TrovaGene Inc.
Form 10-12G/A
February 15, 2012
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As filed on February 14, 2012

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

**Amendment No. 2**

**to**

# FORM 10

**GENERAL FORM FOR REGISTRATION OF SECURITIES**

**Pursuant to Section 12(b) or 12(g) of the Securities Exchange Act Of 1934**

# TROVAGENE, INC.

(Exact name of registrant as specified in its charter)

**Delaware**

(State of other jurisdiction of incorporation)

**27-2004382**

I.R.S. Employer Identification Number

**11055 Flintkote Avenue, Suite B**

**San Diego, CA 92121**

(Address of Principal Executive Office) (Zip Code)

**858-217-4838**

(Registrant s Telephone Number)

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

| **Title of each class To be so registered** | **Name of each exchange on which each class is to be registered** |
|---|---|
| None | None |

Securities to be registered under Section 12(g) of the Act:

| | |
|---|---|
| **Common stock, par value $0.0001 per share** (Title of class) | None |

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

| | |
|---|---|
| Large accelerated filer o | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company x |

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**Item 1. Business.**

**Background**

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 focus is to leverage our urine-based testing platform to facilitate improvements in 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 (i.e. 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: prenatal genetic testing, infectious diseases, tumor detection and monitoring, 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 the 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 biological, as well as instrumentation and equipment. The only custom components we use are specific 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 is available from multiple vendors including IDT. Special chemical modifications of synthetic DNA 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 focus on improving Women s Healthcare, 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, or 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 Obstetrics and Gynecology, or OB/Gyn pathology. The anticipation is that 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 marketing, providing key advantages versus the current tests which are all based on cervical samples, such as patient convenience and privacy, non-invasive sample collection, etc.

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. Such a test would address a huge unmet need for an accurate, reliable and 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 will 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 diagnostics. We have finalized the system architecture, operating procedure and software specifications for our CMOS technology.

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. 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 and in the teens on sublicense income received and in the single digits on all sublicense royalties received. The term of the license ends on October 28, 2025. The license can terminate at our option for a commercially reasonable reason or in the event of a material breach. In the event that the licensor decides to sell or convey the licensed rights, we shall have an option to acquire such property. Since 2006 we have executed out-licenses incorporating this biomarker with Sequenom, Inc. which was terminated in March of 2011, and with Ipsogen S.A. (Europe) and Asuragen Inc. (U.S.), who 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 be providing lab testing services for

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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. Though February 9, 2012, the amount paid to us under the agreement is $234,718. 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 February 9, 2012, the amount paid to date to us under the agreement is $312,049. 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 February 9, 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 February 9, 2012, the amount paid to us under the agreement is $21,932. 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 February 9, 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 February 9, 2012, the amount paid to us under the agreement is $27,500. The term of the license ends on October 28, 2025 which is the date of expiration of the issued patent rights. The license terminates if Skyline fails to pay, or upon 60 days written notice to us.

*MLL Münchner Leukämielabor,* . On February 8, 2011, we entered into a sublicense agreement with MLL Münchner Leukämielabor, or MLL. Pursuant to the agreement, we are obligated to manage the filing, prosecution, and maintenance of the NPM1 patent rights including improvements. MLL is obligated to use diligent effort to develop and sell laboratory services 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 February 9, 2012, the amount paid to us under the agreement is $16,250. The term of the

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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 sell in case of non-compliance of us with respect to the royalty payments.

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 which 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

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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 others, 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 and Asia and other international markets. Our objective is to establish a worldwide network in order to provide the greatest potential return for our shareholders.

**History**

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

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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 widely regarded and world renowned 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.

In addition, we are actively involved in 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 completely 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.

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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, or about 3 to 4 orders of magnitude more sensitive than other amplification based technologies on the market, at a small fraction of the expense.

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 a 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 is projected to approach $7.0 billion in 2011. 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. By 2012, the United States and Europe markets are projected to surpass $4.0 billion and $1.0 billion respectively. 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

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 and beyond.

