income Taxes

TrovaGene has not filed any Federal tax returns since inception. The amount of any tax liability that could arise since inception is undetermined at this time, however, the Company believes that because it has sustained losses since inception, the amount of any tax liability, if any, that could arise would be immaterial to the Company's Consolidated Financial Statements.

At December 31, 2011, TrovaGene has net operating loss carryforwards (NOLs) of approximately \$20 million, which, if not used, expire beginning in 2019. The utilization of these NOLs is subject to limitations basd on past and future changes in ownership of TrovaGene 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. The Company has no other material deferred tax items. TrovaGene records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or

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

#### **Notes to Consolidated Financial Statements (Continued)**

#### 10. Income Taxes (Continued)

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 of the deferred tax. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying consolidated statements of operations to offset pre-tax losses.

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 (an inactive subsidiary), a company formed in the United Kingdom during the year ended January 31, 2007, 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

#### License Agreements

On May 10, 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 royalties of 6% of royalty revenues and/or 10% of any sublicense income. During the years ended December 31, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded license fee expenses of approximately \$0, \$23,000, and \$23,000, respectively.

Additionally, the Company paid \$100,000 and issued warrants for the purchase of 100,000 shares of common stock at \$1.80 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, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$50,000, \$40,000, and \$247,000, respectively. During the years ended December 31, 2011, 2010 and from inception (August 4, 1999) to December 31, 2011, the Company recorded license fee expenses of approximately \$0, \$0 and \$3,700 respectively.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 11. Commitments and Contingencies (Continued)

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, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$50,000, \$50,000, and \$355,000, respectively. During the years ended December 31, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded license fee expenses of approximately \$0, \$0, and \$15,800 respectively.

In January 2008, the Company signed a sublicensing agreement with Warnex Medical Laboratories for the non-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification 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 has not received any royalty and license fee revenues nor recorded any license fee expenses in connection with this license agreement.

In August 2008, the Company signed a sublicensing agreement with LabCorp for the non-exclusive rights to develop, manufacture and market, research and diagnostic products for the stratification 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, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$20,000, \$27,000, and \$67,000, respectively. During the years ended December 31, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company has not recorded any license fee expenses.

On October 29, 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. payable in two installments, \$500,000 on the date of the agreement and \$500,000 on or before January 7, 2009. Sequenom will also pay the Company a royalty on any net revenues during the term of the agreement, subject to certain minimums. In March 2011, Sequenom notified the Company, in accordance with the agreement, that it was terminating the agreement effective after 60 days. The Company has also billed Sequenom for its prorata share of the minimum royalties due in 2011. During the years ended December 31, 2011, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$40,000, \$139,000, and \$1,179,000, respectively. During the years ended December 31, 2011, and from inception (August 4, 1999) to December 31, 2011, the Company has not recorded any license fee expenses.

In December 2008, the Company signed a sublicensing agreement with InVivoScribe Technologies, Inc. for the co-exclusive rights to develop, manufacture and market, research and

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

## **Notes to Consolidated Financial Statements (Continued)**

### 11. Commitments and Contingencies (Continued)

diagnostic products for the stratification 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, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$20,000, \$0 and \$30,000, respectively. During the years ended December 31, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, 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, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of approximately \$30,000, \$10,000 and \$40,000, respectively. During the years ended December 31, 2011, 2010, and from inception (August 4, 1999) to December 31, 2011, the Company has not recorded any license fee expenses.

In January, 2011, the Company entered into an asset purchase agreement 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 the aggregate amount of 10% of all royalties received by the Company from licensees pursuant to any licenses of rights to the antibody. In addition, the Company agreed to pay (i) 10% of all cash consideration received from licensees as an upfront license fee pursuant to any licenses of the product and (ii) 7% of all cash consideration received from licensees as milestone payments. The agreement may be terminated at any time by either TrovaGene or the seller in case of non-fulfillment of the obligations of the agreement or by seller in case of non-compliance of us with respect to the royalty payments. For the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, no royalty expense, license fee or milestone payments have been recorded related to this agreement.

In February, 2011, the Company entered into a sublicense agreement with MLL Münchner Leukämielabor, or MLL. 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. For the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of \$35,000.

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 11. Commitments and Contingencies (Continued)

In July, 2011, the Company entered into a sublicense agreement with Fairview Health Services ("Fairview"). 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. For the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, the Company recorded royalty and license fee revenues of \$10,000.

In October 2011, the Company entered into an exclusive license agreement 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 develop the license product rights. For the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, no royalty expense has been recorded related to this agreement.

In December, 2011, the Company entered into an exclusive license agreement 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. For the year ended December 31, 2011 and from inception (August 4, 1999) to December 31, 2011, no royalty expense has been recorded related to this agreement.

In total, during the years ended December 31, 2011 and 2010, the Company recorded \$30,000 and \$10,000 of license fees and \$227,696 and \$255,665 of royalty income, respectively. From inception (August 4, 1999) to December 31, 2011, the Company recorded \$1,363,175 of license fees and \$645,070 of royalty income.

## Litigation

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.

## TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## 11. Commitments and Contingencies (Continued)

**Employment and Consulting Agreements** 

On June 24, 2005, TrovaGene 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 consist 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 957,780 units, consisting of 957,780 shares of the Company's common stock and 957,780 warrants to purchase 957,780 shares of common stock of the Company, calculated by dividing the obligation by \$.50 per share, as approved by the Board of Directors. 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 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 4,800,000 ten year options to purchase shares of the Company's stock at \$0.50 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 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. As of December 31, 2010, 1,600,000 options were vested. During the years ended December 31, 2011 and 2010, the Company recorded stock based compensation in the amount of approximately \$48,000 and \$143,000, respectively.

In March 2010, the Board of Directors in an Unanimous Written Consent agreed to settle the amount of \$100,000 in full due to Thomas Adams by issuing 200,000 units with each unit consisting of one share of common stock and one warrant to purchase shares of common stock at \$0.50 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 200,000 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 4,800,000 options granted with 1,822,500 new options with the following terms:

- a) New grant date of August 5, 2011
- b) Exercise price of \$0.53 per share
- c) 800,000 options vested immediately, with the remaining 340,833 to vest on August 5, 2012, 340,833 to vest on August 5, 2013 and 340,834 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

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

## **Notes to Consolidated Financial Statements (Continued)**

### 11. Commitments and Contingencies (Continued)

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. 800,000 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.

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. 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 3,800,000 non-qualified stock options which have an exercise price of \$0.50 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 \$1.25 or more and the volume 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
- (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 \$1.25 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 \$2.40 per share, \$3.80 per share or \$5.00 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 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, TrovaGene 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 100,000 incentive stock options with an exercise price of \$1.86 per share which vested in equal amounts over a period of three years beginning January 3, 2007. The agreement contained a provision

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

## **Notes to Consolidated Financial Statements (Continued)**

#### 11. Commitments and Contingencies (Continued)

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.

## Consulting Agreements

- (i) 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 150,000 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 350,000 units upon the achievement of certain milestones. During the year ended December 31, 2011, the Company issued 50,000 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 \$.50 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. See Note 8.
- (ii) 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 300,000 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 were immediately vested. 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 \$.50 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. See Note 8.

