UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2015

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

FOR THE TRANSITION PERIOD FROM TO

COMMISSION FILE NUMBER 000-54556

TROVAGENE, INC.

(Exact name of registrant as specified in its charter)

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

11055 Flintkote Avenue, Suite B, San Diego, California 92121
(Address of principal executive offices) (Zip Code)
Registrant's telephone number, including area code: **(858) 952-7570**

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**.

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on a closing sale price of $10.15 per share, which was the last sale price of the common stock as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was $195,681,564.

As of February 29, 2016, 29,757,810 shares of the registrant's common stock, $0.0001 par value per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2016 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days of the end of the fiscal year ended December 31, 2015, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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PART I

ITEM 1. BUSINESS

We are a molecular diagnostic company that focuses on the development and commercialization of a proprietary molecular diagnostic technology for use in disease detection and monitoring across a variety of medical disciplines. Our primary internal focus is to leverage our novel cell-free molecular diagnostic platform to facilitate improvements in the field of oncology, while our external focus includes entering into license agreements or collaborations to develop our technology in areas such as infectious disease, transplant medicine and prenatal genetics.

We are leveraging our proprietary molecular diagnostic technology for the detection of cell-free DNA originating from diseased cell death that can be isolated and detected from urine, blood, and tissue samples to improve disease management. These genetic materials are also collectively referred to as "cell-free nucleic acids", which result when cells in the body die and release their DNA contents into the bloodstream. The circulating fragments of genetic material are eventually filtered through the kidneys, and therefore, can be detected and measured in urine. Cell-free nucleic acids can be used as genetic markers of disease. As such, the contents of urine or blood samples represent systemic liquid biopsies that allow for simple, non-invasive or minimally-invasive sample collection methods.

Our fundamental cell-free molecular diagnostic platform for oncology applications, also known as our "Precision Cancer Monitoring®" ("PCM") platform, is protected by a strong intellectual property portfolio. We have developed significant intellectual property around cell-free nucleic acids in urine, and the extraction of cell-free nucleic acids from urine, as well as novel assay designs, particularly our proprietary non-naturally occurring primers. Through this proprietary technology, we believe that we are at the forefront of a shift in the way diagnostic medicine is practiced, using simple, non-invasive or minimally invasive sampling and analysis of nucleic acids, which we believe will ultimately lead to more effective treatment monitoring, better management of serious illnesses such as cancer, and the ability to detect the success of cancer treatment, the recurrence of cancer, or the progression of cancer earlier. As of December 31, 2015, our intellectual property portfolio consisted of over 85 issued patents and over 60 pending patent applications in the U.S. and abroad. Our patent estate includes the detection of cell-free nucleic acids that pass through the kidney into the urine, as well as their application in specific disease areas, including oncology, infectious disease, transplantation, and prenatal genetics.

We believe that our proprietary PCM platform is uniquely positioned to address a high unmet clinical need in the field of oncology. Our PCM platform is designed to offer better cancer monitoring by tracking and quantifying levels of cell-free DNA from either urine or blood samples, and is intended to provide important clinical information beyond the current standard of care. Using urine as a sample, our cancer monitoring technology enables frequent, non-invasive monitoring of oncogene mutation status, disease progression and disease recurrence. Our extensive research and development efforts were strengthened, due to investments to expand our intellectual property portfolio, and were made commercially feasible following improved next-generation sequencing ("NGS") technologies, which are now available at a significantly lower cost. This combined with our extensive patent portfolio around cell-free DNA in urine gives us a competitive advantage to leverage an emerging trend of monitoring cancer using cell-free DNA as a marker of disease status. Our proprietary sample preparation process forms the basis of our PCM platform. It includes novel technology for the extraction and isolation of cell-free DNA from either a urine or blood sample, proprietary non-naturally occurring primers to enrich the sample for mutant alleles and the ability to detect nucleic acids of interest using one of several leading gene sequencing technologies such as NGS or droplet digital polymerase chain reaction ("ddPCR"). We believe that our quantitative cell-free DNA detection and monitoring platform offers industry leading sensitivity, featuring single nucleic acid molecule detection.

Our PCM platform is poised to overcome a significant clinical dilemma in the area of cancer treatment. Recent scientific evidence supports the molecular basis of cancer and has resulted in a paradigm shift in the way cancer is diagnosed and treated. Researchers and clinicians are now focused on specific oncogene mutations and alterations that are believed to be the drivers of cancer at the molecular level, and, as a result, there is a trend in the pharmaceutical research community toward developing targeted therapies. As such, there is a need for oncologists to have an ability to track the mutational status of their patients and to assess a given patient's response to treatments designed to target driver oncogene mutations. Current monitoring tools such as imaging procedures, tissue biopsy and circulating tumor cells are insufficient to meet the challenge of monitoring oncogene mutations. Imaging only provides a rough indication of tumor size and is an important tool for surgeons, but provides little practical information to oncologists regarding mutational status and appropriate treatment options, especially for molecular targeted therapies. Tissue biopsy usually involves a surgical procedure and, in many cases, is not repeatable as there are limitations related to access for serial biopsies. In some cases, biopsies may not be available, significantly increasing the need to determine mutational status using an alternative method. In addition, tumor heterogeneity is important, as the surgeon may not obtain the proper tissue from the tumor sample. In the case of circulating tumor cells, which are typically measured using blood tests, sensitivity is traditionally low, and such tests can be technically difficult and expensive to conduct.

Targeted drug therapies themselves are not without issues. Targeted therapies are typically very expensive, can have significant side effects and are not effective in every patient. In order to measure effectiveness, repeated monitoring is needed and serial biopsies can be difficult to obtain. If resistance develops, fast and accurate detection of emerging or changing oncogene mutation status is critical. Our PCM platform provides a novel solution using urine, a non-invasive, plentiful sample source, and we are continuing to build a growing body of evidence supporting the clinical utility of our technology to monitor cancer using cell-free DNA.

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

Developing a Market for Molecular Diagnostic Tests based on Liquid Biopsies using Cell-free DNA

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

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

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

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

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

In September 2015, we established Trovagene Srl, also known as the Trovagene Research Institute ("TRI"), a European subsidiary focused on expanding the capabilities and adoption of the PCM platform. Alberto Bardelli, Ph.D., an internationally recognized leader in cell-free DNA cancer research, is the Scientific Chair of TRI. Concurrent with the establishment of TRI, we entered into a collaboration agreement with the Department of Oncology at the University of Torino, a leading research center in Southern Europe. The collaboration seeks to leverage the superior benefits of urine as a specimen for the detection and monitoring of oncogenic mutations, along with the capabilities and relationships of the University of Torino and Dr. Bardelli's team. Under the terms of the agreement, we may pay our collaborator in the study approximately $529,000 for services provided. As of December 31, 2015, we incurred approximately $188,000 related to this agreement.

In September 2014, under the strategic partnership we established in March 2014 with Catholic Health Initiatives Center for Translational Research, we entered into a Sponsored Research Agreement with Catholic Health Initiatives Center for Translational Research to conduct clinical studies to evaluate the use of our PCM technology in the management of cancer patients. Under the terms of the agreement, we may pay our collaborator in the study approximately $151,000 for services provided. During the years ended December 31, 2015 and 2014, we incurred approximately $39,000 and $30,000, respectively, related to this agreement.

In June 2014, we entered into a Sponsored Research Agreement with Dana Farber Cancer Institute to conduct a clinical study to evaluate the use of our precision cancer monitoring technology in the management of lung cancer patients. Under the agreement, we may pay our collaborator in the study approximately $42,000 for services provided. During the years ended December 31, 2015 and 2014, we incurred approximately $1,000 and $8,000, respectively, related to this agreement.

In June 2014, we entered into a Sponsored Research Agreement with Memorial Sloan Kettering Cancer Center to conduct a clinical study for the detection of oncogenic tumor mutations in the urine of lung cancer patients. Under the agreement with Memorial Sloan Kettering Cancer Center, we may pay our collaborator approximately $146,000 for services provided. During the years ended December 31, 2015 and 2014, we incurred approximately $35,000 and $25,000, respectively, related to this agreement.

In May 2014, we entered into a Strategic Research Alliance with the Robert H. Lurie Comprehensive Cancer Center of Northwestern University to conduct one or more research agreements to evaluate the use of our precision cancer monitoring technology in the management of cancer patients. Under the agreement, each party is responsible for its own costs and obligations under the agreement. No services or costs had been incurred by us as of December 31, 2015.

