TrovaGene Inc.
Form 10-K
March 30, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 000-54556

TROVAGENE INC.

(Name of small business issuer in its charter)

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

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

(Address of principal executive offices) (Zip Code)

Issuer s telephone Number: **(858) 217-4838**

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

Securities registered under Section 12(g) of the Exchange Act: **Common Stock, $0.0001 par value**

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

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

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

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

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

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o	Smaller reporting company x

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates (based on a closing sale price of $0.16 per share which was the last sale price of the common stock as of June 30, 2011) was $7,150,585.

As of March 29, 2012, the issuer had 67,146,857 outstanding shares of Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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PART I

ITEM 1. BUSINESS

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. 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 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, 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 very simple, non-invasive and convenient screening and monitoring tests for their patients by identifying specific biomarkers involved in a disease process. Our 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.

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 IDT. Special chemical modifications of synthetic DNA and RNA are available from ABI (now part of Life Technologies) 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 very well respected 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.

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

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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 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 23, 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. 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 23, 2012, the amount paid to date to us under the agreement is $334,211. The license terminates if Asuragen fails to pay, or upon 30 day 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 second year, $20,000 for the third year and $25,000 thereafter. Through March 23, 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 23, 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 23, 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 23, 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.

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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 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 23, 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 $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 23, 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 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 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) approval and licensing documentation, laboratory procedures, customer lists and marketing materials. A CLIA lab is a clinical reference laboratory that can perform high complexity diagnostic assays (e.g. those requiring PCR amplification). Through this CLIA laboratory we are able to offer laboratory developed tests, 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. In connection with the acquisition, we issued 750,000 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.

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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 2,000,000 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 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 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, 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. We believe this patent position compares favorably to the Roche PCR and Gen-Probe ribosomal RNA patents in the molecular diagnostic field.

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 very 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, an impressive 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 test is non-invasive, much more convenient and private for the patient, simpler, less technically demanding in terms of cytology proficiency and cost effective. Our unique primer pair focused on the E1 region of the HPV genome should provide freedom to operate within the HPV patent landscape (i.e. we are confident 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 and launch of a product in the market.

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

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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 should 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 conservatively speaking 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 impressive 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

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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., 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 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

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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 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.

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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.

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. At 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, rules and it is our plan to establish an initial market presence and generate revenues prior to FDA clearance or approval.

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.

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Because 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 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, market and sell our transrenal products in predefined fields of use and geographic territories. We plan to become a fully integrated business in which we develop, manufacture, register, market and sell our products.

In comparison with many other genetic tests, our Tr-DNA or Tr-RNA tests will be very cost effective. It involves a very simple process and can easily be automated. Therefore, major advantages of our Tr-DNA or Tr-RNA test, when commercially available, will be the ease of sample collection, excellent sensitivity and specificity, patient convenience (i.e. home-based test), non-invasive and will 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 would 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.

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 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 March 12, 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. Additionally, we have filed three provisional patent applications with claims directed to methods of detecting Down Syndrome, detecting specific diseases caused by parasites, and methods for the purification of Nucleic Acids from urine. 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.

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

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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, 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, a cost/benefit analysis, assessing other available options and reviewing the published literature with respect to the results obtained from our clinical studies. Currently, CPT codes 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.

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 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

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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.

Employees

As of March 23, 2012 we had four full-time employees.

ITEM 1A. RISK FACTORS

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

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, we have an accumulated total deficit of $43,598,431. For the fiscal year ended December 31, 2011, we had net losses attributable to common stockholders of $2,277,452. 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.

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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.

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 March 29, 2012 our cash balance was $582,146 and our working capital deficit was $673,434. 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 three 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;
- 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 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

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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 as safe and effective diagnostic products,
- 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 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.

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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.

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 March 23, 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.

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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 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 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 tests, 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

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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 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 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 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 tests, 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

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

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

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

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

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

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

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

We cannot rely solely on our current patents to be successful. The standards that the U.S. Patent and Trademark Office and foreign patent 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 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.

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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.

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Risks Related to Our Common Stock

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 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.

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

Our Series A Convertible Preferred Stock includes various covenants limiting our ability to pay dividends and make other distributions and issuing securities senior or equivalent to the Series A Convertible Preferred Stock. We also granted the investors a participation right in future financings. These covenants may limit us in raising additional capital, competing effectively, or taking advantage of new business opportunities.