## **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.

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

## **Notes to Consolidated Financial Statements (Continued)**

### 11. Commitments and Contingencies (Continued)

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 September 15, 2004, the Company entered into a seven year lease for its previous corporate headquarters in New York City with an average annual rent of approximately \$78,000 through September 30, 2011. On July 28, 2008, the Company entered into a License Agreement with Synergy Pharmaceuticals, Inc. ("Synergy") for a portion of the above premises commencing on August 1,2008 and ending on September 30,2008 for a license fee of \$9,000. On July 28, 2009, the Company assigned its rights, title and interest in the above lease to Synergy. As a result of this assignment, Synergy has assumed all of the obligations of the lease. Simultaneously with the lease assignment, Synergy delivered a check in the amount of \$12,926 as a security deposit for meeting its obligations under the aforementioned lease.
- b) On September 1, 2004, the Company entered a two year lease for laboratory space in New Jersey, with an approximate annual rent of \$125,000 through August 31, 2006. On August 26, 2009, the company entered into a Lease Settlement Agreement ("Settlement") with the landlord. Under the terms of the Settlement the Company agreed to pay the landlord the sum of \$15,000 in full satisfaction of its obligations under the lease. The company also assigned to the landlord ownership of all the tangible property, laboratory equipment and other such equipment located at the premises.
- c) 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.
- d) During the years ended December 31, 2011 and 2010, total rent expense was approximately \$164,000 and \$151,000, respectively. The Company is also 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:

2012	\$ 135,168
2013	22,704
Total	\$ 157,872

## TrovaGene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Consolidated Financial Statements (Continued)**

## 11. Commitments and Contingencies (Continued)

Settlement Agreements

In November 2010, Mr. Umansky and the estate of the late Mr. Melkonyan settled their employment lawsuits against the Company as follows:

- A) 1) Mr. Umansky received cash payments totaling \$150,000 payable in six equal installments of \$25,000 commencing December 1, 2010 and ending May 1, 2011.
  - 2) Stock options, fully vested, to purchase a total of 450,000 shares of Common Stock, \$.001 par value, with an exercise price of \$.50 per share and expiring November 1, 2020. The stock based compensation expense associated with these options of \$81,901, using the Black Scholes fair value method, is included in Stockholders' Equity (Deficiency) for the year ended December 31, 2010.
    - 3) At the closing Mr. Umansky received an additional sum of \$75,000 as a partial reimbursement of legal fees.
- B) 1) Mr. Melkonyan's estate received cash payments totaling \$50,000 payable in six equal installments of \$8,333.34 commencing December 1, 2010 and ending May 1, 2011.
  - 2) Stock options, fully vested, to purchase a total of 200,000 shares of Common Stock, \$.001 par value, with an exercise price of \$.50 per share and expiring November 1, 2020. The stock based compensation expense associated with these options of \$36,401, using the Black Scholes fair value method, is included in Stockholders' Equity (Deficiency) for the year ended December 31, 2010.

As of December 31, 2010, \$225,000 has been expensed in general and administrative expenses in the consolidated statements of operations. At December 31, 2011 and 2010, \$0 and \$133,333, respectively, were outstanding and accrued for.

In November 2010, the Company entered into a Mutual Release, Settlement and Indemnification Agreement with Kira Sheinerman with respect to an action against the Company. As a result of this agreement, Ms. Sheinerman received a fully vested stock option, expiring November 17, 2020, to purchase a total of (i) 50,000 shares of Common Stock, \$.001 par value, with an exercise price of \$.50 per share and (ii) 75,000 shares of Common Stock, \$.001 par value, with an exercise price of \$.75 per share. The stock based compensation associated with these options totaling \$13,211, using the Black Scholes fair value method, is included in Stockholders' Equity (Deficiency) for the year ended December 31, 2010.

## EMPLOYEE BENEFIT PLANS

Defined Contribution 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 % 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.

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

## **Notes to Consolidated Financial Statements (Continued)**

## 13. Related Party Transactions

Gabriele M. Cerrone, the Company's former Co-Chairman, 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 4, *Merger Activities, Note 6, Stockholders'Equity (Deficiency), Note 7, Stock Option Plan* and Note 12, *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 6, *Stockholders' Equity (Deficiency)*.

Stanley Tennant, a director of the company, and a Debenture holder in the principal amount of \$137,500 received 338,126 shares of common stock relating to the Forbearance Agreement. R. Merrill Hunter, a principal stockholder of the company, and a Debenture holder in the principal amount of \$550,000 received 1,352,504 shares of common stock relating to the Forbearance Agreement.

See Note 12 relating to Thomas Adams, Chairman of the Board, consulting arrangement.

See Note 6 relating to shares of common stock and warrants to purchase common stock issued to shareholder as finders' fees.

## 14. Subsequent Events

## Private Placements

During the period from January 1 to March 4, 2012 the Company closed private placement financings which raised gross proceeds of \$950,000. The Company issued 900,000 shares of its common stock and warrants to purchase 374,700 shares of common stock in these transactions. The purchase price paid by the investors was \$.50 for each unit. The warrants expire after eight years and are exercisable at \$.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, TrovaGene has determined that the units, which are price protected, issued in connection with these private placements should be recorded as derivative liabilities.

## Asset Purchase Agreement

On February 1, 2012, the Company entered into an asset purchase agreement with MultiGen Diagnostics, Inc.. The Company determined that the acquired assets do not meet the definition of a business, as defined in ASC 805, *Business Combinations* and will be accounted for under ASC 350, *Intangibles Goodwill and Other*. In connection with the acquisition, the Company issued 750,000 shares of restricted common stock to MultiGEN. In addition, up to an additional \$3.7 million in common stock and cash may be paid to MultiGEN upon the achievement of specific sales and earnings targets. In addition, in connection with the acquisition, we 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 CLIA lab.

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

**Notes to Consolidated Financial Statements (Continued)** 

## 14. Subsequent Events (Continued)

**Employment and Consulting Agreements** 

On February 1, 2012, the Company entered into an executive agreement with Steve Zaniboni in which he agreed to serve as TrovaGene's 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. 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 1,000,000 non-qualified stock options which have an exercise price of \$0.60 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.

## Trovagene, Inc. and Subsidiaries (A development stage company)

## CONDENSED CONSOLIDATED BALANCE SHEETS

		March 31, 2012	D	December 31, 2011
Assets				
Current assets:				
Cash and cash equivalents	\$	586,777	\$	700,374
Accounts receivable		76,533		99,140
Prepaid expenses		42,441		42,658
Total current assets		705,751		842,172
Property and equipment, net		114,323		22,504
Other assets		362,081		174,581
Total assets	\$	1,182,155	\$	1,039,257
		, ,		, ,
Liabilities and Stockholders' Deficiency				
Current liabilities:				
Accounts payable	\$	946,952	\$	928,364
Accrued expenses	Ψ.	585,775	Ψ	501,517
- Notice Capellists		200,770		001,017
Total current liabilities		1,532,727		1,429,881
Derivative financial instruments		3,983,430		3,840,644
Derivative intarctal institutions		3,703,130		3,010,011
Total liabilities		5 516 157		5 270 525
Commitments and contingencies (Note 8)		5,516,157		5,270,525
Stockholders' deficiency				
Preferred stock, \$0.001 par value, 20,000,000 shares authorized, 95,600 shares outstanding at				
March 31, 2012 and December 31, 2011, designated as Series A Convertible Preferred Stock with				
liquidation preference of \$956,000 at March 31, 2012 and December 31, 2011		96		96
Common stock, \$0.0001 par value, 100,000,000 shares authorized, 67,146,857 and 64,422,157 issued		70		70
and outstanding at March 31, 2012 and December 31, 2011, respectively		6,714		6,442
and outstanding at March 31, 2012 and December 31, 2011, respectively		0,711		0,112
Additional paid-in capital		40,429,821		39,360,625
Deficit accumulated during development stage		(44,770,633)		(43,598,431)
2 cites accommend during development surge		(11,770,033)		(.5,575,151)
Total stockholders' deficiency		(4,334,002)		(4,231,268)
Total stockholders deficiency		(4,334,002)		(4,231,200)
	Ф	1 100 155	ф	1 020 257
	\$	1,182,155	\$	1,039,257