In May 2014, we entered into a Patent Assignment and License Agreement, effective as of April 23, 2014, with GenSignia IP Ltd., a United Kingdom company (“GenSignia”), pursuant to which we assigned to GenSignia all of our miRNA patents, including methods of using miRNA for detection of in vivo cell death and detecting cell-free miRNA in urine and blood. Concurrent with the assignment, GenSignia granted to us an exclusive, world-wide, royalty-free, fully paid, perpetual license under the transferred patents in the urine field. Pursuant to the agreement, GenSignia will pay us a low single digit royalty on net sales and will pay an aggregate of $6.5 million in milestone payments upon the achievement of up to $150 million in net sales. GenSignia is responsible for the preparation, filing and maintenance of all patents under the agreement. During the years ended December 31, 2015 and 2014, we recorded $0 and $10,000, respectively, in license fee revenue related to the agreement. Costs have been incurred through December 31, 2015 and reimbursed by GenSignia.

In December 2013, we entered into a Clinical Trial Agreement with US Oncology Research LLC (“USOR”), pursuant to which USOR will provide the principal investigator and conduct a clinical study related to examining the utility of cell-free quantitative KRAS testing to monitor disease in patients with metastatic pancreatic cancer. Under the agreement, we committed to pay USOR approximately $270,000 for services provided. During the years ended December 31, 2015, 2014, and 2013, we incurred and recorded approximately $59,000, $16,000, and $29,000, respectively, of research and development expense related to this agreement.

In August 2013, we entered into a Clinical Trial Agreement with the University of Southern California (“USC”), pursuant to which USC will provide the principal investigator and conduct a clinical study related to the genetic characterization of metastatic colorectal cancers. Under the agreement, we are committed to pay USC approximately $232,000 for services provided. In June 2015, we entered into an amendment to the agreement that increased the total fees to be paid to USC for services provided to $277,000. During the years ended December 31, 2015, 2014, and 2013 we incurred approximately $28,000, $38,000, and $0, respectively, for expenses related to this agreement.

During 2012, we entered into research agreements with the University of Texas MD Anderson Cancer Center (“MDACC”) to provide samples and evaluate methods used by us to identify pancreatic cancer mutations, as well as to measure the degree of concordance between the results of cell-free DNA mutation analysis from urine samples and tumor tissue. An amendment in 2013 increased the scope of the research agreements. We have committed to pay approximately $451,000 for the services performed by MDACC under the research agreement. During the years ended December 31, 2015, 2014, and 2013, we incurred and recorded approximately $71,000, $124,000 and $142,000, respectively, of research and development expense related to these agreements.

In December 2012, we entered into a sublicense agreement with Genoptix, Inc. for non-exclusive worldwide rights to develop and market laboratory testing services for nucleophosmin protein (“NPM1”) for the diagnosis and monitoring of patients with acute myeloid leukemia (“AML”). Under this agreement, we granted a license to Genoptix, Inc. to certain NPM1 patents in exchange for a one time license fee of $100,000 due upon execution of the agreement and royalty payments on net

revenues. During the years ended December 31, 2015, 2014 and 2013, we recorded royalty and license fee revenues of approximately $40,000, $30,000 and $10,000, respectively.

In November 2012, we entered into a sublicense agreement with Duke University and Duke University Health Systems for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, we granted a license to Duke University and Duke University Health Systems to certain NPM1 patents in exchange for a one time license fee of $5,000 due upon execution of the agreement and royalty payments on net revenues. During the years ended December 31, 2015, 2014 and 2013, we recorded $2,000, $1,000 and $0, respectively, for royalty and license fee revenues related to this agreement.

In September 2012, we entered into a collaboration and license agreement with Strand Life Sciences Pvt. Ltd. ("Strand Life Sciences") related to the validation and commercial launch of a urine-based DNA test for Human Papillomavirus ("HPV"). Under this agreement, we granted a license to Strand Life Sciences for the use of our tests in exchange for royalty payments on net sales earned in the territory specified in the agreement. During the years ended December 31, 2015, 2014, and 2013, no royalties or license fees were received under this agreement.

In September 2012, we entered into a sublicense agreement with Quest Diagnostics Incorporated for non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Under this agreement, we granted a license to Quest Diagnostics Incorporated to certain NPM1 patents in exchange for a one time license fee of $20,000 due upon execution of the agreement and royalty payments on net sales of Quest Diagnostics Incorporated and its affiliates. During the years ended December 31, 2015, 2014 and 2013, we recorded royalty and license revenues of approximately $26,000, $26,000 and $14,000, respectively.

In December 2011, we entered into an exclusive license agreement with Columbia University to license the patent rights to hairy cell leukemia biomarkers. In consideration for the license, we paid $1,000 as an upfront license fee and agreed to make royalty payments as a single digit percentage of net sales if sales are made by us or a single digit royalty rate as a percentage on sublicense income received by us if sales are made by sublicensees. The license agreement will continue in effect 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 Columbia University or by us if we determine that it is not commercially or scientifically appropriate to further develop the license product rights. No royalty expense was recorded related to this agreement during the years ended December 31, 2015, 2014 and 2013.

In October 2011, we entered into an exclusive license agreement with Gianluca Gaidano, Robert Foa and Davide Rossi for the patent rights to a specific gene mutation with respect to chronic lymphoblastic leukemia. In consideration for the license, we paid $1,000 as an upfront license fee and agreed to make royalty payments as a single digit percentage of net sales if sales are made by us or a single digit royalty rate as a percentage of sublicense income received by us if sales are made by sublicensees. We have an option to purchase the licensed patent rights in the event the licensor decides to sell such licensed patent rights. The license agreement will continue in effect until September 29, 2031, which is the date of the last to expire of the licensed patent rights covering the license product. The license agreement may also be terminated upon a material breach by any party or by us if it is determined that it is not commercially or scientifically appropriate to further develop the license product rights. No royalty expense was recorded related to this agreement during the years ended December 31, 2015, 2014 and 2013.

In July 2011, we entered into a sublicense agreement with Fairview Health Services ("Fairview") for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. Fairview paid an initial license fee of $10,000 upon execution of the agreement and also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. Fairview is obligated to pay a royalty with annual minimums of $1,000 each year. During the years ended December 31, 2015, 2014, and 2013, we recorded royalty and license fee revenues of approximately $1,000, $2,000 and $1,000, respectively.

In February 2011, we entered into a sublicense agreement with MLL Münchner Leukämielabor ("MLL") for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. MLL paid an initial license fee of $20,000 upon execution of the agreement and agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. MLL was obligated to pay a minimum royalty of $15,000 for the first year and is currently obligated to pay a royalty with annual minimums of $20,000. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. During the years ended December 31, 2015, 2014, and 2013, we recorded royalty and license fee revenues of approximately $69,000, $81,000 and $85,000, respectively.

In June 2010, we signed a sublicensing agreement with Skyline Diagnostics BV for the non-exclusive rights to develop, commercialize and market research and diagnostic laboratory services for the stratification and monitoring of patients with AML. Skyline Diagnostics BV paid an initial licensing fee of $10,000 upon execution of the agreement and may make future payments to us upon the attainment of certain regulatory and commercial milestones. Skyline Diagnostics BV is also obligated to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. During the years ended December 31, 2015, 2014 and 2013, we recorded no royalty and license revenues and no license fee expenses.

In December 2008, we signed a sublicensing agreement with InVivoScribe Technologies, Inc. for the non-exclusive rights to develop and market lab testing services for NPM1 for the diagnosis and monitoring of patients with AML. InVivoScribe Technologies paid an initial licensing fee of $10,000 upon execution of the agreement. InVivoScribe Technologies also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025, which is the expiration date of the issued patent rights. We recorded royalty revenues of approximately $25,000 during each of the years ended December 31, 2015, 2014 and 2013. During those same periods, we did not record any license fee expenses.

In August 2008, we signed a sublicensing agreement with Laboratory Corporation of America Holdings (“LabCorp”) for the non-exclusive rights to develop and market laboratory testing services for NPM1 for the diagnosis and monitoring of patients with AML. LabCorp paid an initial licensing fee of $20,000 upon execution of the agreement. LabCorp also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends August 25, 2018. During the years ended December 31, 2015, 2014 and 2013, we recorded royalty and license fee revenues of approximately $30,000, $28,000 and $20,000, respectively. During those same periods, we did not record any license fee expenses.