***Women s Healthcare - Human Papilloma Virus (HPV)*** - HPV Screening and Monitoring is one of our key priority areas. This specifically relates to our development-stage urine-based HPV test. The rationale for screening HPV is that high-risk subtypes cause virtually all cases of cervical cancer. Cervical cancer is the third most commonly diagnosed cancer, and the fourth leading cause of cancer deaths in females worldwide. Deaths due to cervical cancer are still a huge global problem, especially in the developing world where screening practices are far from ideal. More than 85% of these cases and deaths occur in developing countries, who 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.

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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 (i.e. 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 (4.2MM tests at $500 to $750 each estimated by us)

***Infectious Diseases*** - Most infectious diseases are caused by viruses, bacteria, fungi, and parasites. 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. This fungal species is difficult to grow and identify via culture techniques resulting in a poor prognosis for these patients. 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 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, the infection and its symptoms are eliminated by antibiotics, 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, Tysabri, are at risk for developing PML. This prompted the FDA to require a black box warning on Tysabri labeling. By monitoring these patients with a test for JC Virus, a physician would be able to routinely check patients to determine if and when the early signs of PML are present and to discontinue Tysabri therapy prior to the onset of full-blown PML. Multiple sclerosis currently affects about 2.5 million patients worldwide with more than 350,000 in the U.S. Tysabri is widely thought of as the most effective treatment for MS, although its use is somewhat restricted due to the black box warning. Another commonly used drug (for rheumatoid arthritis, or RA, and numerous hematologic cancers) associated with a high risk of JCV/PML is Genentech s immunomodulator 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.

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***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 (K-ras) and released from pre-cancerous colon polyps can be detected in the urine of patients. Studies have shown that cancer patients who have K-ras mutations do not respond successfully to treatment with anti-EGFR drugs such as Erbitux, Iressa, Tarceva, Tykerb and Vectibix. These EGFR (epidermal growth factor receptor) 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 K-ras 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 K-ras 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 K-ras 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 500,000 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 monitoring of transplantation patients on immunosuppressive drugs, detection of metastasis following tumor surgery, monitoring of response and tumor

progression during chemotherapy, and the development of optimal hormonal and chemotherapeutic treatment protocols.

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

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(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, we recently 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 which will further enhance the acceptance and use of our urine-based assays incorporating our transrenal platform. In this regard, there are several alternatives which 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.

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.

If 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.

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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 (i.e. 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 that 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 December 27, 2011, 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 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

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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 which 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 LTDs 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 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 which 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.

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**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 February 9, 2012 we had three 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, 2010 and September 30, 2011, we have an accumulated total deficit of $41,320,979 and $42,341,534, respectively. For the fiscal year ended December 31, 2010 and the nine months ended September 30, 2011, we had net losses attributable to common stockholders of $5,487,378 and $1,020,555, respectively. To date, we have experienced negative cash flow from development of our transrenal molecular technology. We currently have no products ready for commercialization, have not generated any revenue from operations except for licensing and royalty income and expect to incur substantial net losses for the foreseeable future to further develop and commercialize the transrenal molecular technology. We cannot predict the extent of these future net losses, or when we may attain profitability, if at all. If we are unable to generate significant revenue from the transrenal molecular technology or attain profitability, we will not be able to sustain operations.

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

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

In their report dated November 23, 2011 our independent registered public accountants stated that our financial statements for the year ended December 31, 2010 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 February 10, 2012 our cash balance was $1,064,545 and our working capital deficit was $99,508. 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 3 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

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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 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 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 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.

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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.

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

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

We will need 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 two full-time employees as of December 27, 2011. 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;

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- maintain sufficient administrative, accounting and management information systems and controls; and

- hire and train additional qualified personnel.

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

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

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

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

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

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**associated with meeting requirements for pre-market clearance or approval and/or experience decreased demand for or reimbursement of our test.**

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

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

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

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

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

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

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

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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 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.

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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.

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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**If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting 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 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. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting if material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. 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 material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

**Risks Related to Our Common Stock**

**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

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

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

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

- technological innovations or new products and services by us or our competitors;
- clinical trial results relating to our tests or those of our competitors;
- 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 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;

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- 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 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 February 9, 2012, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 31% of our outstanding shares of common stock. As a result, these stockholders, acting together, would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, would have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;

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

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

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

No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do

not pay dividends, our common stock may be less valuable because a return on an investor s investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income.