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

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Operations and Comprehensive Loss

	Three months ended March 31,			Aı (I	or the period ugust 4, 1999 (nception) to	
		2012	_	2011		arch 31, 2012
Royalty income	\$	34,153	\$	89,082	\$	679,223
License fees						1,363,175
Total revenues		34,153		89,082		2,042,398
Operating expenses:						
Research and development		337,407		258,016		15,866,560
Purchased in-process research and development expense-related party						2,666,869
General and administrative		826,964		551,044		23,367,818
Total operating expenses		1,164,371		809,060		41,901,247
Operating loss		(1,130,218)		(719,978)		(39,858,849)
Other income (expense):						
Interest income				171		266,883
Interest expense				(28,511)		(1,325,372)
Amortization of deferred debt costs and original issue discount						(2,346,330)
Change in fair value of derivative instruments		(32,424)		196,331		1,193,582
Gain on extinguishment of debt						623,383
Liquidated damages and other forbearance agreement settlement costs						(1,758,111)
Net loss and Comprehensive loss		(1,162,642)		(551,987)		(43,204,814)
Preferred stock dividend		(9,560)		(9,560)		(317,478)
Cumulative effect of early adoption of ASC 815-40 on November 1, 2006		(2,200)		(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		(455,385)
Series A convertible preferred stock beneficial conversion feature accreted as a						( / /
dividend						(792,956)
Net loss and Comprehensive loss attributable to common stockholders	\$	(1,172,202)	\$	(561,547)	\$	(44,770,633)
The 1000 and Completions to 1000 and formation of Common Stockholders	Ψ	(1,172,202)	Ψ	(501,517)	Ψ	(11,770,033)
Weighted average shares of common stock outstanding:						
Basic and diluted		66,010,076		54,137,893		
Net loss per common share:		(0.65		(0.6.:		
Basic and diluted	\$	(0.02)	\$	(0.01)		

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency)

	Addition		Additional	Deferred Stock	Deficit Accumulated During	Total Stockholders'		
	Common S Shares	Stock Amount	Treasury Shares		Paid-In	Based Compensation	Development Stage	Equity (Deficiency)
Balance, August 4, 1999 (Inception)	0				-	\$ 0		
Issuance of common stock to	U	Ψ	U	Ψ 0	Ψ	Ψ	Φ 0	Ψ 0
founders for cash at \$0.0002 per								
share	222,000,000	22,200			19,800			42,000
Net loss	222,000,000	22,200			17,000		(14,760)	(14,760)
11011033							(14,700)	(14,700)
Balance, January 31, 2000	222,000,000	22,200	0	0	19,800	0	(14,760)	
Net loss							(267,599)	(267,599)
Balance, January 31, 2001	222,000,000	22,200	0	0	19,800	0	(282,359)	(240,359)
Capital contribution of cash					45,188		` ' '	45,188
Net loss							(524,224)	(524,224)
							, , ,	` ' '
Dalamas January 21 2002	222 000 000	22.200	0	0	64.000	0	(006 502)	(710 205)
Balance, January 31, 2002 Issuance of common stock for cash	222,000,000	22,200	U	U	64,988	U	(806,583)	(719,395)
at \$0.0005 per share	7 5 4 9 000	755			2,645			3,400
Capital contribution of cash	7,548,000	133			2,500			2,500
Net loss	*				2,300		(491 600)	(481,609)
Net loss							(481,609)	(481,009)
Balance, January 31, 2003	229,548,000	22,955	0	0	70,133	0	(1,288,192)	(1,195,104)
Net loss							(383,021)	(383,021)
Balance, January 31, 2004	229,548,000	22,955	0	0	70,133	0	(1,671,213)	(1,578,125)
Waiver of founders' deferred	, ,,,,	,,,,,,		_	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	_	(-,-,-,)	(=,= : =,===)
compensation					1,655,031			1,655,031
Private placement of common stock	2,645,210	265			2,512,685			2,512,950
Redemption of shares held by	2,010,210	200			2,012,000			2,012,700
Panetta Partners, Inc.	(218,862,474)	(21,886)			(478,114)			(500,000)
Costs associated with	(210,002,171)	(21,000)			(170,111)			(200,000)
recapitalization					(301,499)			(301,499)
Share exchange with founders	2,258,001	226			(226)			0
Issuance of treasury shares	2,200,001		350,000	35	(35)			0
Issuance of treasury shares to escrow	350,000	35	(350,000)					0
Issuance of common stock and	,		(,,	, (==)				
warrants for cash at \$1.95 per share	1,368,154	136			2,667,764			2,667,900
Issuance of 123,659 warrants to	-,,				_,,,			_,,
selling agents					403,038			403,038
Finders warrants charged to cost of					102,020			.02,020
capital					(403,038)			(403,038)
Deferred stock-based compensation					1,937,500	(1,937,500)		0
Amortization of deferred					, ,. 30	( ). = . ,= 30)		
stock-based compensation						245,697		245,697
Options issued to consultants					1,229,568	213,057		1,229,568
Warrants issued to consultants					2,630,440			2,630,440
Net loss					2,050,110		(5,371,027)	(5,371,027)
							(=,=,1,021)	(=,=,1,0=1)
D-1 1 21 2005	17 206 901	¢ 1.721	0	Φ Δ	¢ 11 022 247	e (1 (01 002)	¢ (7.042.240)	¢ 2 100 025
Balance, January 31, 2005	17,306,891	\$ 1,731	0	\$ 0	\$ 11,923,247	\$ (1,691,803)	\$ (7,042,240)	\$ 3,190,935