In October 2007, we signed a co-exclusive license agreement with ASURAGEN, Inc. for the co-exclusive rights to develop, manufacture and market research and diagnostic products for the stratification and monitoring of patients with AML. ASURAGEN paid an initial licensing fee of $120,000 upon execution of the agreement and may make future payments to us upon the attainment of certain regulatory and commercial milestones. In June 2010, we signed an amendment no. 1 to the co-exclusive license agreement. The amendment provides that we may require a license from a third-party to perform laboratory testing services. ASURAGEN also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. In March 2013, we signed an amendment no. 2 to the co-exclusive sublicense agreement with ASURAGEN, pursuant to which the field of use was limited to research use only (“RUO”) kits. ASURAGEN was also granted a non-exclusive sublicense for NPM1 laboratory testing services. We recorded royalty and license fee revenues of approximately $50,000 during each of the years ended December 31, 2015, 2014 and 2013. During those same periods, we had no license fee expenses related to this agreement.

In August 2007, we signed a sublicensing agreement with IPSOGEN SAS, a leading molecular diagnostics company with operations in France and the U.S. for the co-exclusive rights to develop, manufacture and market research and diagnostic products for the stratification and monitoring of patients with AML. Upon execution of this agreement, IPSOGEN SAS paid an initial licensing fee of $120,000 and may make milestone payments upon the attainment of certain regulatory and commercial milestones. IPSOGEN SAS also agreed to pay us a royalty on any net revenues during the term of the agreement, subject to certain minimums. The term of the license ends on October 28, 2025, which is the date of expiration of the issued patent rights. In September 2010, we signed an amendment no. 1 to the sublicensing agreement. Pursuant to the amendment, we may require a license from a third-party to perform laboratory testing services. During the years ended December 31, 2015, 2014 and 2013, we recorded royalty, milestone and license fee revenues of approximately $52,000, $60,000 and $60,000, respectively. During those same periods, we had no license fee expenses.

In May 2006, we entered into a license agreement with Drs. Falini and Mecucci, pursuant to which we obtained the exclusive rights for the genetic marker for AML with the intention to utilize these rights for the development of new diagnostic tools. In connection with this agreement, we paid $70,000 to Drs. Falini and Mecucci in the aggregate. In August 2010, we signed an amendment no.1 to the license agreement, pursuant to which we agreed to pay royalties of 6% on royalty revenues and/or 10% of any sublicense income to Drs. Falini and Mecucci. During the years ended December 31, 2015, 2014 and 2013, we recorded royalty expenses of approximately $22,000, $23,000 and $30,000, respectively.

History

On April 26, 2002, we were incorporated in the State of Florida. In January 2010, we re-incorporated from the State of Florida to the State of Delaware and changed our name to Trovagene, Inc. In June 2012, our common stock was listed on The NASDAQ Capital Market under the ticker symbol TROV.

Our corporate website address is www.trovagene.com. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, proxy statements, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge at www.trovagene.com as soon as reasonably practicable after electronically filing such reports with the Securities and Exchange Commission. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way a part of, this Annual Report on Form 10-K.

Operating Segment and Geographic Information

We operate in one business segment, using one measurement of profitability to manage our business. We do not assess the performance of our geographic regions on measures of revenue or comprehensive income or expense. In addition, all of our principal operations, assets and decision-making functions are located in the U.S. We do not produce reports for, or measure the performance of, our geographic regions on any asset-based metrics. Therefore, geographic information is not presented for revenues or long-lived assets.

The Basis for Our Urine-based Molecular Diagnostic Technology

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

In the human body, about 10_{11} - 10_{12} cells die each day primarily as a consequence of natural physiological processes for tissue and organ maintenance, but also as a result of disease. Together, these dead and dying cells contain more than one gram of DNA, which is mostly degraded into short fragments by specific enzymes. A small proportion of these cell-free nucleic acids escapes complete degradation and appears in the bloodstream. Our scientists were the first to discover that circulating cell-free nucleic acids cross the kidney barrier and can be found in the urine as cell-free DNA. This simple yet remarkable discovery that genetic information from various cells throughout the body is present in urine enabled the development of new, non-invasive techniques for molecular diagnostics and genetic testing.

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

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

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

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

Determining DNA and RNA signatures using urine as a "systemic biopsy" may provide a more powerful and effective tool for following and uncovering both pre-clinical and clinical changes, which may include:

- monitoring cancer patients to determine therapeutic response or non-response and disease recurrence;
- determining mutational status when tissue biopsy is unavailable or infeasible;
- monitoring for minimal residual disease ("MRD") after surgical resection of a malignant tumor, following organ transplant status to watch for rejection;
- non-invasively securing samples for the clinical diagnosis of infectious diseases; and
- screening and testing expectant mothers, whose fetuses may be at risk for certain genetic abnormalities.

Currently, these clinical needs are addressed by the use of invasive blood and bone marrow tests, tissue biopsies, and amniocentesis, as well as costly CT, MRI, and PET scans.

Urine is a relatively simple aqueous solution and, unlike plasma, contains few components that can attack and break down cell-free nucleic acid fragments. Cell-free nucleic acid fragments can be accurately analyzed using conventional methods that are either in use or in development within many molecular genomics laboratories.

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

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

Characteristics of Urine-based Cell-free Nucleic Acid Testing

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

Clinical Applications

We believe that our urine-based cell-free molecular diagnostic tests will make it easier to address important health problems worldwide and will lead to significant advances in personalized medicine for improved patient care. We intend to

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

We believe that there are several specific applications of our PCM platform technology with regard to helping oncologists monitor a patient's mutational status, thereby optimizing the treatment approach and improving outcomes. Our technology can be used to determine a patient's mutational status for the first time when a tissue biopsy is not feasible, or it can be used to monitor changes in mutational load over time to provide information that can be useful to direct treatment regimens. Should a patient have their tumor removed surgically, our technology can be used to broadly search for minimal residual disease, which can confirm a successful procedure or enable early detection of recurrent disease for improved patient management. Treatment-emergent mutations can also be a major problem and may be drivers of resistance to first-line therapy. Examples of this include the emergent mutation epidermal growth factor receptor ("EGFR") T790M in lung cancer or KRAS mutations in colorectal cancer. Because our platform uses a non-invasive, easy to obtain sample from the patient, the ability to monitor more accurately and more often with fewer barriers to doing so can provide us with key competitive advantages in the marketplace, particularly with regard to monitoring for treatment-emergent mutations.

Oncology

Urine may offer an alternative to biopsy, medical imaging, and less optimal blood-based tests such as those that use circulating tumor cells. By tracking mutations, we can inform medical practice. Our initial pilot study was focused on the BRAF mutation because of its link to discreet cancers and associated treatments, as well as the KRAS mutation because of its broad applicability in many cancers. We are now developing oncogene tracking tests using ddPCR and NGS for a variety of mutations seen in many cancer types. We believe the potential exists to expand the use of these tracking tests across many cancer types for multiple mutations in test panels.

During 2015, we had over 25 ongoing clinical studies with leading cancer centers and pharmaceutical companies to demonstrate the qualitative and quantitative clinical utility of our tests. Clinical study sites include MD Anderson Cancer Center, Memorial Sloane Kettering Cancer Center, USC Norris Cancer Center, US Oncology, pharmaceutical collaborators, and other top cancer centers. In 2014 and 2015, we entered into clinical study collaboration agreements with Memorial Sloan Kettering Cancer Center, Dana-Farber Cancer Institute, City of Hope Comprehensive Care Center, and Genomac International Ltd. (also known as the Center for Applied Genomics of Solid Tumors, Genomac Research Institute), among others.

Clinical proof of concept for KRAS and BRAF mutation assays

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

Results from the MD Anderson Cancer Center clinical study were published at the AACR-NCI-EROTC International Conference in October 2013. During the study, urine samples from metastatic cancer patients known to have BRAF V600E, KRAS G12D or KRAS G12V mutations were assessed. Our researchers analyzed the urine samples using our urine-based cell-free molecular diagnostic assays. Results demonstrated high concordance between urine and tissue mutational status. In addition, preliminary results indicate that cell-free BRAF V600E mutation monitoring in urine correlates with clinical response to therapy. The clinical study demonstrated that BRAF V600E mutations were detected in urine irrespective of the cancer type, and a multitude of different cancer types, including brain cancer ("glioblastoma"), were included in the initial study results.