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

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

Our 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;
- reimbursement decisions by Medicare and other managed care organizations;
- FDA regulation of our products and services;
- the establishment of partnerships with clinical reference laboratories;

- health care legislation;
- intellectual property disputes;
- additions or departures of key personnel;
- sales of our common stock;
- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- 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

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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.

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

As of March 29, 2012, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 28.6% 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.

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

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

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

Our common stock is traded on the Pink Sheets 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. 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.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock currently trades over the counter on the pink sheets 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 Bulletin Board. Such over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly since our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market. The closing price of our common stock on the Pink Sheets on March 29, 2012 was $0.76 per share.

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

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

Number of Stockholders

As of March 29, 2012, we had 145 stockholders of record of our common stock.

Dividend Policy

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

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2011.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options and Warrants (a)	Weighted-Average Exercise Price of Outstanding Options and Warrants (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) ©

Equity Compensation Plans Approved by Stockholders(1)	9,982,151	$	1.03	2,017,849
Equity Compensation Plans Not Approved by Stockholders(2)	26,183,843	$	.53	
Total	36,165,994			

(1) Consists entirely of options.

(2) Of such amount, 21,608,843 are warrants. Such warrants have an exercise price equal to $0.50 per share except for 100,000 warrants which have an exercise price of $1.80 per share. All warrants are exercisable immediately and expire on December 31, 2018 except for (i) 100,000 warrants which expire on June 29, 2014, (ii) 140,000 warrants which expire on November 14, 2012, (iii) 100,000 warrants which expire on October 12, 2012 and (iv) 438,596 warrants which expire on October 29, 2013. The remaining amount equal to 4,575,000 consist of stock options not approved by the stockholders. We intend to obtain stockholder approval to increase the number of options available for issuance under our stock option plan as soon as possible.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Forward-Looking Statements

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

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

Overview

From August 4, 1999 (inception) through December 31, 2011 and 2010, we have sustained cumulative total deficits of $43,598,431 and $41,320,979, respectively. From inception through December 31, 2011, 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 completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 15. Financial Statements Note 3 *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.

- 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, 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 and $75,000 at December 31, 2011 and 2010, respectively, represent the minimum royalty payments due as of those dates.

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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, the fair value of such warrants was $994,627 and $609,155, 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, respectively. 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, the fair value of such price protected units was $2,846,017 and $1,476,783, respectively, which are included in the derivative financial instruments liability on our balance sheet.

At December 31, 2011 and 2010, 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 and $2,085,938, 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,		August 4, 1999 (Inception) to
	2011	2010	December 31, 2011
Salaries and staff costs	$ 468,893	$ 656,740	$ 9,776,573
Outside services, consultants and lab supplies	283,350	180,429	2,648,160
Facilities	137,793	157,467	2,598,693
Other	20,649	29,523	505,728
Total Research and development	$ 910,685	$ 1,024,159	$ 15,529,153

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.

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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 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.

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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 $0.55 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 5,437,472 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 6,083,763 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 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 in the year ended December 31, 2009.

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 our Board of Directors
- Conditions regarding the determination of compensation to be paid to our officers and directors
- 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 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 $128,421and $256,856, respectively, that was paid in 770,568 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.

On July 18, 2011 we 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 we issued an additional 467,010 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 $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 14, 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 the year ended December 31, 2011 on the 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.

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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. 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.

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Results of Operations

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:

	For the years 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.

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) approximately $264,000 in accounting fees (ii) an increase in outside consultants expense of approximately $160,000. This increase included $150,000 for the value of common stock issued to a consultant in the year ended December 31, 2011 and (iii) approximately $28,000 in legal fees 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

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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 December 31, 2011, we had $700,374 in cash and cash equivalents. Net cash used in operating activities for the year ended December 31, 2011 was $1,930,301, compared to $2,088,716 for the year ended December 31, 2010. Our use of cash was primarily a result of the net loss of $2,239,212 for the year ended December 31, 2011, adjusted for non-cash items related to stock-based compensation of $250,978, stock issued in connection with consulting service of $175,000, a gain on extinguishment of debt of $623,383, the gain on the change in fair value of financial instruments of $170,673, which were offset by other non-cash items totaling $66,921. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses and a decrease in prepaid expenses and other assets that resulted in a cash provision of $634,207, offset by an increase in accounts receivable that resulted in a cash usage of $24,141. 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 $1,528 in cash during the year ended December 31, 2011, compared to $132,447 for the same period in 2010.