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

	Preferred Stock	Common	ı Stock	Treasury Sha	ares	Additional Paid-In	Deferred Stock Based		Total Stockholders'
	Shares Amount	Shares	Amount	Shares Am	ount		Compensation	Development Stage	Equity (Deficiency)
Balance, January 31, 2005	0 \$ 0	17,306,891		0 \$		-	•	\$ (7,042,240)	
Private placement of common stock		102,564	10			199,990			200,000
Payment of selling agents fees and									
expenses in cash						(179,600)	)		(179,600)
Common stock issued to selling									
agents		24,461				(2)	)		0
Private placement of common stock		1,515,384	152			2,954,847			2,954,999
Payment of selling agents fees and						(200,000			(200,000)
expenses in cash						(298,000)	)		(298,000)
Issuance of 121,231 warrants issued to selling agents						222,188			222,188
Selling agents warrants charged to						222,100			222,100
cost of capital						(222,188	)		(222,188)
Private placement of preferred stock						(222,100	,		(222,100)
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)	0
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 105,432 warrants issued						167.007			167.207
to selling agents						167,397			167,397
Selling agents warrants charged to cost of capital						(167,397)	`		(167,397)
Return of treasury shares from						(107,397)	)		(107,397)
escrow		(350,000	)) (35)	350,000	35				0
Retirement of treasury shares		(330,000	(33)	(350,000)	(35)	35			0
Common stock issued for services		5,000	0	(220,000)	(55)	16,500			16,500
Stock-based compensation expense		2,000				20,200			,
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	18,604,300	\$ 1,860	0 \$	0 3	\$20,264,807	\$ (1,045,971)	\$ (15,740,263)	\$ 3,480,710

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

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

	Preferred Stock	Common	Stock	Additional Paid-In	Deferred Stock Based	Deficit Accumulated During Someone	Total tockholders' Equity		ry Equity istered on Stock
	Shares Amount	Shares	Amount		Compensation		Deficiency)	Shares	Amount
Balance, January 31, 2006	277,100 \$ 277	18,604,300	\$ 1,860			\$ (15,740,263)			\$
Conversion of Series A preferred									
stock and issuance of common									
stock	(174,000) (174)	826,431	83	91					
Implementation of ASC 718				(1,045,971)	1,045,971		0		
Private placement of common									
stock		754,721	75	943,326			943,401		
Payment of selling agents fees and									
expenses in cash				(118,341)	)		(118,341)		
Issuance of 94,672 warrants to									
selling agents				55,568			55,568		
Selling agents warrants charged to									
cost of apital				(55,568)	)		(55,568)		
Issuance of common stock and									
warrants for cash at \$1.00 per									
share								1,000,000	1,000,000
Payment of finders fees and									
expenses in cash									(80,000)
Value of warrants classified as									
derivative financial instrument									
liability									(15,000)
Issuance of 164,550 units to finder				167,856			167,856		
Common Stock issued for services		8,696	1	9,565			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 ASC 815-40				567,085		(455,385)	111,700		
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	20,194,148	\$ 2,019	\$24,516,416	\$ 0	\$ (23,388,879)	\$ 1,129,659	1,000,000	\$ 905,000

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## $Condensed\ Consolidated\ Statements\ of\ Stockholders'\ Equity\ (Deficiency)\ (Continued)$

	Preferred	l St	ock	Common	Stock	Additional Paid-In	Deficit Accumulated During Development	Total Stockholders' Equity	Temporar Unregis Common	stered
	Shares	Am	ount	Shares	Amount		Stage	(Deficiency)	Shares	Amount
Balance, January 31, 2007	103,100			20,194,148	\$ 2,019		\$ (23,388,879)		1,000,000	\$ 905,000
Conversion of preferred stock to										
common stock	(7,500)	)	(7)	46,875	5	2				
Private placement of common										
stock				1,700,000	170	849,830		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)	. , ,		
Net loss							(4,683,141)	(4,683,141)		
Balance, December 31, 2007	95,600	\$	96	21.941.023	\$ 2.194	\$26,458,991	\$ (28,107,074)	(1,645,793)	1,000,000	\$ 905,000
Reclassification of common stock	,			, , , , ,	. , .	,,	1 ( 2, 21,21 )	( ): : ):: : )	,,,,,,,,,	, ,
initially recorded as temporary										
equity				1,000,000	100	904,900		905,000	(1,000,000)	(905,000
Private placement of common				2,000,000		, , , , , , ,		, ,,,,,,,	(2,000,000)	(, ,,,,,,,,,,
stock				1,984,091	198	1,144,802		1,145,000		
Payment of selling agents fees and				, , , , , ,		, ,		, ,,,,,,		
expenses						(74,500)		(74,500)		
Conversion of debenture to						(- , /		(- , ,		
common stock				187,282	19	93,622		93,641		
Derivative liability warrants at				,-0 <b>-</b>		, , , , , , ,		, -,		
issuance						(201,122)		(201,122)		
Donated services						390,750		390,750		
Stock based compensation						543,697		543,697		
Preferred stock dividend							(38,240)			
Net loss							(5,166,240)	. , ,		
Balance, December 31, 2008	95,600	\$	96	25,112,396	\$ 2,511	\$29,261,140	\$ (33,311,554)	\$ (4,047,807)	0	\$ 0

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

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

						Additional	Deficit Accumulated During	Total Stockholders'	
	Preferre	referred Stock		Preferred Stock Common Stock		on Stock Paid-In		During	Equity
	Shares	Amo	ount	Shares	Amount	Capital	Stage	(Deficiency)	
Balance December, 31, 2008	95,600	\$	96	25,112,396	\$ 2,511	\$ 29,261,140	\$ (33,311,554)	\$ (4,047,807)	
Issuance of shares of common stock in connection									
with convertible debenture forbearance agreement				5,437,472	544	1,739,415		1,739,959	
Issuance of shares of common stock in payment of									
convertible debenture interest				360,881	36	112,255		112,291	
Private placements of common stock				2,930,000	293	1,464,707		1,465,000	
Issuance of common stock pursuant to a									
non-exclusive selling agent's agreement '				413,379	41	306,696		306,737	
Issuance of shares of common stock re settlement									
for consulting services rendered				957,780	96	478,794		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	35,211,908	\$ 3,521	\$ 32,043,275	\$ (35,833,601)	\$ (3,786,709)	

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

							Accumulated Deficit	Total
	Preferre	d St	ock	Common	Stock	Additional Paid-In	During Development	Stockholders' Equity
	Shares	Am	ount	Shares	Amount	Capital	Stage	(Deficiency)
Balance, December 31, 2009	95,600	\$	96	35,211,908	\$ 3,521	32,043,275	(35,833,601)	\$ (3,786,709)
Issuance of shares of common stock in								
payment of convertible debenture interest				513,712	51	115,920		115,971
Issuance of common stock to selling agents				476,000	48	(48)		
Private placement of units				3,469,400	347	1,734,353		1,734,700
Derivative liability price protected units upon								
issuance						(1,010,114)		(1,010,114)
Consulting services settled via issuance of								
stock				425,000	43	212,457		212,500
Shares issued in settlement of legal fees				175,439	17	99,983		100,000
Stock issued in payment of deferred salary to								
former CEO				76,472	8	28,338		28,346
Shares issued in connection with								
Agreement & Plan of Merger with								
Etherogen, Inc,				12,262,782	1,226	2,770,163		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	52,610,713	\$ 5,261	36,320,257	\$ (41,320,979)	\$ (4,995,365)

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## Condensed Consolidated Statements of Stockholders' Equity (Deficiency) (Continued)