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

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

CLIA validated BRAF mutation assay

In October 2013, our first urine test for cancer mutation monitoring was made available to clinicians through our CLIA laboratory. The robustness of our ultra-sensitive assay procedure has been demonstrated for the detection of the BRAF V600E mutation from cell-free DNA in urine. This mutation commonly occurs in melanoma. Of the more than 70,000 cases of melanoma diagnosed each year in the U.S., up to 70 percent harbor a BRAF-type mutation and of those, 80 percent may be positive specifically for BRAF V600E. There are several approved targeted therapies for the treatment of BRAF-positive melanoma, making mutational status monitoring an area of clinical interest among treating physicians.

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

In April 2014, we announced the presentation of clinical study results at the American Association for Cancer Research ("AACR") Annual Meeting. Of the 33 patients enrolled in the study, our BRAF V600E oncogene mutation assay was able to identify the mutation in 29 patients (88%) at least one time during the study, demonstrating a high level of concordance with tissue biopsy.

Longitudinal analysis was performed in 17 patients who had more than one urine-based test during the monitoring period. Of these patients, 13 (76%) showed a correlation between response to treatment and mutational status observed by the urine-based test. The results were presented by Filip Janku, M.D., Ph.D., University of Texas MD Anderson Cancer Center.

In June 2014, we announced that expanded clinical study results demonstrating the utility of our PCM platform were released at the 50th Annual Meeting of the American Society of Clinical Oncology ("ASCO"). Data from a study in multiple cancer types were published in the 2014 ASCO Annual Meeting Proceedings, a Journal of Clinical Oncology by Filip Janku, M.D., Ph.D., University of Texas MD Anderson Cancer. In this study, longitudinal analysis of sequential urine samples demonstrated a statistically significant correlation between changes in the amount of BRAF V600E mutation load and treatment response with targeted drug therapy (p=0.002), per RECIST 1.1 criteria. Results also demonstrated that patients with a decrease in BRAF V600E mutation load had a longer median time to treatment failure compared to those that did not (259 days versus 61 days; p=0.002). Patients in the study had melanoma (n=7), NSCLC (n=3), colorectal cancer (n=2) and other forms of cancer (n=5). Additionally, clinical results from a study in patients with histiocytic disease were presented by Eli Diamond, M.D., Memorial Sloan Kettering Cancer Center. In this study, our PCM technology demonstrated 93% concordance for identifying the BRAF V600E mutation and confirmed the absence of the mutation in the six patients whose biopsies tested negative. Our assay also detected the BRAF V600E mutation in two patients for whom tissue biopsy material was inadequate to determine mutational status, and these results were subsequently confirmed with follow-up biopsies. Our PCM platform showed 100% concordance in monitoring response to therapy in six study subjects who tested positive for the mutation and were treated with a BRAF inhibitor. Results from this study were published in the medical journal, *Cancer Discovery*, and in clinical consensus guidelines for the diagnosis and treatment of patients with the histiocytic disease, Erdheim-Chester disease.

CLIA validated KRAS mutation assay

In March 2014, our urine based test for KRAS mutations became available to clinicians through our CLIA laboratory. This assay detects and monitors the seven most commonly encountered mutations of the KRAS oncogene and is our first multiplexed oncogene mutation assay utilizing next-generation sequencing as a mutation detection platform. The robustness of

our ultra-sensitive assays has been demonstrated for the detection of KRAS mutations from cell-free DNA in urine. This mutation commonly occurs in patients diagnosed with either colorectal cancer, pancreatic cancer, or lung cancer. Of the more than 1.1 million estimated cases of colorectal cancer in the U.S., up to 40% are estimated to harbor KRAS mutations. In pancreatic cancer and lung cancer, approximately 90% and 15% of patients harbor KRAS mutations, respectively. Because of the prevalence of this mutation in several important cancer types, detecting and quantitatively monitoring KRAS mutational status is an area of clinical interest among treating physicians.

The clinical study being conducted at the USC Norris Cancer Center is focused on mutation monitoring and the emergence of KRAS resistant mutations in colorectal cancer. With multiple targeted therapies for colorectal cancer on the market, detection of KRAS mutations in tissue has a direct impact on the initial treatment selection for these patients. The primary purpose of the collaborative study is to determine whether KRAS mutations can be evaluated in urine to monitor treatment response in patients that test either positive or negative for the mutation.

The U.S. Oncology clinical study will test detection and monitoring of KRAS mutations in pancreatic cancer patients. In addition to the U.S. Oncology Research-affiliated community cancer care sites participating in this study, additional academic research institutions that specialize in oncology have also elected to participate. CT scans and CA19-9 blood levels are currently the only two methods available to clinicians to monitor metastatic pancreatic cancer tumor burden and response to therapy. However, approximately 11%-17% of patients will not display elevated CA 19-9, even with high tumor load. For patients that test negative for CA19-9, our method to follow disease status by detecting and monitoring KRAS mutations could be distinctly beneficial.

In November 2015, we presented clinical results at the EORTC-AACR-NCI International Symposium highlighting our ability to detect and quantitate KRAS mutations in blood and urine samples from patients with advanced colorectal cancer. Results showed a highly correlated response. Of the blinded retrospective plasma cell-free DNA samples evaluated, 95% displayed the KRAS mutation concordant with tumor tissue, and for evaluable urine samples in the study, 92% displayed the KRAS mutation concordant with tumor tissue. The majority of patients in the study underwent surgery and received neo-adjuvant or adjuvant therapy, and serial monitoring of KRAS mutations using our assay showed a clear correlation between blood and urine samples. An estimated analytical limit of detection of two copies per ~100,000 genome equivalents, or 0.002% was observed in the study, demonstrating very high analytical sensitivity.

CLIA validated EGFR mutation assays

In the first quarter of 2015, our urine-based tests for the activating mutations, *EGFR L858* and *EGFR Exon 19 Deletion*, as well as the resistance mutation, *EGFR T790M*, became available to clinicians through our CLIA laboratory. These assays detect and monitor three critical mutations that are believed to drive the progression of NSCLC. The robustness of our ultra-sensitive assays has been demonstrated for the detection of these three EGFR mutations from cell-free DNA in urine.

While lung cancer is one of the most aggressive malignancies, progress has been made in the advancement of therapeutic strategies against the disease. In particular, epidermal growth factor receptor tyrosine kinase inhibitors (*EGFR*-TKIs), such as gefitinib and erlotinib, in NSCLC patients with activating *EGFR* mutations have demonstrated clinical response rates as high as 80%. However, after approximately six to twelve months, most tumors develop acquired resistance to these targeted therapies. Research into such resistance has identified the secondary *EGFR T790M* mutation, which occurs in approximately 60% of patients with acquired resistance to *EGFR*-TKIs and is reported to negate the benefits of treatment. In November 2015, the first targeted treatment for *EGFR T790M* mutation-positive NSCLC, Tagrisso, was approved by the U.S. Food and Drug Administration (“FDA”). Additional drug candidates such as rociletinib are in advanced clinical development for this indication. We believe that our non-invasive assays for the detection and monitoring of both activating and resistance EGFR mutations have potential to play an important role in the treatment of NSCLC.

A clinical study being conducted at UC San Diego Moores Cancer Center (“UCSD”) is focused on the determination and monitoring of EGFR T790 resistance mutations in lung cancer patients. With new targeted therapies for *EGFR T790M* mutation-positive lung cancer on the market or in late-stage clinical development, detection of this resistance mutation has a direct impact on treatment selection for patients who are progressing on first-line targeted therapy. The primary purpose of this collaborative study is to determine whether *EGFR T790M* mutations can be evaluated in urine to monitor treatment response in patients that are found to be positive for the mutation.

In April 2015, we presented clinical results at the European Lung Cancer Conference demonstrating that our urine-based PCM platform outperformed tissue biopsy for the detection and monitoring of *EGFR T790M* mutations in metastatic lung cancer patients. In an interim analysis of 34 patients from an ongoing clinical study, our PCM platform detected the *EGFR T790M* mutation in all patients who were positive for the mutation in tissue biopsy. Our urine-based assay identified additional

patients as *EGFR T790M*-positive, including those who had clinical suspicion of *EGFR T790M*-progressive disease, but were either negative by tissue biopsy or had not yet undergone tissue biopsy for confirmation. Based on the study results, our PCM platform detected *EGFR T790M* resistance mutations months earlier than radiologic detection of progression in patients. Early pharmacodynamic events occurring within hours or days of anti-*EGFR* drug treatment were evaluated in the study by implementing daily monitoring of urinary ctDNA. Initial results demonstrated that immediate changes in *EGFR* mutational load using a urine specimen may identify patients who respond to anti-*EGFR* therapy much earlier than follow-up CT-scans.