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

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

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

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

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.

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**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.**

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock.

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**ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*You should read this discussion together with the Financial Statements, related Notes and other financial information included elsewhere in this Form 10. The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under Risk Factors, and elsewhere in this Form 10. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

OVERVIEW

From August 4, 1999 (inception) through December 31, 2010 and September 30, 2011, we have sustained cumulative total deficits of $41,320,979 and $42,341,534, respectively. From inception through September 30, 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 such 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*

Under our royalty and license agreements, payments are received which include minimum royalty and milestone payments as well as license fees. License fees are recognized when earned. Royalty income is recorded in the same period as the sales that generated such income. Milestone payments are recognized in the period when the milestone is achieved. Please see Item 1. Business - Background for a description of our royalty and license agreements.

*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, 2010 and 2009 and September 30, 2011 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 $91,508, $75,000 and $27,965 at September 30, 2011, December 31, 2010 and December 31, 2009 respectively, represent the minimum royalty payments due as of those dates.

*Derivative Financial Instruments-Warrants*

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

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

The fair value of warrants is determined using the Black-Scholes option-pricing model using assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus use model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820. At December 31, 2009, 2010 and September 30, 2011, the fair value of such warrants was $740,617, $609,155 and $880,137, respectively, which we classified as derivative financial instruments liability on our balance sheet.

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We have issued units that were price protected during the years ended December 31, 2010 and 2009, 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, 2009, December 31, 2010 and September 30, 2011, the fair value of such price protected units was $602,133, $1,476,783 and $2,103,409, respectively, which we classified as derivative financial instruments liability on our balance sheet.

At December 31, 2009, December 31, 2010 and September 30, 2011, 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 $1,342,750, $2,085,938 and $2,983,546, 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.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | August 4, 1999 (Inception) to |
|---|---|---|---|---|---|
| | 2011 | 2010 | 2011 | 2010 | September 30, 2011 |
| Salaries and staff costs | $ 106,245 | $ 161,276 | $ 395,289 | $ 432,592 | $ 9,702,969 |
| Outside services, consultants and lab supplies | 44,768 | 16,387 | 90,232 | 64,826 | 2,455,042 |
| Facilities | 44,112 | 36,233 | 97,802 | 127,359 | 2,558,701 |
| Other | 5,800 | 15,631 | 18,905 | 26,234 | 503,984 |
| Total Research and development | $ 200,924 | $ 229,527 | $ 602,228 | $ 651,011 | $ 15,220,696 |

| | For the years ended December 31, | |
|---|---|---|
| | 2010 | 2009 |
| Salaries, compensation and benefits | $ 656,740 | $ 354,962 |
| Outside Services, consultants and lab Supplies | 180,429 | 139,434 |
| Facilities | 157,467 | 67,157 |
| Other | 29,522 | 669 |
| Total Research and development | $ 1,024,159 | $ 562,212 |

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.

In June 2007, the EITF of the FASB reached a consensus on ASC Topic 730, *Research and Development* which 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. We adopted ASC Topic 730 on January 1, 2008 and the adoption did not have a material effect on our consolidated financial position, results of operations or cash flows.

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*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

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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.

*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 forebearance 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.

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.

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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 $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.

During the twelve months ended December 31, 2010 and 2009, we incurred interest expense of $256,856 and $244,656, respectively, that was paid in 1,003,021 shares. The Debenture Holders were entitled to interest expense at 11%. The total value of the shares was $256,901 based on the stock price allocation in the fair value of the price protected units issued during the years ended December 31, 2010 and 2009. The difference in the fair value of the consideration given and the amounts due to the debt holder was $244,605 and 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 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 three and nine months ended September 30, 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, 2010 and 2009 and for the three and nine months ended September 30, 2011and inception (August 4, 1999) to September 30, 2011 was a loss of $31,999, a gain of $491,586 losses on valuation of $463,463 and $40,714 and a gain of $607,389 respectively. The losses for the three and nine months ended September 30, 2011and the gain from inception (August 4, 1999) to September 30, 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.