								Deficit Accumulated	
	Preferred	Pref	erred	Common	Co	ommon	Additional	During	Total
	Stock	Sto	ock	Stock	5	Stock	Paid-In	Development	Stockholders'
	Shares	Am	ount	Shares	A	mount	Capital	Stage	Deficiency
Balance, December 31, 2010	95,600	\$	96	52,610,713	\$	5,261	\$ 36,320,257	\$ (41,320,979)	\$ (4,995,365)
Issuance of shares of common stock in payment of convertible									
debenture interest in accordance with Forbearance Agreement				385,284		38	85,237		85,275
Private placement of units				5,147,000		515	2,572,985		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				250,500		25	125,225		125,250
Issuance of common stock to shareholder as finder's fees				541,550		54	(54)		
Issuance of common stock in connection with consulting services				350,000		35	174,965		175,000
Stock issued in connection with conversion of convertible									
debentures				5,137,110		514	1,129,650		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	64,422,157	\$	6,442	\$ 39,360,625	\$ (43,598,431)	\$ (4,231,268)
Private placement of units	,			1,900,000	_	190	949,810	+ (10,000,100)	950,000
Derivative liability-fair value of warrants and price protected				-,,,			, ,,,,,,		20,000
units issued							(385,329)		(385,329)
Correction of error in derivative liability fair value of warrants							(= == ,= == )		(===,==,)
price protected units issued							274.967		274,967
Issuance of common stock and warrant to shareholder as finder's							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		, ,
fees				74,700		7	(7)		
Payment of selling agent fees and expenses							(60,500)		(60,500)
Issuance of common stock in connection with Asset Purchase							, , ,		
Agreement with MultiGen Diagnostics, Inc.				750,000		75	187,425		187,500
Stock based compensation							102,830		102,830
Preferred stock dividend							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	(9,560)	(9,560)
Net loss								(1,162,642)	(1,162,642)
								, , ,	
Balance, March 31, 2012	95,600	\$	96	67,146,857	\$	6,714	\$ 40,429,821	\$ (44,770,633)	\$ (4,334,002)

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

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## **Condensed Consolidated Statements of Cash Flows**

Operating activities	ended	e Months March 31, 2012	Three Mon ended Marcl 2011		Au (Ir	r the period gust 4, 1999 aception) to rch 31, 2012
· •	\$	(1.162.642)	¢ (551	007)	¢	(42 204 914)
Net loss	\$	(1,162,642)	\$ (55)	,987)	\$	(43,204,814)
Adjustments to reconcile net loss to net cash used in operating activities:  Depreciation and amortization		6,190	_	2,555		227,989
*		102,830		1,160		
Stock based compensation expense Founders compensation contributed to equity		102,830	02	F,10U		11,583,155 1,655,031
Donated services contributed to equity						
Settlement of consulting services in stock						829,381 478,890
Amortization of deferred debt costs and original issue discount						2,346,330
Liquidated damages and other forbearance agreement settlement costs paid in stock Interest expense on convertible debentures paid in stock			20	3,511		1,758,111
1		22.424		1		757,198
Change in fair value of financial instruments		32,424	(190	5,331)		(1,193,582)
Gain on extinguishment of debt						(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 issued in connection with consulting services						287,500
Changes in operating assets and liabilities:			(4.4			(60,004)
Decrease (increase) in other assets		22 (07	,	),824)		(69,881)
Decrease (increase) in accounts receivable		22,607	,	,093)		(76,533)
Decrease (increase) in prepaid expenses		217	,	),157)		(42,441)
Increase (decrease) in accounts payable, accrued expenses and other		93,286	17/2	1,513		1,509,654
Net cash used in operating activities		(905,088)	(568	3,653)		(20,982,180)
Investing activities:						
Assets acquired in Etherogen, Inc. merger						(104,700)
Capital expenditures		(98,009)	(1	,528)		(342,312)
Net cash used in investing activities		(98,009)	(1	,528)		(447,012)
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		889,500	600	0,000		18,321,505
Proceeds from a non-exclusive selling agent's agreement						142,187
Note (repayment)						
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		889,500	600	0,000		22,015,969
Net change in cash and equivalent-(decrease)increase  Cash and cash equivalents Beginning of period		(113,597) 700,374		9,819 3,703		586,777
Cash and cash equivalents End of period	\$	586,777	\$ 88	3,522	\$	586,777
Supplementary disclosure of cash flow activity:						

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Cash paid for taxes	\$ \$		\$
Cash paid for interest	\$ \$		\$
Supplemental disclosure of non-cash investing and financing activities:	·		
Conversion of 174,000 shares of preferred stock into 826,431 shares of common stock:			
Surrender of 174,000 shares of preferred stock	\$ \$		\$ (1,740,000)
Issuance of 826,431 shares of common stock	\$ \$		\$ 1,740,000
Issuance of 750,000 shares of common stock pursuant to Asset Purchase Agreement with			
Multigen Diagnostics, Inc.	\$ 187,500 \$		\$ 187,500
Issuance of 250,500 shares of common stock for Board of Directors' fees in lieu of cash			
payment	\$ \$	125,250	\$ 125,250
Conversion of \$2,335,050 of 6% debentures	\$ \$		\$ 1,130,164
Series A Preferred beneficial conversion feature accreted as a dividend	\$ \$		\$ 792,956
Preferred stock dividends accrued	\$ 9,560 \$	9,560	\$ 152,960
Interest paid on common stock	\$ \$	28,511	\$ 1,325,372

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

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

#### **Notes to Condensed Consolidated Financial Statements**

## 1. Condensed Consolidated Financial Statements

**Business Overview** 

Trovagene, Inc. ("Trovagene" or the "Company") is a development stage molecular diagnostic company that focuses on the development and marketing of urine-based nucleic acid tests for patient/disease screening and monitoring. The Company's novel tests predominantly use transrenal DNA (Tr-DNA) and transrenal RNA (Tr-RNA). Trovagene's primary focus is to leverage its urine-based (i.e. transrenal) testing platform to facilitate improvements in the management of cancer care and women's healthcare. Tr-DNAs and Tr-RNAs are fragments of nucleic acids derived from dying cells inside the body. The intact DNA is fragmented in dying cells and released into the blood stream. These fragments have been shown to cross the kidney barrier and can be detected in urine. In addition, there is evidence that some species of RNA or their fragments are stable enough to cross the renal barrier. These RNA can also be isolated from urine, detected and analyzed. The Company believes its technology is applicable to all transrenal nucleic acids (Tr-NA). Trovagene's patented technology uses safe, non-invasive, cost effective and simple urine collection which can be applied to a broad range of testing including: tumor detection and monitoring (e.g., KRAS mutations in pancreatic cancer), prenatal genetic testing, infectious diseases, tissue transplantation, forensic identification and for patient selection in clinical trials. Trovagene believes that its 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 the disease process. If the Company is successful, its novel assays may facilitate improved testing compliance resulting in earlier diagnosis of disease, more targeted treatment which will be more cost effective, and improvements in the quality of life for the patient.

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Trovagene, which include its wholly owned subsidiary Xenomics, Inc., a California corporation ("Xenomics Sub") 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. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements as of December 31, 2011 and December 31, 2010 and from inception (August 4, 1999) to December 31, 2011 and for each of the two years ended December 31, 2011 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2012. The accompanying financial statements have been prepared by the Company without audit. In the opinion of management, all adjustments (which include only normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at March 31, 2012, and for all periods presented herein, have been made. The results of operations for the periods ended March 31, 2012 and 2011 are not necessarily indicative of the operating results for the full year.