We have several programs to evaluate the detection and monitoring of EGFR mutational status in lung cancer patients. A focus of these studies is the emergence of the resistant mutation EGFR T790M in lung cancer patients, which can be important for therapeutic selection when this mutation type is or becomes present. In addition to our studies with UCSD, our collaborators for evaluating our technology in NSCLC include Memorial Sloan Kettering Cancer Center, City of Hope Comprehensive Cancer Center, Clovis Oncology, and Genomac Research Institute.

Additional mutation assays and clinical programs

We remain focused on expanding the mutation coverage of our platform to address the relevant clinically actionable driver and resistance mutations in cancers for which the National Comprehensive Cancer Network guidelines recommend targeted therapies, such as lung cancer, colorectal cancer, pancreatic cancer, and melanoma. In addition to our assays for the *BRAF*, *KRAS*, and *EGFR* oncogenes, we are also developing more comprehensive mutation coverage for these other cancers and are adding additional oncogenes with an initial focus on lung cancer, as well as targeting clinically validated gene rearrangements such as *ALK*, *RET*, and *ROS*. The primary objective of our clinical development program is to demonstrate utility for non-invasive, near real-time detection and monitoring of oncogene mutations for any tumor type with our highly sensitive urine- and blood-based platform. Our clinical programs with top-tier cancer centers will continue to drive multiple opportunities for data presentations and publications in peer-reviewed journals. We believe that data from our clinical studies, and those from peer-reviewed manuscripts, once published, will help support our ongoing commercial efforts to build physician demand and health insurance reimbursement for our cancer monitoring platform.

Infectious Disease

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

In August 2014, we presented results from two clinical studies at the 29th International Papillomavirus conference for our urine-based diagnostic test for the detection of high risk strains of HPV. Results from both pilot studies consistently demonstrated that our urine-based HPV assay had sensitivity greater than 90% for identifying women with high grade cervical intraepithelial neoplasia (CIN2/3). Assay performance was comparable to traditional HPV testing with commercially available tests in patient-matched cervical samples. In one of the studies, urine collection was examined to establish standardization of urine as a clinical specimen for high-risk HPV testing.

In February 2015, clinical results from the PREDICTORS 4 trial were presented at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) 2015 Congress, which demonstrated high sensitivity for our non-invasive, urine-based HPV assay when determining HPV types and cervical lesions or cervical intraepithelial neoplasia (CIN) Grade 2/3. Within the PREDICTORS 4 trial, urine and cervical samples were collected from 501 women, and data from this large patient subset demonstrated that sensitivity with our HPV assay for cervical samples was comparable to established cervical screening tests. Sensitivity of our HPV assay using cervical samples was 96.3% for CIN Grade 3+ and 94.5% for CIN Grade 2+. Sensitivity for urine samples was 91.4% for CIN Grade 3+ and 89.0% for CIN Grade 2+. Furthermore, detection of high risk HPV in urine was not different from cervical samples for all age groups of women in the study (18-29 years, 30-39 years and 40-69 years). The study authors concluded that while there is a small loss of sensitivity in urine, the greater than 90% sensitivity for CIN Grade 3+ is still better than conventional Pap cytology, which makes this assay a good candidate in our efforts to increase adoption of HPV testing, especially for women who are not currently being screened for cervical cancer.

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

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

Prenatal Genetics

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

Transplant

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

Changing the Molecular Diagnostic Paradigm

Diagnosis and detection of severe and life-threatening diseases are among the most important outcomes of the Human Genome Project ("HGP"). There are four requirements to realize the full benefit of the HGP in relation to advances in the war on cancer: (1) large catalogues of cancer mutations, (2) affordable sequencing of patient samples, (3) detection technologies capable of identifying and quantifying rare instances of mutations at affordable prices, and (4) abundant samples that can be collected easily and frequently in order to monitor an individual's cancer.

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

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

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

The Market

The global molecular diagnostics market is forecast to reach nearly $8.0 billion by 2018, a compound annual growth rate ("CAGR") of 9.7%, from 2013-2018. This molecular diagnostics market is segmented on the basis of application, technology, end user, product, and geography. Based on application, the market is further segmented into infectious diseases, oncology, genetics, blood screening, microbiology, and others. Infectious diseases secured the largest market share, whereas oncology was the fastest growing segment amongst the rest. The driving forces of the molecular diagnostics market include the rising incidences of infectious diseases, genetic disorders, and cancer, as well as technological advancements such as assay improvements, new diagnostic tests with novel clinical utility, and portability of equipment. The technology segment of the molecular diagnostics market is comprised of polymerase chain reaction ("PCR"), Isothermal Nucleic Acid Amplification Technology, hybridization, DNA sequencing and NGS, microarray, and others.

Based on products, the molecular diagnostics market is segmented into instruments, reagents, services and software. Reagents occupy the largest market share and will also register the maximum growth rate in the forecasted period of 2013 to 2018. These reagents include assays that detect and diagnose diseases and are also used as biomarkers that predict the biological properties of potential drug compounds.

North America accounts for the largest share of the market and is poised to grow at a high rate in the forecast period from 2013 to 2018. The growth can be attributed to the rising incidences of infectious diseases, cancer prevalence, and genetic disorders that are further adding to the overall prevalence of chronic diseases. Europe is the second leading contributor to the molecular diagnostics market. However, the growth of this region is expected to be sluggish in the forecast period and is estimated to grow at a lower CAGR than North America, due to factors such as the uneven reimbursement policies and the European economic crisis. Asia is the most promising region for molecular diagnostics in the coming five years. It is expected

to grow at a higher CAGR than North America and Europe over the forecast period. The large population base and improved purchasing power of patients are the major drivers of this market.

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

Commercial Markets — Internal Focus

Oncology

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

According to the American Cancer Society's ("ACS") 2015 report, there are approximately 565,000 patients that die every year from cancer, not including cancers of the blood, bone marrow or lymphatic system. Using this number as a proxy for metastatic cancers, it can be assumed that all of these patients are being treated within 12 months of death for their disease. Testing and monitoring these patients for response to therapy or progression while on therapy, or for markers of resistance to therapy (like EGFR *T790M* for lung cancer), would be a natural extension of our technology. The average lung, breast, or colon cancer patient receives between 18-21 radiographic imaging procedures (PET, CT, MRI, etc.) during the two years following their diagnosis. This averages to approximately nine to ten scans per patient per year. Use of a urine-based monitoring test at the start of therapy, at several points in time during therapy, and at the completion of therapy would represent approximately six to ten separate testing events that could occur within a 12 month period. At a reimbursed price of approximately $1,000 per test, the total available market ("TAM") for treatment response monitoring in the U.S. could be worth between $3.0 billion and $5.0 billion annually.

Once patients with cancer, primary or metastatic, have completed therapy, they will require monitoring for possible progression and for the appearance of resistance markers, since many metastatic patients may remain on lower-dose "maintenance therapy" during the remainder of their lives, or until treatment is no longer considered an option. According to the ACS, as of January 2014, there were nearly 14.5 million patients alive in the U.S. who had been treated for cancers that have metastatic potential. Use of a urine-based mutation monitoring test once a year at $1,000 per test would equate to a TAM for recurrence monitoring in the U.S. of approximately $14.5 billion annually.

Both of these markets, treatment response and recurrence monitoring, are sizeable economic opportunities. Capturing 10% of the response monitoring market would produce annual revenues of between $300 million and $500 million, and 5% of the recurrence monitoring market would yield annual revenues of over $700 million.

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

Studies have shown that cancer patients who have *KRAS* mutations do not respond successfully to treatment with anti-

EGFR drugs such as Erbitux, Iressa, Tarceva, Tykerb, and Vectibix.

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

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

Simple urine-based assays would likely lead to improved personalized medicine for patients, resulting in the right drug being prescribed for the right disease at the right time. We believe this technology will lead to an improved quality of life for patients and will become part of a new standard of care for those patients and physicians fighting the war on cancer.