Net cash provided by financing activities was $2,573,500 during the year ended December 31, 2011, compared to $1,734,700 in 2010. Financing activities during the year ended December 31, 2011 and 2010 were from proceeds received related to the sale of common stock.

As of December 31, 2011, and 2010, we had working capital deficits of $587,709 and $3,136,916, respectively. As of March 29, 2012, our working capital deficit was $673,434.

On July 18, 2011, we 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 we 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, 2017. 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.

On February 10, 2012, we closed a private placement which raised gross proceeds of $800,000. We issued 1,600,000 shares of our common stock and warrants to purchase 1,600,000 shares of common stock in this transaction. In addition, we issued 74,700 shares of common stock and warrants to purchase 74,700 shares of common stock as a finder s fee. The purchase price paid by the investors was $.50 for each unit. The warrants expire December 31, 2018 and are exercisable at $.50 per share.

On February 14, 2012, we closed a private placement which raised gross proceeds of $150,000. We issued 300,000 shares of our common stock and warrants to purchase 300,000 shares of common stock in this transaction. The purchase price paid by the investors was $.50 for each unit. The warrants expire December 31, 2018 and are exercisable at $.50 per share.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

This annual report does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Disclosure Controls and Procedures

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2011. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, as of December 31, 2011, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are not effective, 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.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter

ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded there were no such changes during the quarter ended December 31, 2011.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

EXECUTIVE OFFICERS, DIRECTORS AND KEY EMPLOYEES

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each as of March 29, 2012.

Name	Age	Position
Thomas H. Adams, PhD	68	Chairman of the Board
Antonius Schuh, Ph.D	47	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

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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 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. 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,

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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.

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 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.

• 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.

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.

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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 two standing committees Audit and Compensation. 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.

Compliance with Section 16(a) of the Exchange Act

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

Based on a review of the copies of such forms received, we believe that during 2011, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

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 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.

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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.

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

Code of Ethics

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

ITEM 11. EXECUTIVE COMPENSATION.

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.

Name & Principal Position	Year	Salary ($)	Option Awards ($) (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(4)	199,038	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 3,800,000 non-qualified stock options upon his appointment as CEO in October 2011.

(3) 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.

Name	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date

Dr. Antonius Schuh	2,850,000(1)		0.50	October 4, 2021
Dr. Andreas Braun	750,000(2)	$	0.60	February 26, 2020

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(1) The unexercisable options of 2,850,000 vest as follows: 950,000 each on October 4, 2012, 2013 and 2014.

(2) The unexercisable options of 750,000 vest as follows: 250,000 each on February 26, 2011, 2012 and 2013.

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	Option Awards(1)	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, 1,822,500 stock options were outstanding, of which 800,000 were exercisable.

(3) As of December 31, 2011, 215,747 stock options were outstanding, of which 182,414 were exercisable.

(4) As of December 31, 20011, 405,000 stock options were outstanding, of which 371,667 were exercisable.

(5) As of December 31, 2011, 2,593,571 stock options were outstanding, of which 2,560,238 were exercisable.

(6) As of December 31, 2011, 50,000 stock options were outstanding, of which 16,667 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 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 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 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.

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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.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding the beneficial ownership of our common stock as of March 29, 2012 by (a) each person who is known by us to beneficially own 5% or more of our common stock, (b) each of our directors and named executive officers, and (c) all of our directors and executive officers as a group.

Name and Address of Beneficial Owner	Amount and nature of beneficial ownership (1)	Percent of class (2)
Thomas Adams	3,153,234(3)	4.6
Antonius Schuh		
Andreas Braun		
Gabriele Cerrone	7,381,759(4)	10.4
Gary Jacob	1,200,334(5)	1.8
John Brancaccio	462,081(6)	*
Stanley Tennant	1,097,913(7)	1.6
All Directors and Officers as a group (7 persons)	13,758,487(8)	18.7
5% or greater stockholder		
R. Merrill Hunter	8,265,004(9)	11.7

* 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.

(2) The calculation in this column is based upon 67,146,857 shares of common stock outstanding on March 29, 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 March 29, 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) 800,000 shares of common stock issuable upon exercise of stock options and (ii) 279,117 shares of common stock issuable upon exercise of warrants.