## Going Concern

Trovagene's condensed consolidated financial statements as of March 31, 2012 have been prepared under the assumption that Trovagene 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,

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Condensed Consolidated Financial Statements (Continued)**

### 1. Condensed Consolidated Financial Statements (Continued)

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 required to raise additional capital within the next two 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 \$905,088 and \$568,653, for the three months ended March 31, 2012 and 2011, respectively. During the three months ended March 31, 2012 and 2011, the Company incurred net losses attributable to common stockholders of \$1,172,202 and \$561,547, respectively.

To date, Trovagene's sources of cash have been primarily limited to the sale of debt and equity securities. Net cash provided by financing activities for the three months ended March 31, 2012 and March 31, 2011 was \$889,500 and \$600,000, 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.

The Company has approximately \$823,000 of cash in the bank at May 11, 2012. Based on the Company's projections of future ordinary expenses and expected receipts the Company has enough cash to pay expenses through July of 2012.

Trovagene will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. Trovagene cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that Trovagene raises additional funds by issuing equity securities, Trovagene's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact Trovagene's ability to conduct business. If Trovagene is unable to raise additional capital when required or on acceptable terms, Trovagene may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more 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 Trovagene would otherwise seek to develop or commercialize ourselves on unfavorable terms.

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### 2. Net Loss Per Share

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 guideance, basic and diluted net income/loss per common share was determined by dividing net income/loss applicable to common stockholders by the weighted-average common shares outstanding during the period.

Diluted weighted-average shares are the same as basic weighted-average shares when the shares issuable pursuant to the exercise of dilutive instruments would have been antidilutive.

For the three months ended March 31, 2012 and 2011, certain of the outstanding stock options and other common stock equivalents were excluded from the calculation of diluted income per share because the effect was anti-dilutive. The amounts excluded in the three months ended March 31, 2012 and 2011 were 41,354,444 and 37,031,089, respectively. Basic and diluted weighted average units outstanding were the same.

## 3. Accounting for Share-Based Payments

## Stock Options

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 to be 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 Trovagene accounts for non-employee stock-based compensation. Trovagene accounts for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the 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" whereas the value of the stock 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.

Stock-based compensation expense related to Trovagene options have been recognized in operating results as follow:

	Three Months Ended March 31,				
		2012		2011	
Included in research and development expense	\$	7,583	\$	21,709	
Included in general and administrative expense		95,247		42,451	
Total stock-based compensation expense	\$	102,830	\$	64,160	

The unrecognized compensation cost related to non-vested employee stock options outstanding at March 31, 2012 and 2011, net of expected forfeitures, was \$875,885 and \$302,726, respectively, to be recognized over a weighted-average remaining vesting period of approximately four years and three

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

## 3. Accounting for Share-Based Payments (Continued)

years, respectively. This unrecognized compensation cost does not include amounts related to stock options which vest upon change of control.

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 weighted-average assumptions during the following periods indicated.

	Three Months Ended March 31, 2012	Three Months Ended March 31, 2011
Risk-free interest rate	1.04%	1.23%
Dividend yield	0%	0%
Expected volatility	90%	90%
Expected term (in years)	5.0 yrs.	5.0 yrs.

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

	Number of Options	Options Per Share				I	intrinsic Value
Balance outstanding, December 31, 2011	14,557,151	\$	0.50 to 2.50	\$	0.87	\$	
Granted	3,270,000		0.50 to 0.78		0.62		396,720
Forfeited	(56,250)		0.50		0.50		
Balance outstanding, March 31, 2012	17,770,901	\$	0.50 to 2.50	\$	0.82	\$	
Exercisable at March 31, 2012	9,550,504	\$	0.50 to 2.50	\$	1.06	\$	
Warrants							

The Company issued 1,974,700 warrants, whose weighted average exercise price was \$.50 per share, in the three months ended March 31, 2012, all of which were issued in connection with private placements of its common stock.

### 4. Stockholder's Deficiency

During the three months ended March 31, 2012, the Company closed two private placement financings which raised gross proceeds of \$950,000. The Company issued 1,900,000 shares of its common stock and warrants to purchase 1,900,000 shares of common stock. The purchase price paid by the investor was \$.50 for each unit, determined by the price paid by investors in recent private placements. The warrants expire after eight years and are exercisable at \$0.50 per share. The Company paid \$60,500 in cash for a finder's fee. 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 these private placements should be recorded as derivative liabilities since they are all price protected (Note 6). The fair value is disclosed in Note 7.

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

## **Notes to Condensed Consolidated Financial Statements (Continued)**

### 4. Stockholder's Deficiency (Continued)

During the three months ended March 31, 2012, the Company issued 74,700 units to a selling agent, who is also a shareholder of the Company, consisting of 74,700 shares of common stock and warrants to purchase 74,700 shares of common stock. The warrants have an exercise price of \$0.50 per share, are immediately exercisable and expire December 31, 2018. The units were issued as a finder's fee in connection with certain private placements closed during the three months ended March 31, 2012. The issuance of these units was treated as a non-compensatory cost of capital.

During the three months ended March 31, 2012, the Company issued 750,000 shares of common stock in connection with an asset purchase agreement with MultiGen Diagnostics, Inc. See Note 5.

#### 5. Asset Purchase Agreement

On February 1, 2012 the Company entered into an asset purchase agreement with MultiGen Diagnostics, Inc. The Company determined that the acquired asset does not meet the definition of a business, as defined in ASC 805, *Business Combinations* and will be accounted for under ASC 350, *Intangibles Goodwill and Other*. In connection with the acquisition, the Company issued 750,000 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.

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 a fair value of \$0 by applying a weighted average probability on the achievement of the milestones developed during the valuation process. The Company will assess the fair value of the contingent consideration at each quarter and make adjustments as necessary until the milestone dates have expired.

## 6. Derivative Financial Instruments

Effective January 1, 2009, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

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 certain of its private placements and with its debentures must be recorded as derivative liabilities. Accordingly the warrants are also being re-measured at each balance sheet date based on estimated fair value, and any resultant changes in fair value is being recorded in the Company's statement of operations.

## Trovagene, Inc. and Subsidiaries (A Development Stage Company)

## **Notes to Condensed Consolidated Financial Statements (Continued)**

## **6. Derivative Financial Instruments (Continued)**

The Company estimates the fair value of the warrants issued in connection with certain of its private placements and with its debentures using the Black-Scholes model in order to determine the associated derivative instrument liability and change in fair value described above. The range of assumptions used to determine the fair value of the warrants at the end of each three month period, March 31, 2012 and March 31, 2011 were as follows:

	Three Mo Endec March : 2012	l Ma	ee Months Ended arch 31, 2011	
Estimated fair value of Trovagene common stock	\$	.25	\$	.23
Expected warrant term	5	years		5 years
Risk-free interest rate		1.04%		2.11%
Expected volatility		90%		100%
Dividend yield				

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	Warrants	Iı	Derivative nstrument Liability
12/31/2011	Balance of derivative financial instruments liability	6,622,359	\$	994,627
	Change in fair value of warrants during the quarter recognized as a loss in the statement of operations			51,340
3/31/2012	Balance of derivative financial instruments liability	6,622,359	\$	1,045,967

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:

	Number of Price Protected Units at	Deriva	Change In Fair value of Derivative Liability For Previously Outstanding Derivative Liability Price Protected		Ending Balance Derivative		
Quarter	Issuance	For I	Issued Units		Units		Liability
Total at 12/31/11	13,928,704	\$	2,967,283	\$	(121,266)	\$	2,846,017
Correction of error	(1,344,524)		(274,967)				2,571,050
Quarter ended 3/31/2012	1,900,000		385,330		(18,916)	\$	2,937,464
	14,484,180	\$	3,077,646	\$	(140,182)	\$	2,937,464

The total derivative liability for the Company at March 31, 2012 was \$3,983,430.