**RESULTS OF OPERATIONS**

**THREE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

We had revenues of $55,000 and $32,569 during the three months ended September 30, 2011 and 2010, respectively, consisting of royalty income of $55,000 and $32,659 in the three months ended September 30, 2011 and 2010, respectively. The increase in royalties related to royalties from seven agreements in 2011 as compared to four in 2010.

Research and development expenses for the three months ended September 30, 2011 decreased by $2,695,472 or, 93%, to $200,924 from $2,896,396 for the three months ended September 30, 2010. This decrease was primarily due to the purchased-in-process research and development expense totaling $2,666,869 recorded in the third quarter of 2010 in connection with the Etherogen Inc. merger.

General and administrative expenses increased by $214,343, or 58%, to $586,230 for the three months ended September 30, 2011 from $371,887 for the three months ended September 30, 2010. This increase was primarily due to an increase in outside consultants fees of $197,563.

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Net income for the three months ended September 30, 2011 was $ 9,269 as compared to a net loss of $3,574,908 incurred for the three months ended September 30, 2010. This decrease in our net loss of $3,584,177, or 100% was primarily the result of (i) the net gain on extinguishment of debt of $623,383 in the third quarter of 2011, (ii) the gain in the fair value of derivative instruments-warrants of approximately $118,000 compared to a loss of approximately $310,000 during the quarter ended September 30, 2010 and (iii) the above decrease in research and development expenses.

**NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

We had revenues of $223,946 and $50,684 during the nine months ended September 30, 2011 and 2010, respectively, consisting of royalty income of $203,946 and $40.684 in the three months ended September 30, 2011 and 2010, respectively, and license fees of $20,000 in 2011 and $10,000 in 2010. The increase in royalty revenues results from royalties from eight agreements in 2011 compared to five in 2010. The license fees in 2011 were related to two new agreements signed in 2011 and one signed in 2010.

Research and development expenses for the nine months ended September 30, 2011 decreased by $2,715,652, or 82%, to $ 602,228 from $3,317,880 for the nine months ended September 30, 2010. This decrease was primarily due to the decrease in purchased-in-process research and development expense totaling $2,666,869 recorded in the third quarter of 2010 in connection with the Etherogen Inc. merger.

General and administrative expenses increased by $428,710, or 33%, to $1,721,301 for the nine months ended September 30, 2011 from $1,292,591 for the nine months ended September 30, 2010. This increase was primarily due to (i) an increase in outside consultants expense of approximately $155,000. The increase of $150,000 was for the value of common stock issued to a consultant in the three and nine months ended September 30, 2011 (ii) approximately $133,000 of other employee expenses in connection with settlements of litigation with former officers and directors, (iii) approximately $133,000 in accounting fees and (iv) approximately $83,000 in legal fees partially offset by (v) a decrease in employee expenses of approximately $59,000, excluding (ii) above.

Net loss for the nine months ended September 30, 2011 was $991,875 compared to a net loss of $4,471,629 incurred for the nine months ended September 30, 2010. This decrease in our net loss of $3,479,754, or 78% 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 third quarter of 2011, and (iii) the gain in fair value of derivative instruments-warrants of approximately $541,000 compared to a loss of approximately $175,000 in the nine months ended September 30, 2010. This was due to a decline in the stock price of $.01, an increase in the risk free interest rate of 1.38% to 2.04% and a decrease in the volatility from 100% to 90%. The above changes were offset by an increase in general and administrative expenses discussed above.

**YEARS ENDED DECEMBER 31, 2010 AND 2009**

We had revenues of $265,665 and $653,994 during the twelve months ended December 31, 2010 and 2009, respectively, consisting of royalty income of $255,665 and and $153,994 in the years ended December 31, 2010 and 2009, respectively, and license fees of $10,000 and $500,000 in the years ended December 31, 2010 and 2009, respectively.

The increase in royalty revenues results from royalties from six agreements in 2011 compared to two in 2010. License fees were received from Skyline in 2010 and from Sequenom in 2009.