Drug Development and Monitoring of Therapeutic Outcomes

Cell-free DNA diagnostic technology has significant potential as a simple, quick, non-invasive way of monitoring clinical responses to drugs in clinical development and evaluating patient-specific responses to already approved and marketed therapies. Specific target applications include, but are not limited to, the detection of metastasis following tumor surgery, monitoring of response and tumor progression during chemotherapy, immunotherapy, and/or radiation therapy, development of optimal hormonal and chemotherapeutic treatment protocols, and monitoring of transplantation patients on immunosuppressive drugs.

With cancer treatment today, it is often difficult to determine if a particular patient is responding to their current therapeutic regimen. Generally, patients are re-examined periodically to determine if a tumor has grown in size, reduced in size (i.e., partial response), disappeared (i.e. no sign of disease - complete response) or remained the same (stable disease). If the tumor has grown in size or remained the same, treatment may be adjusted. By measuring and monitoring tumor specific genetic markers in a patient's urine pre-, peri- and post-chemotherapy, it may be possible to more quickly determine whether a patient is responding to therapy. Use of cell-free DNA diagnostics may permit more rapid and real-time therapeutic decisions on a patient-specific basis. Approximately 1.7 million new cancer cases are diagnosed annually, and there are several hundred companies developing therapeutic agents in the U.S. alone. We believe this indicates a large potential application to use cell-free DNA diagnostic technology for both drug development and the monitoring of therapeutic outcomes.

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

Commercial Markets — External Focus

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

Infectious Diseases — **HPV**

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

According to the ACS, India alone accounts for 27% (77,100) of total worldwide cervical cancer deaths. A recent clinical trial conducted in rural India found that a single round of HPV DNA testing was associated with an approximately 50% reduction in the risk of developing advanced cervical cancer and associated deaths. In the U.S., better patient compliance and

screening guidelines reduced cervical cancer death rates to only 4,290 cases in 2011. The major drivers of poor screening in these developing regions are cultural acceptance, limited screening resources and funding, and poor cytology proficiency. Further exacerbating the compliance hurdles is that the primary screening mechanism involves an invasive cervical scraping procedure (e.g., Pap smear). It is generally agreed that the early detection of cervical cancer leads to much higher recovery rates and lower rates of invasive disease.

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

Other areas beyond HPV detection and monitoring include those infectious diseases caused by viruses, bacteria, fungi, and parasites. Cell-free nucleic acid assays that detect molecular targets in organisms can provide a quick, accurate, simple, and cost effective method for screening and monitoring disease. Specific areas of interest include testing for molecular targets from organisms that cause Lyme disease, John Cunningham 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.

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

Technologies for the collection, shipment and storage of urine specimens, and cell-free nucleic acid extraction

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

We intend to invest in the research and development of new nucleic acid preservatives or methods, which improve the stability of urine as a cell-free nucleic acid specimen. We will also explore the feasibility of automating cell-free nucleic acid extraction from urine in collaboration with industry leaders in robotics, liquid handling, and other applicable technologies. Upon the completion of such projects, it is our expectation that a simple and streamlined method can be “kitted” as a stand-alone product to provide academic researchers with reagents that they can purchase and utilize in their own laboratories.

This program serves three primary purposes: it will (1) accelerate the rate of publications and development of the body of evidence supporting urine as a viable specimen and, therefore, market acceptance of urine-based nucleic acid testing, (2) create an RUO product for direct sale, and (3) provide a foundation for our technology transfer programs to partner reference laboratories seeking to bring cell-free nucleic acid testing technology in-house.

Expansion of Analytically Validated Instrumentation, Systems, and Platforms

A unique element of our cell-free nucleic acid testing method is its design, which is focused on “counting” the target molecules already enriched through our initial proprietary specimen collection, isolation, and amplification procedures. This molecular counting is currently achieved in our Clinical Services Laboratory by using Illumina MiSeq systems as the detection platform; however, this molecular counting is not limited to just this type of system. Alternative NGS systems, Mass Spectrometry-based systems, ddPCR, or MicroArray reading systems may also be used in conjunction with our front-end sample preparation technology. As we expand our menu of targeted biomarker tests, we will also broaden the available platforms that can be used as detectors. When coupled with the RUO kitting program referenced above, the benefit of multiple

analytically validated detection systems will increase the addressable market for our technology transfer program and future commercial partnerships.

Our Business Strategy

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

The U.S. Congress passed the CLIA in 1988 to regulate development, evaluation, and use of LDTs. The 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 regulations. These regulations, which were finalized in 2003, establish standards to help ensure the quality and accuracy of laboratory testing. While most common laboratory tests are commercial tests, manufactured and marketed to multiple laboratories, some new tests are developed, evaluated, and validated within one particular laboratory. These LDTs are used solely within that laboratory and are not distributed or sold to any other laboratories or health care facilities.

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

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

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

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. Our technology is commercially available and reimbursement is available under the current procedural terminology (“CPT”) codes for molecular-based testing. We are marketing our tests directly to physicians, and we process those tests through our CLIA laboratory. We are working with public and private payors for appropriate reimbursement of processed tests. We believe this strategy, coupled with strong clinical results supporting the use of our cell-free molecular diagnostic technology, will lead to broad market adoption of our technology.

Research and Development

As of December 31, 2015, we had 41 dedicated scientists located in our office in San Diego, California. We plan to continue to grow our research and development organization as needed to support our product development goals and expect that our research and development team will represent a good mix of senior lead researchers and scientists (Ph.Ds.), laboratory associate scientists, and experts in clinical development and regulatory affairs of molecular diagnostics. We plan to rapidly introduce new products to the market that can be used as LDTs within our CLIA lab, and simultaneously continue funding and

collaborating on the necessary clinical studies that can support the utility of our tests, and potentially support regulatory submissions for marketing approval or clearance of our tests depending upon the nature of the product. We currently have sufficient resources to complete these projects extending into 2017. We plan to seek additional funding as required to supplement current commercial and licensing revenue. Information and documentation systems infrastructure (e.g., design history files and firewalls) must be in place to support the confidentiality of multiple partnering programs and the rigorous scientific and regulatory oversight needed for products in the in-vitro diagnostics markets. Research and development expenses for the years ended December 31, 2015, 2014 and 2013 were approximately $10.6 million, $6.7 million and $3.9 million, respectively.

Intellectual Property

We consider the protection of our proprietary technologies and products to be a critical element in the success of our business. As of December 31, 2015, our wholly-owned and licensed intellectual property included over 85 issued patents and over 60 pending patent applications in the U.S. and abroad. The pending applications include multiple international applications filed under the Patent Cooperation Treaty ("PCT applications") that will be used as the basis for multiple additional patent applications.

One group of patents and patent applications includes seven U.S. patents, with 30 counterpart patents in Japan, Hong Kong and Europe, including the major markets of the European countries. These patents are directed to the detection of nucleic acid sequences in urine and nucleic acid modifications and alterations in urine. This patent family includes claims directed to prenatal analysis of fetal DNA, the determination of the sex of a fetus and the detection of diseases such as Down Syndrome caused by genetic alterations. Other patented claims are directed to detecting and monitoring cancer through urine-based testing, nucleic acid screening, and monitoring in cases of transplantation and infectious diseases, including infection by viruses and pathogens, and other potential diagnostic and genetic testing applications. Members of this patent group expire between 2018 and 2026. Additional pending claims are directed to the preparation of cell-free nucleic acids, as well as detection of short cell-free nucleic acid molecules which, if granted, will expire between 2028 and 2033.

A second group is directed to the detection of specific gene mutations and indicators of disease. These include *NPM1* mutations, *BRAF* mutations, *SF3B1* mutations, HPV, AML, and hairy cell leukemia. The detection includes analysis of cell-free nucleic acid molecules. This group includes U.S. patent numbers 8,222,370 B1, 8,501,924 B1, 8,642,261 B1, and 9,222,137 B1 as well as seven pending U.S. patent applications. There are also 25 pending non-U.S. and PCT patent applications. Members of this patent group expire between 2025 and 2034.

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

Applications are also pending that are directed to detecting and enriching small concentrations of short nucleic acid sequences, detecting and monitoring mutations in histiocytosis, and detecting and monitoring mutations in diseases, such as cancer, over time.

Wherever possible, we seek to protect our inventions by filing U.S. patents as well as foreign counterpart applications in select 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 our 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 we could find that the development, manufacture or sale of products requiring such licenses are not possible.