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

## **Notes to Condensed Consolidated Financial Statements (Continued)**

#### **6. Derivative Financial Instruments (Continued)**

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 price protected units at issuance. The effect of this correction on the statement of operations for the quarter ended March 31, 2012 was deminimus.

## 7. Fair Value Measurements

Fair value of financial instruments

The Company has 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. Financial instruments consist of cash and cash equivalents, accounts receivable and accounts payable. These financial instruments are stated at their respective historical carrying amounts which approximate fair value due to their short term nature.

The following tables present the Company's 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, 2011 and March 31, 2012:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of March 31, 2012
Derivative liabilities related to Warrants	\$	\$	\$ 3,983,431	\$ 3,983,431

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the three months ended March 31, 2012:

			Fair Value of Warrants			
			Exercised			
			and	Fair value of		
			Reclassified	New		
			to	Warrants		
	Balance at		Additional	Issued	Unrealized	Balance as of
	December 31,	Correction	Paid in	During	(gains) or	March 31,
Description	2011	of error	Capital	the Period	losses	2012
Derivative liabilities related						
to Warrants	\$ 3,840,644	\$ (274,967)	\$	\$ 385,329	\$ 32,424	\$ 3,983,431

# Trovagene, Inc. and Subsidiaries (A Development Stage Company)

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### 7. Fair Value Measurements (Continued)

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.

## 8. Commitments and Contingencies

**Employment and Consulting Agreements** 

On February 1, 2012, the Company entered into an executive agreement with Stephen Zaniboni in which he agreed to serve as Trovagene's 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. 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 1,000,000 non-qualified stock options which have an exercise price of \$0.60 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.

## Consulting Agreements

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 1,000,000 shares of common stock at \$0.75 per share. Options to purchase 200,000 shares of common stock vest ratably over a four year period. Options to purchase 800,000 shares of common stock vest upon achievement of various milestones. See Note 3.

On February 1, 2012 the Company entered into a consulting agreement whereby the Company retained the services of an independent contractor who will provide public relations and publicity services for the Company. As compensation for the consultant's services, the Company will pay a monthly fee and issue 8,500 shares of restricted common stock monthly. See Note 3.

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

#### **Notes to Condensed Consolidated Financial Statements (Continued)**

#### 9. Subsequent Events

Private Placements

On April 13, 2012, the Company closed a private placement financing which raised gross proceeds of \$650,000. The Company issued 1,300,000 shares of its common stock and warrants to purchase 1,300,000 shares of common stock in this transaction. The purchase price paid by the investors was \$.50 for each unit. The warrants expire on December 31, 2018 and are exercisable at \$.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovagene has determined that the units, which are price protected, issued in connection with these private placements should be recorded as derivative liabilities. In connection with the financing 54,000 shares of common stock and warrants to purchase 54,000 shares of common stock were issued for finder's fees, as well as a cash payment for finder's fees in the amount of \$18,000. The Company also entered into a registration rights agreement with the investors pursuant to which the Company agreed to file a registration statement registering the shares of common stock and the shares of common stock underlying the warrants ninety days after the date that the Company's common stock is listed on Nasdaq or the NYSE Amex.

On May 2, 2012 the Company closed a private placement financing which raised gross proceeds of \$300,000. The Company issued 600,000 shares of its common stock and warrants to purchase 1,300,000 shares of common stock in this transaction. The purchase price paid by the investors was \$.50 for each unit. The warrants expire on December 31, 2018 and are exercisable at \$.50 per share. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Trovagene has determined that the units, which are price protected, issued in connection with these private placements should be recorded as derivative liabilities. In connection with the financing 54,000 shares of common stock and warrants to purchase 54,000 shares of common stock were issued for finder's fees, as well as a cash payment for finder's fees in the amount of \$18,000. The Company also entered into a registration rights agreement with the investors pursuant to which the Company agreed to file a registration statement registering the shares of common stock and the shares of common stock underlying the warrants ninety days after the date that the Company's common stock is listed on Nasdaq or the NYSE Amex.

#### Consulting Agreement

On April 26, 2012 the Company entered into a consulting agreement whereby the Company retained the services of an independent contractor to serve on Trovagene's Scientific Advisory Board. As compensation for the consultant's services, the Company granted a stock option to purchase up to 600,000 shares of common stock at \$0.61 per share. Options to purchase the shares of common stock vest ratably over a three year period.

Special Meeting of Stockholders

On April 27, 2012, the Company held a special meeting of stockholders where the following items were approved:

- 1. An amendment to the Company's 2004 Stock Option Plan to increase the number of shares issuable thereunder to 22,000,000 shares from 12,000,000 shares;
- 2. An amendment to 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 more than one-for-six at any time prior to April 27, 2013, with

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

## **Notes to Condensed Consolidated Financial Statements (Continued)**

## 9. Subsequent Events (Continued)

the exact ratio to be set at a whole number within this range as determined by the Board of Directors in its sole discretion (this has not occurred as of the date of this filing); and

3. An amendment to the Company's Amended and Restated Certificate of Incorporation to effect an increase in the authorized shares of common stock, par value \$0.0001 per share, of the Company from 100,000,000 to 150,000,000.

F-77

4,500,000 Shares

**Common Stock** 

PROSPECTUS

# **Aegis Capital Corp**

**Summer Street Research Partners** 

Brean Murray, Carret & Co.

, 2012

#### PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 13. Other Expenses of Issuance and Distribution

The following table provides information regarding the various actual and anticipated expenses (other than underwriters' discounts) payable by us in connection with the issuance and distribution of the securities being registered hereby. All amounts shown are estimates except the Securities and Exchange Commission registration fee, the FINRA filing fee and the NASDAQ initial listing fee.

Item	Amount
SEC registration fee	\$ 2,877.61
FINRA filing fee	\$ 2,903.75
NASDAQ initial listing fee	75,000
Legal fees and expenses	225,000
Accounting fees and expenses	90,000
Printing and engraving expenses	50,000
Transfer agent and registrar fees and expenses	3,000
Miscellaneous fees and expenses	1,218.64
·	
Total	\$ 450,000

To be completed by amendment.

## Item 14. Indemnification of Directors and Officers

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

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

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

any breach of the director's duty of loyalty to the corporation or its stockholders;

acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

payments of unlawful dividends or unlawful stock repurchases or redemptions; or

#### **Table of Contents**

any transaction from which the director derived an improper personal benefit.

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

#### Item 15. Recent Sales of Unregistered Securities

During the year ended December 31, 2010, the Company closed twelve private placement financings which raised aggregate gross proceeds of \$1,734,700. The Company issued 693,880 shares of its common stock and warrants to purchase 693,880 shares of common stock in these transactions. The purchase price paid by the investors was \$2.50 for each unit. Each of the investors was an accredited investor. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share.