For the twelve months ended December 31, 2010, research and development expenses increased by $3,128,816 or 556.5% to $3,691,028 as compared to $562,212 during the twelve months ended December 31, 2009. This increase in research and development expenses was primarily attributable to (i) purchased in-process-research and development expense relating to the merger with Etherogen, Inc. ( the Merger ) which was $2,666,689. In accordance with ASC 805 *Business Combinations* the excess of the fair value of the consideration issued and the fair value of the net assets acquired has been recorded as purchased in process research and development expense-related party, (ii) salaries and related expenses increased by $146,489, or 37%, from $398,132 for the twelve months ended December 31, 2009,(iii) outside consultant services increased by $128,349 to $111,033 for the twelve months ended December 31, 2010 and (iv) stock based compensation expense increased by $64,429 from $21,611 for the twelve months ended December 31, 2009.

For the twelve months ended December 31, 2010, general and administrative expenses increased by approximately $293,000, or 13.0%, to approximately $1,954,000, as compared to approximately $1,661,000 during the twelve months ended December 31, 2009. The increase in expenses was primarily attributable to an increase in salaries and wages, stock based compensation and related employee benefits of approximately $720,000, which were $279,000, or 63%, higher as compared to $441,000 during the twelve months ended December 31, 2009 offset by various other items.

Net loss for the twelve months ended December 31, 2010 was $5,449,138 compared to a net loss of $2,483,807 incurred for the twelve months ended December 31, 2009. This increase in our net loss of $2,965,331, or 119%, was a result primarily of the above increases in research and development expenses and general and administrative expenses.

**LIQUIDITY AND CAPITAL RESOURCES**

As of September 30, 2011, we had $157,467 in cash and cash equivalents. Net cash used in operating activities was $1,409,707 for the nine months ended September 30, 2011 and $2,088,716 and $1,234,506, for the twelve months ended December 31, 2010 and December 31, 2009, respectively. Net cash provided by financing activities was $1,510,000 for the nine months ended September 30, 2011 and was $1,734,700 and $1,651,736 for the twelve months ended December 31, 2010 and December 31, 2009, respectively.

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As of September 30, 2011 we had a negative working capital of $859,566 as compared to working capital deficits of $3,136,916 and $2,557,157 as of December 31, 2010 and December 31, 2009. As of February 10, 2012, our working capital deficit was $99,508.

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 three and nine months ended September 30, 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. Each of the investors was an accredited investor. In connection with the issuance of the units, we relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended.

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 September 30, 2011 and December 31, 2010 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, 2010 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 3. PROPERTIES.**

Our corporate offices and laboratory are located at 11055 Flintkote Avenue, Suite B, San Diego, CA 92121 where we lease approximately 5,300 square feet for $9,768 per month. Our lease expires in February 2013. We believe that our facilities are adequate to support foreseeable growth in our business.

**ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.**

The following table sets forth information regarding the beneficial ownership of our common stock as of February 9, 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 | 3,148,234(3) | 4.8 |
| Antonius Schuh | | |
| Andreas Braun | | |
| Gabriele Cerrone | 7,376,757(4) | 10.7 |
| Gary Jacob | 1,189,334(5) | 1.8 |
| John Brancaccio | 340,081(6) | * |
| Stanley Tennant | 1,082,913(7) | 1.7 |
| David Robbins | 462,500(8) | 1.0 |
| All Directors and Officers as a group (8 persons) | 13,599,819(9) | 19.1 |
| 5% or greater stockholder | | |
| R. Merrill Hunter | 8,265,004(10) | 12.0 |

* 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 65,172,157 shares of common stock outstanding on February 9, 2012. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with

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respect to the subject securities. Shares of common stock that are currently exercisable or exercisable within 60 days of November 15, 2011 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) 274,117 shares of common stock issuable upon exercise of warrants.

(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) 2,576,905 shares of common stock issuable upon exercise of stock options held by Mr. Cerrone, (iv) 984,496 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) 388,334 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) 174,801 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 16,667 shares of common stock exercisable upon exercise of stock options.