We may rely on trade secrets to protect our technology, which are difficult to protect. We seek to protect our proprietary technology and processes by entering into confidentiality agreements with our employees, certain consultants, and contractors. These agreements may be breached, we may not have adequate remedies for any breach and our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees or our consultants

or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Manufacturing and Distribution

In 2016, we plan to continue introducing our LDTs into the marketplace through our CLIA licensed and CAP accredited laboratory. We source all reagents and consumables needed for our LDTs from third party vendors, and we currently do not manufacture reagents kits for use in our own laboratory, or to distribute to third party laboratories.

We have established a sales and marketing organization to directly market our LDTs for oncogene mutations to end users in the oncology market segment. As of December 31, 2015, we had 16 employees dedicated to the sales and marketing of our LDTs in the U.S. market. We intend to add additional employees as needed to support the introduction of new LDTs planned for 2016.

Reimbursement

Medicare and other third-party payors 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 that has been prescribed 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.

Reimbursement of our novel tests is a top priority, as physician and patient access to our technology is essential for widespread adoption of our products. To gain initial reimbursement, our qualitative tests will be billed and reimbursed under established Tier I codes for their respective mutation (i.e., BRAF, KRAS, and EGFR). These are CPT codes from the American Medical Association (MoPath system), which should enable us to bill and obtain reimbursement for our tests without delay. As we develop our tests and demonstrate novel clinical utility in cancer monitoring, supported by our high analytical sensitivity, quantitative performance over a large dynamic range, and clinical experience, we will pursue a Not Otherwise Classified ("NOC") code for billing and reimbursement. Under these conditions, premium pricing is expected. Over time, we intend to pursue permanent CPT codes unique to our cancer monitoring diagnostics once sufficient value is assigned under the NOC code system. We will engage with third party payors including integrated healthcare networks and Medicare, for reimbursement of our tests, with the goals of obtaining strong adoption of our tests, positive coverage decisions and appropriate valuation of our tests on a widespread basis over time. In 2016, we plan to continue developing clinical evidence around the utility and performance of our testing platform and interacting with payors for the reimbursement of our commercially available urine-based cell-free nucleic acid diagnostics.

Government Regulation

Regulation by governmental authorities in the U.S. 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 our LDTs. 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 reagents as Analyte-Specific Reagents ("ASRs"). ASR's generally do not require FDA pre-market approval or clearance if they are (1) sold to clinical laboratories certified under the CLIA to perform high complexity testing and (2) 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 or removal of reagents must be documented and reported to the FDA. The FDA also regulates product labeling, promotion and, in some cases, advertising, of medical devices. As discussed above, we must comply with the FDA's Quality System Regulation that establishes extensive requirements for design control, quality control, validation, and manufacturing. Thus, even with FDA approval or clearance, we must continue to be diligent in maintaining compliance with these various regulations, as failure to do so can lead to enforcement action. The FDA periodically inspects facilities to determine compliance with these and other requirements.

Competition

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

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

Employees

As of February 29, 2016 we had a total of 72 employees, all of whom were full-time.

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 Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones we face. 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 investors in our company may lose all or part of their investment.

Risks Related to Our Business

We are a development stage company and may never earn a profit.

We are a development stage company and have incurred losses since our formation. As of December 31, 2015, we have an accumulated total deficit of approximately $108.9 million. For the fiscal year ended December 31, 2015, we had a net loss and comprehensive loss attributable to common stockholders of approximately $27.5 million. To date, we have experienced negative cash flow from development of our cell-free molecular diagnostic technology. We have not generated any revenue from operations except for licensing, milestone and royalty income, and we expect to incur substantial net losses for the foreseeable future as we seek to further develop and commercialize our cell-free molecular diagnostic 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 our cell-free molecular diagnostic 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 cell-free molecular diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will attain profitability, 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 our cell-free molecular diagnostic technology or any future tests we may develop, and our business may not be successful.

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

As of December 31, 2015, our cash balance was approximately $67.5 million and our working capital was approximately $60.2 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. At December 31, 2015 we had $16.5 million outstanding under debt agreements. In order to raise additional capital, we may seek to sell additional equity and/or debt securities or obtain a credit facility or other loan, 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 unfavorable terms.

Our Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or SVB, and our Loan and Security Agreement with SVB for equipment, each contain certain covenants that could adversely affect our operations. Additionally, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than expected and possibly at a time when we do not have sufficient capital to meet these obligations, which could materially adversely affect our business, prospects and financial condition.

We have entered into a Loan and Security Agreement, dated as of June 30, 2014, with Oxford and SVB, or the Lenders, as amended, or the Loan and Security Agreement, for a term loan of $15.0 million. The term loan is secured by all of our assets, other than our intellectual property. In addition, we have entered into a Loan and Security Agreement, dated as of November 17, 2015, with SVB that provides for cash borrowings for equipment of up to $2.0 million, secured by the equipment financed, or the Equipment Line of Credit. The Loan and Security Agreement and the Equipment Line of Credit each contain affirmative and negative covenants that, among other things, restrict our ability to:

- incur additional indebtedness or guarantees;
- incur liens;
- make investments, loans and acquisitions;
- consolidate or merge with or into other entities;
- sell or assign any part of our business or property;
- engage in transactions with affiliates; and
- pay dividends.

Additionally, we may be deemed to be in default under the Loan and Security Agreement and the Equipment Line of Credit upon the occurrence of certain events, including, among other things, payment defaults; breaches of representations, warranties or covenants; certain insolvency events; and the occurrence of certain material adverse changes. Upon the occurrence of an event of default and following any cure period (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balance, and the Lenders may declare all outstanding obligations immediately due and payable and take certain other actions set forth in the Loan and Security Agreement and the Equipment Line of Credit.

The Loan and Security Agreement and the Equipment Line of Credit could prevent us from taking certain actions without the consent of the Lenders and, if an event of default should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the Lenders may elect to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the Loan and Security Agreement and the Equipment Line of Credit, as applicable. Even if we are able to repay the indebtedness upon the occurrence of an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could materially adversely affect our business, prospects and financial condition.

The commercial success of our product candidates will depend upon the degree of market acceptance of these product candidates among physicians, patients, healthcare payors and the medical community and on our ability to successfully market our product candidates.

The use of our cell-free molecular diagnostic 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 our cell-free molecular diagnostic technology, in which event we may be unable to generate significant revenue or become profitable. Acceptance of our cell-free molecular diagnostic technology by physicians, patients, healthcare payors and the medical community will depend on a number of factors, including, but not limited to:

- 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 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 cell-free molecular diagnostic tests for their patients and, consequently, would limit our revenue and profitability.

We currently have limited experience in marketing our products. If we are unable to expand our marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We have limited experience in marketing our products. We intend to expand our in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other molecular diagnostic companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or later decide not to expand our internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements for the sales and marketing of our product candidates or future products; however, we may not be able to establish or maintain such collaborative arrangements or, if we are able to do so, we cannot guarantee that any sales force we use through such arrangements will be effective. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates internally. We also face competition in our search for third parties to assist us with the sales and marketing of our product candidates, which may negatively impact our ability to enter into favorable collaborative arrangements for the sale and marketing of our product candidates.

If our potential medical diagnostic tests are unable to compete effectively with current and future medical diagnostic tests targeting similar markets as our product candidates, 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 the 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. These competitors also 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 greater financial, marketing and human resources than we do; therefore, there can be no assurance that we can successfully compete with current or potential competitors, and any such competition could materially adversely affect our business, financial position or results of operations.

Since our cell-free molecular diagnostic technology is under development, we cannot predict the relative competitive position of any product based upon our cell-free molecular diagnostic technology. However, we expect that the following factors, among others, will determine our ability to compete effectively: safety and efficacy; product price; turnaround time; ease of administration; performance; reimbursement; and marketing and sales capabilities.

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 our cell-free 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 product candidates

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

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

Cell-free nucleic acids in urine are stable at room temperature for extended periods of time with the addition of a simple preservative. Successful implementation of our cell-free nucleic acid technology in molecular testing is closely linked to the availability of techniques and procedures for cell-free nucleic acid preservation, purification and analysis. In the event urine specimens are not adequately preserved or are improperly stored or contaminated, we may be delayed in pursuing our clinical studies, and we may incur additional costs associated with procuring new human urine samples.

If the validity of an informed consent from a subject was to be challenged, we could be forced to stop using some of our resources, which would hinder our product development efforts.