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(4) Consists of (i) 3,740,356 shares of common stock held by Panetta Partners, Ltd., (ii) 37,500 shares of common stock held by Mr. Cerrone, (iii) 2,581,905 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, (iv) 984,498 shares of common stock issuable upon exercise of warrants held by Panetta and (v) 37,500 shares of common stock issuable upon exercise of warrants held by Mr. Cerrone. Mr. Cerrone 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.

(5) Includes (i) 399,334 shares of common stock issuable upon exercise of stock options and (ii) 63,000 shares of common stock issuable upon exercise of warrants.

(6) Includes (i) 296,081 shares of common stock issuable upon exercise of stock options and (ii) 83,000 shares of common stock issuable upon exercise of warrants.

(7) Includes 350,000 shares of common stock issuable upon exercise of warrants and 31,667 shares of common stock exercisable upon exercise of stock options.

(8) Includes 4,572,153 shares of common stock issuable upon exercise of stock options and 1,792,115 shares of common stock issuable upon exercise of warrants.

(9) Includes 3,600,000 shares of common stock issuable upon exercise of warrants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

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 12,262,782 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 1,800,000, 600,000 and 1,800,000 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 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 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 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, we entered into an agreement with Thomas Adams 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

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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

Stanley Tennant, a director of our 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 our 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.

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

Board Determination of Independence

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Audit Fees

The aggregate fees billed by our principal accountant for the audit of our annual financial statements, reviews of financial statements included in the quarterly reports and filing of Form 10 and amendments for the fiscal years ended December 31, 2011 and 2010 were $291,990 and $41,770, respectively.

Audit-Related Fees

There were no aggregate fees billed by our principal accountant for audit related services for the fiscal years ended December 31, 2011 and 2010.

All Other Fees

There were no aggregate fees billed for other services provided by our principal accountant for the fiscal years ended December 31, 2011 and 2010.

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

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. No non-audit services were performed by our principal accountants during the fiscal years ended December 31, 2011 and 2010. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

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ITEM 15. EXHIBITS.

Exhibit Number	Description of Exhibit
(a)(1)	*Financial Statements*
	The financial statements required by this item are submitted in a separate section beginning on page F-1 of this annual report.

b) Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among TrovaGene, Inc., E Acq corp. and Etherogen, Inc. dated as of August 6, 2010 (incorporated by reference to Exhibit 2.1 to the Company s Form 10-12G filed on November 25, 2011).
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	By-Laws of TrovaGene, Inc. (incorporated by reference to Exhibit 3.2 to the Company s Form 10-12G filed on November 25, 2011).
4.1	Form of Common Stock Certificate of TrovaGene, Inc. (incorporated by reference to Exhibit 4.1 to the Company s Form 10-12G filed on November 25, 2011).
4.2	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company s Current Report on Form 8-K filed on July 19, 2004).+
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).+
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).

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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).
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)
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

+ Indicates a management contract or compensatory plan or arrangement

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SIGNATURES

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

TROVAGENE, INC.

/s/ Dr. Antonius Schuh

March 30, 2012 Chief Executive Officer

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

SIGNATURE	TITLE	DATE
/s/ Dr. Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2012
/s/ Steve Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2012
/s/ Thomas H. Adams	Chairman of the Board	March 30, 2012
/s/ John P. Brancaccio	Director	March 30, 2012
/s/ Gary S. Jacob	Director	March 30, 2012
/s/ Gabriel M. Cerrone	Director	March 30, 2012
/s/ Stanley Tennant	Director	March 30, 2012

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TROVAGENE, INC.

(A Development Stage Company)

Index to Consolidated Financial Statements

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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

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TrovaGene, Inc. and Subsidiaries

(A development stage company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2011	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
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
Total Liabilities	5,270,525	5,507,589
Commitments and contingencies (Note 11)		
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)
	$ 1,039,257	$ 512,224