During the year ended December 31, 2010, the Company granted to its directors, officers and employees options to purchase 320,600 shares of its common stock with per share exercise prices ranging from \$2.50 to \$3.60 under its 2004 Stock Option Plan. In addition, the Company granted to former officers of the Company non-plan options to purchase 155,000 of its common stock with per share exercise prices ranging from \$2.50 to \$3.75 in settlement of litigation.

During the year ended December 31, 2011, the Company closed eighteen private placement financings which raised aggregate gross proceeds of \$2,573,500. The Company issued 1,029,400 shares of its common stock and warrants to purchase 1,029,400 shares of common stock in these transactions. In addition, the Company issued 7,000 shares of common stock and 7,000 warrants to purchase 7,000 shares of common stock as a finder's fee. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share. Each of the investors was an accredited investor.

During the year ended December 31, 2011, the Company granted to its officers, employees and consultants options to purchase 776,800 shares of its common stock with a per share exercise price of \$2.50 under its 2004 Stock Option Plan.

During the three months ended March 31, 2012, the Company closed two private placements which raised aggregate gross proceeds of \$950,000. The Company issued 380,000 shares of its common stock and warrants to purchase 380,000 shares of common stock in this transaction. In addition, the Company issued 14,940 shares of common stock and warrants to purchase 14,940 shares of common stock as a finder's fee. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share. Each of the investors was an accredited investor.

During the three months ended March 31, 2012, the Company granted to its directors, officers, employees and consultants options to purchase 654,000 shares of its common stock with per share exercise prices ranging from \$2.50 to \$3.75 under its 2004 Stock Option Plan. In addition, in January 2012, the Company issued 150,000 shares of its common stock as consideration to a company in connection with its purchase of certain assets from the company.

On April 13, 2012, the Company closed a private placement which raised gross proceeds of \$650,000. The Company issued 260,000 shares of its common stock and warrants to purchase 260,000 shares of common stock in this transaction. In addition, the Company issued 10,800 shares of common stock and warrants to purchase 10,800 shares of common stock as a finder's fee. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire December 31, 2018 and are exercisable at \$2.50 per share. Each of the investors was an accredited investor.

## Table of Contents

On April 24, 2012, the Company issued a warrant to purchase 60,000 shares of common stock to a director for consulting services with a per share exercise price of \$3.45.

On April 26, 2012, the Company granted to a new member of its Scientific Advisory Board options to purchase 120,000 shares of common stock with a per share exercise price of \$3.05 under its 2004 Stock Option Plan.

On May 2, 2012, the Company closed a private placement which raised gross proceeds of \$300,000. The Company issued 120,000 shares of its common stock and warrants to purchase 120,000 shares of its common stock in this transaction. In addition, the Company issued 10,800 shares of common stock and warrants to purchase 10,800 shares of common stock as a finder's fee. The purchase price paid by the investors was \$2.50 for each unit. The warrants expire on December 31, 2018 and are exercisable at \$2.50 per share. Each of the investors was an accredited investor.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

#### Item 16. Exhibits and Financial Statement Schedules

- 1.1 Form of Underwriting Agreement.\*\*
- 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 Proposed Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed March 20, 2012).
- 3.3 Bylaws of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011).
- 4.1 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).
- 4.2 Form of Representative's Warrant Agreement.\*\*
- 4.3 Form of Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on April 16, 2012)
- 4.4 Form of Registration Reports Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on April 16, 2012)
- 5.1 Opinion of Sichenzia Ross Friedman Ference LLP.\*\*
- 10.1 Employment Agreement between TrovaGene, Inc. and David Robbins dated October 7, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Form 10-12G filed on November 25, 2011).
- 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).

#### **Table of Contents**

- 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).
- 10.7 Amendment to Co-Exclusive Sublicense Agreement dated June 1, 2010 between TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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).
- 10.12 Asset Purchase Agreement dated as of January 18, 2011 by and between TrovaGene, Inc. and TTFactor S.r.l. (incorporated by reference to Exhibit 10.12 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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).

#### **Table of Contents**

- 10.17 Asset Purchase Agreement dated as of January 6, 2012 by and among TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TroyaGene, 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 TrovaGene, 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).
- 10.23 Exclusive License Agreement effective as of May 2006 by and between Brunangelo Falini, Cristina Mecucci and TrovaGene, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Form 10-12G/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).
  - 21 List of Subsidiaries (incorporated by reference to Exhibit 21 to the Company's Form 10-12G filed on November 25, 2011).
- 23.1 Consent of Independent Registered Public Accounting Firm\*\*
- 23.2 Consent of Sichenzia Ross Friedman Ference LLP (included in Exhibit 5.1)\*\*
- 24.1 Power of Attorney (included on the signature page to this Registration Statement)\*

Previously filed.

Filed herewith

## Item 17. Undertakings.

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

## Table of Contents

public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

- (i) The undersigned Registrant hereby undertakes that it will:
  - (1) for determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant under Rule 424(b)(1), or (4) or 497(h) under the Securities Act as part of this registration statement as of the time the Commission declared it effective.
  - (2) for determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 2 to registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, California, on May 18, 2012.

ΓROVAGENE. INC.	
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By:	/s/ ANTONIUS SCHUH, PH.D		
_	Antonius Schuh, Ph.D.		
	Chief Executive Officer and Director		

## POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

	Signature	Title	Date
	/s/ ANTONIUS SCHUH	Chief Executive Officer and Director	May 18, 2012
	Antonius Schuh	(Principal Executive Officer)	
	*	Chief Financial Officer	
	Steve Zaniboni	(Principal Financial and Accounting Officer)	May 18, 2012
	*		May 18, 2012
	Thomas H. Adams	Chairman of the Board	
	*		10.2012
John P. Branc	John P. Brancaccio	Director	May 18, 2012
	*		
	Gary S. Jacob	Director	May 18, 2012
	*		
	Gabriel M. Cerrone	Director	May 18, 2012
	*		
	Stanley Tennant	Director	May 18, 2012
Ву:	/s/ ANTONIUS SCHUH		
	Antonius Schuh As Attorney-in-Fact		

#### **EXHIBIT INDEX**

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- 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).
- 10.7 Amendment to Co-Exclusive Sublicense Agreement dated June 1, 2010 between TrovaGene, 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 TrovaGene, 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 TrovaGene, Inc. and Ipsogen SAS (incorporated by reference to Exhibit 10.9 to the Company's Form 10-12G/A filed on February 15, 2012).

## Table of Contents

- 10.10 Sublicense Agreement dated as of January 8, 2008 between TrovaGene, 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 TrovaGene, 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).
- 10.12 Asset Purchase Agreement dated as of January 18, 2011 by and between TrovaGene, Inc. and TTFactor S.r.l. (incorporated by reference to Exhibit 10.12 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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 TrovaGene, 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).
- 10.23 Exclusive License Agreement effective as of May 2006 by and between Brunangelo Falini, Cristina Mecucci and TrovaGene, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Form 10-12G/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).

## Table of Contents

- 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 (incorporated by reference to Exhibit 21 to the Company's Form 10-12G filed on November 25, 2011).
- 23.1 Consent of Independent Registered Public Accounting Firm.\*\*
- 24.1 Power of Attorney (Included on the signature page to this Registration Statement).\*

Previously filed.

Filed herewith