(8) Consists of 462,500 shares of common stock issuable upon exercise of stock options.

(9) Includes 4,419,207 shares of common stock issuable upon exercise of stock options and 1,792,113 shares of common stock issuable upon exercise of warrants.

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

**Item 5. Directors and Executive Officers.**

The names, ages and positions of our directors and executive officers as of February 9, 2012 are as follows:

| 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 |
| David Robbins. PhD | 55 | Vice President Research and Development |
| John Brancaccio | 63 | Director |
| Gary S. Jacob | 64 | Director |
| Gabriele M. Cerrone | 39 | Director |
| Dr. Stanley Tennant | 60 | Director |

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

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 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

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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.

**Steve Zaniboni.** Mr. Zaniboni joined us in January 2012. He currently is our Chief Financial Officer. From June 2010 to February 2011, Mr. Zaniboni 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 (NASTIQ: SQNM), 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.

**David Robbins.** David Robbins joined us in 2006. He is currently our Vice President of Research. Prior to joining us Dr. Robbins served as founding Vice President of Research and Development at ChromoLogic. Prior to ChromoLogic, Dr. Robbins was the founding Director at ViaLogy Before joining ViaLogy, Dr. Robbins served as Research Manager at SmithKline Beecham Clinical Labs (now Quest Diagnostics) from 1997-2000. From 1994-1997 he served as Manager of Assay Development for SmithKline Pharmaceuticals Molecular Diagnostics Venture (now diaDexus). From 1988-1994, Dr. Robbins was a Project Manager at Abbott Labs. He received his BA in Chemistry from the Johns Hopkins University in 1978 and his Ph.D. in Biochemistry from the University of Texas at Austin in 1983.

**John Brancaccio** . John Brancaccio, a retired CPA, has served as a director of our company since December 2005. Since April 2004, Mr. Brancaccio has been the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Alfacell Corporation as well as a director of Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. Mr. Brancaccio s chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as a director of our company.

**Gary S. Jacob.** Gary S. Jacob has served as a director of our company since February 2009. Since July 2008, Dr. Jacob has been President, Chief Executive Officer and a Director of Synergy Pharmaceuticals, Inc. and as Chairman of a subsidiary of Synergy from October 2003 until July 2008. Dr. Jacob currently serves as Chief Executive Officer and a director of Callisto Pharmaceuticals, Inc., Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England. Dr. Jacob s broad management expertise in the pharmaceutical and biotechnology industries provides relevant experience in a number of strategic and operational areas and led to the Board s conclusion that he should serve as a director of our company.

**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 currently serves as a director of Inhibitex, Inc. 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:

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- 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 Board s Role in Risk Oversight**

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

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

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

The board of directors has 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.

**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. Jacob, Tennant and Brancaccio to be independent.

*Board Committees*

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,

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

Compensation Committee

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

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

Compensation Committee Interlocks and Insider Participation

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

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 6. 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 |

**(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.

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**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 |

(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 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.

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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.

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.

On December 26, 2005, we 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 our company. The above options were fully vested at January 3, 2009.

On October 7, 2011, we entered into an employment agreement with David Robbins, Ph.D. in which he agreed to serve as our 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 by us without cause, Dr. Robbins shall be entitled to a severance payment equal to three months of base salary.

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**ITEM 7. 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

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.

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 8. LEGAL PROCEEDINGS.**

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.

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We are not currently a party to any material legal proceedings.

**ITEM 9. MARKET PRICE OF AND DIVIDENDS ON THE REGISTRANT S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.**

**Market Information**

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 February 9, 2012 was $0.89 per share.

| **Fiscal 2012** | **High** | **Low** |
|---|---|---|
| **First Quarter** (through February 9, 2012) | $ 0.89 | $ 0.42 |

| **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 February 9, 2012 there were 143 holders 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.

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**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) | 12,000,000 | $ .90 | 0 |
| Equity Compensation Plans Not Approved by Stockholders(2) | 24,165,994 | $ | |
| Total | 36,165,994 | | 7,442,849 |

(1) Consists entirely of options.

(2) Of such amount, 21,608,843 are warrants. Such warrants have an exercise p