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

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

Consolidated Statements of Operations and Comprehensive Loss

	For the years ended December 31, 2011	2010	For the period August 4, 1999 (Inception) to 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 expenses:			
Research and development	910,685	1,024,159	15,529,153
Purchased in-process research and development expense-related party		2,666,869	2,666,869
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):			
Interest income	171	182	266,883
Interest expense	(56,636)	(115,585)	(1,325,372)
Amortization of deferred debt costs and original issue discount		(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		623,383
Liquidated damages and other forbearance agreement settlement costs			(1,758,111)
Net loss and Comprehensive loss	(2,239,212)	(5,449,138)	(42,042,172)
Preferred stock dividend	(38,240)	(38,240)	(307,918)
Cumulative effect of early adoption of ASC 815-40 on November 1, 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)
Weighted average shares of common stock outstanding:			
Basic and diluted	58,269,113	42,952,748	
Net loss per common share:			
Basic and diluted	$ (.04)	$ (0.13)	

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

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

Consolidated Statements of Stockholders Equity (Deficiency)

	Common Stock		Treasury Shares		Additional Paid-In	Deferred Stock Based	Deficit Accumulated During Development	Total Stockholders Equity
	Shares	Amount	Shares	Amount	Capital	Compensation	Stage	(Deficiency)
Balance, August 4, 1999 (Inception)	0	$ 0	0	$ 0	$ 0	$ 0	$ 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)
Balance, January 31, 2000	222,000,000	22,200	0	0	19,800	0	(14,760)	27,240
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 at $0.0005 per share	7,548,000	755			2,645			3,400
Capital contribution of cash	*				2,500			2,500
Net loss							(481,609)	(481,609)
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 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

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

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TrovaGene, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Stockholders Equity (Deficiency) (Continued)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Treasury Shares	Treasury Shares Amount	Additional Paid-In Capital	Deferred Stock Based Compensation	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
Balance, January 31, 2005	0	$ 0	17,306,891	$ 1,731	0	$ 0	$ 11,923,247	$ (1,691,803)	$ (7,042,240)	$ 3,190,935
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			(2)			0
Private placement of common stock			1,515,384	152			2,954,847			2,954,999
Payment of selling agents fees and 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 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)	350,000	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
								645,832		645,832

Amortization of deferred stock-based compensation										
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	$ 20,264,807	$ (1,045,971)	$ (15,740,263)	$ 3,480,710

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

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TrovaGene, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Stockholders Equity (Deficiency) (Continued)

	Preferred Stock		Common Stock		Additional	Deferred	Deficit Accumulated	Total	Temporary Equity	
	Shares	Amount	Shares	Amount	Paid-In Capital	Stock Based Compensation	During Development Stage	Stockholders Equity (Deficiency)	Unregistered Common Stock Shares	Amount
Balance, January 31, 2006	277,100	$ 277	18,604,300	$ 1,860	$ 20,264,807	$ (1,045,971)	$ (15,740,263)	$ 3,480,710		$
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		
					101,131			101,131		

Warrants issued for services										
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 consolidated financial statements.

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TrovaGene, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Stockholders Equity (Deficiency) (Continued)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)	Temporary Equity Unregistered Common Stock	
	Shares	Amount	Shares	Amount				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						(35,054)	(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 initially recorded as temporary equity			1,000,000	100	904,900		905,000	(1,000,000)	(905,000)
Private placement of common 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 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	

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

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TrovaGene, Inc. and Subsidiaries
(A Development Stage Company)
Consolidated Statements of Stockholders Equity (Deficiency) (Continued)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount	Shares	Amount			
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 consolidated financial statements.

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TrovaGene, Inc. and Subsidiaries

(A Development Stage Company)

Consolidated Statements of Stockholders Equity (Deficiency) (Continued)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit During Development Stage	Total Stockholders Equity (Deficiency)
	Shares	Amount	Shares	Amount			
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 liabilitiy 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 consolidated financial statements.

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TrovaGene, Inc. and Subsidiaries

(A Development Stage Company)

Consolidated Statements of Stockholders Equity (Deficiency)

	Preferred Stock Shares	Preferred Stock 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, Devember 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

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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:			
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
Settlement of consulting services in stock			478,890
Amortization of deferred debt costs and original issue discount		221,373	2,346,330
Liquidated damages and other forbearance agreement settlement costs paid in stock			1,758,111
Interest expense on convertible debentures paid in stock	56,636	115,585	757,198
Change in fair value of financial instruments	(170,673)	(266,926)	(1,226,002)
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)

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	2,573,500	1,734,700	17,432,005
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	2,573,500	1,734,700	21,126,469
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.

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

Consolidated Statements of Cash Flows

	Twelve months ended December 31, 2011	Twelve months ended December 31, 2010	For the period August 4, 1999 (Inception) to December 31, 2011
Supplementary disclosure of cash flow activity:			
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 250,500 shares of common stock for prior year Board of Directors fees in lieu of cash payment	$ 125,250	$	$ 125,250
Conversion of $2,335,050 of 6% debentures	$ 1,130,164	$	$ 1,130,164
Series A Preferred beneficial conversion feature accreted as a dividend	$	$	$ 792,956
Preferred stock dividends accrued	$ 38,240	$ 38,240	$ 152,960
Interest paid on common stock	$ 56,636	$ 115,585	$ 1,325,372

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

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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 2009, 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 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.

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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 was $2,573,500 and $1,734,700, 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 $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.

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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. 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.

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

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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).

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.

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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.

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.

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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

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 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-

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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, a California corporation (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, Used Kar Parts, Inc. (the Company) was incorporated 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 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.

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

6) Issued and transferred 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 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 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	
	December 31, 2011	**December 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.

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(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% (iv) volatility of 80%. This service agreement was terminated by TrovaGene on June 12, 2006.

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 are 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 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 5 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 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 have 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 120 th 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 is 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 will expire 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 are 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 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 5 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

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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 have an exercise price of $2.00 per share and expire 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 have an exercise price of $2.00 per share and expire 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.

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, are 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 has 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 has 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 is silent as to any penalties or liquidated damages if the obligations described above are not met. Consequently, since the Company s ability to meet the above obligations are not within its control and the penalties are 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.

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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 has 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 has 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 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 sold 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 as of February 1, 2008 (the Private Placement). The warrants have a two-year term and are 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 has 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 has 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

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connection with this transaction should not be recorded as a derivative liability and have been recorded as equity. See Note 13.

On June 30, 2009 and October 2, 2009, in accordance with an exchange agreement, a selling agent invested $164,550 in exchange for the issuance of a) 413,379 shares of common stock, b) warrants to purchase 418,854 shares of common stock and c) $164,550 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 of 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 of 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 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. The fair value of the warrants on the date of issuance was $113,376.

During the year ended December 31, 2011, the Company closed eighteen private placement financings which raised gross proceeds of $2,573,500. The Company issued 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.

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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 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 $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.

(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 Warrants		Weighted Average Exercise price	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	$	0.54	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

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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.

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 are 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 $277,102 and issued an aggregate 105,432 warrants to purchase common stock to certain selling agents. The warrants issued to the selling agents are immediately exercisable at $2.50 per share and will expire 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 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.

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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.

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 has 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 6% per annum, payable semi-annually on April 1 and November 1 of each year beginning November 1, 2007. The

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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 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

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- 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 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 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, 2011and 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 (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 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 allows the holder thereof to purchase up to 2,727,272 additional

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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 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.

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.

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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 33-1/3% of the options granted to each officer vesting on each of the first three anniversaries of the date of grant. The options pertaining to 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 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

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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 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:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price 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	$

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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.

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 December 31, 2011	Year ended 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.

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		Derivative Instrument 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		$	(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

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During the years ended December 31, 2011 and 2010, 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.

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:

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Quarter	Number of Price Protected Units at Issuance	Derivative Liability For Issued 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
Quarter 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:

Description	Quoted Prices in Active Markets for Identical Assets and Liabilities	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of December 31, 2011

	(Level 1)			
Derivative liabilities related to Warrants	$	$	$ 3,840,644	$ 3,840,644

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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:

Description	Balance at December 31, 2010	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of December 31, 2011
Derivative liabilities related to Warrants	$ 2,085,938	$ 1,343,876	$ 410,830(1)	$ 3,840,644

Description	Balance at December 31, 2009	Fair Value of warrants upon issuance	Unrealized (gains) or losses	Balance as of December 31, 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 operationg 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 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.

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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 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 licensing 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.

In October 2007, the Company signed a licensing 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 licensing 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 licensing 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.

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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, 2010, 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, 2010, 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 licensing agreement with InVivoScribe Technologies, Inc. for the co-exclusive rights to develop, manufacture and market, research and 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 licensing 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.

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

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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 and2010, 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.

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

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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

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.

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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 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.

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

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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

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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.

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.

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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 1,900,000 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.

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.