We have measures in place to ensure that all clinical data and other samples that we receive from our clinical collaborators have been collected from subjects who have provided appropriate informed consent for the data and samples provided to be used for purposes that include commercial diagnostic product and test development activities. We have measures in place to ensure that data and samples that have been collected by our clinical collaborators are provided to us on a subject de-identified manner. We also have measures in place to ensure that the subjects from whom our data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. We rely on our clinical collaborators for appropriate compliance with the informed consent provided by each subject and with applicable regulations. A subject's informed consent could be challenged in the future, and any informed consent could prove invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our clinical collaborators, could deny us access to or force us to stop using some of our clinical samples, which would hinder our diagnostic product and test development efforts. We could become involved in legal challenges relating to the validity of one or more informed consents from subjects, which could require substantial dedication of time and financial resources.

If our clinical studies do not prove that our technologies are superior and demonstrate the clinical utility of our technology, we may never commercialize our product candidates and services.

The results of our clinical studies may not show that tests using our cell-free molecular diagnostic technology are superior to existing testing methods and may not demonstrate clinical utility. 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 may obtain from any future studies, including our next two clinical studies, which will include substantially more samples and a larger percentage of normal-risk patients.

We have limited experience in establishing strong business relationships with leading clinical reference laboratories to perform cell-free molecular diagnostic tests using our technologies, which could limit our revenue growth.

A key step in our strategy is to sell diagnostic products that use our proprietary technologies to leading clinical reference laboratories that will perform cell-free molecular diagnostic tests. We have limited experience in establishing these business relationships. If we are unable to establish and maintain these business relationships, we may not be able to generate revenue beyond the revenue we can generate from our limited in-house test processing capabilities.

We depend upon our officers and other key employees, 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, especially Dr. Antonius Schuh, our Chief Executive Officer, and other key employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field and, in order to pursue our test development and commercialization strategies, we will need to attract, hire and retain, 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. Additionally, 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 tests we may develop in the future 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 67 full-time employees as of December 31, 2015. Future growth of our company will impose significant additional 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 cell-free molecular diagnostic technology. Our future financial performance and our ability to commercialize cell-free molecular diagnostic tests and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

There is no guarantee that we will be able to accomplish these tasks, and our failure to accomplish any of them could materially adversely affect our business, prospects and financial condition.

All of our diagnostic technology and services are performed at a single laboratory, and in the event this facility is affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.

We are performing all of our diagnostic services in our laboratory located in San Diego, California. Despite precautions taken by us, any future natural or man-made disaster at this laboratory, such as a fire, flood, earthquake or terrorist act, could cause substantial delays in our operations, damage or destroy our equipment and urine samples or cause us to incur additional expenses.

In addition, we are leasing the facilities where our laboratory operates. We are currently in compliance with all of our lease obligations, but should the lease terminate for any reason, or if the laboratory is moved due to conditions outside of our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of our laboratory, we may be unable to perform

our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could materially adversely affect our operating results and financial condition.

Further, if we have to use a substitute laboratory while our facility is closed, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA-certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to certification under CLIA and licensure by various states, which would take a significant amount of time and expense and result in delays in our ability to continue our personalized medicine services operations.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, the Health Insurance Portability and Accountability Act, or HIPAA, imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed: notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

General economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the U.S. and other countries have contributed to increased volatility and diminished expectations for the global economy. If the economic climate does not improve, or if it deteriorates, our business, including our access to patient samples and the addressable market for tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be negatively impacted, which could materially adversely affect our business, prospects and financial condition.

We incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the

Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, and The NASDAQ Stock Market LLC. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. For example, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There is significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Act and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

We may become subject to federal and state tax assessments, penalties and interest with respect to past compensation paid to certain of our executives.

During our internal review process, contingencies were identified regarding various federal and state tax exposures with respect to past compensation paid to certain of our executives. We have not recorded any accrued liabilities related to the potential federal and state tax exposure. If we become subject to any material tax assessment, penalties and interest by federal and state tax authorities in the future, our results of operations, financial performance and cash flows could be materially adversely affected.

Risks Related to Our Regulatory Environment

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

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

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

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

Market acceptance, sales of products based upon our cell-free molecular diagnostic technology, and our profitability may depend on reimbursement policies and healthcare 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 healthcare 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 product candidates. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement for our current and future tests. Since each payor makes its own decision as to whether to establish a policy to reimburse a 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 product candidates in the future. If reimbursement is not available or is limited, we may not be able to commercialize our product candidates.

In addition, 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 able to obtain reimbursement for our tests, insurers may withdraw their coverage policies or cancel their contracts with us at any time, stop paying for our tests or reduce the payment rate for our tests, each of 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 tests, our revenues could decline.

If we do not receive regulatory approvals, we may not be able to develop and commercialize our cell-free molecular diagnostic technology.

We may need approval from the U.S. Food and Drug Administration, or the FDA, to market products based on our cell-free molecular diagnostic technology for diagnostic uses in the U.S. and approvals from foreign regulatory authorities to market products based on our cell-free molecular diagnostic technology outside the U.S. 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 our cell-free molecular diagnostic technology, we will be unable to sell such product candidates 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 U.S. If we seek to market products or services such as a urine-based Human Papillomavirus, or HPV, high-risk, or HR, Detection test in Europe, we will need to receive a CE Mark. If we do not obtain a CE Mark for our urine-based HPV HR Detection test, we will be unable to sell this product candidate in Europe and countries that recognize the CE Mark.

The regulatory review and approval process, which may include evaluation of preclinical studies and clinical studies of product candidates based on our cell-free molecular diagnostic technology, as well as the evaluation of manufacturing processes and contract manufacturers' facilities, is lengthy, expensive and uncertain. Securing regulatory approval for products based on our cell-free molecular diagnostic technology may require the submission of extensive preclinical and clinical data and supporting information to regulatory authorities to establish such product candidates' 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 one or more of our applications or may decide after review of an application that the data submitted is insufficient to allow for approval of any product based upon our cell-free molecular diagnostic technology. If regulatory authorities do not accept or approve our applications, they may require that we conduct additional preclinical, clinical 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 substantially more resources than we had budgeted for such applications. It is also possible that additional studies may not suffice in helping us obtain approval of our applications. If any of these outcomes occur, we may be forced to abandon our applications for approval, which may force us to cease or curtail operations.

If we do not comply with governmental regulations applicable to our Clinical Laboratory Improvement Amendments, or CLIA, certified laboratory, we may not be able to continue our operations.

The establishment and operation of our laboratory is subject to regulation by numerous federal, state and local governmental authorities in the U.S. Our laboratory holds a CLIA certificate of compliance and is licensed by every state (other than the State of New York) and the District of Columbia, as required, which enables us to provide testing services to residents of almost every state. Failure to comply with state regulations or changes in state regulatory requirements could result in a substantial curtailment or even prohibition of the operations of our laboratory and could materially adversely affect our business. CLIA is a federal law that regulates clinical laboratories that perform testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of disease. To renew CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of these laboratories. If we were to lose our CLIA certification or our state licenses, whether as a result of a revocation, suspension or limitation of our license, we would no longer be able to continue our testing operations, which would materially adversely affect our business, prospects and financial condition. Potential sanctions for violations of these statutes and regulations also

include significant fines, the suspension or loss of various licenses, certificates and authorizations, or product suspension or recalls.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the controlled use of potentially harmful biological materials and chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could materially adversely affect our business, prospects and financial condition. Moreover, in the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

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 U.S. 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 healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products and services that we believe are fair, which may impact our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and judicial 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 or force us 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 U.S., new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, has substantially changed the way healthcare is financed by both government health plans and private insurers. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our 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, such provisions could materially adversely affect our business, prospects and financial condition.

The Food and Drug Administration Amendments Act of 2007 gives the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical studies of products, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical studies and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products, all of which could materially adversely affect our business, prospects and financial condition.

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

We intend to develop products that are considered to be medical devices and are subject to federal regulations, including, but not limited to, those covering the FDA's Quality System Regulation, or QSR, and Medical Device Reporting, or 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 QSR. The quality systems for FDA-regulated products are known as current good manufacturing practices, or 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, or 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 QSR.

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

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

We are subject to MDR through two routes. As a manufacturer of products for sale within the U.S., we are required to report to the FDA any deaths, serious injuries, malfunctions or events requiring remedial action to prevent an unreasonable risk of substantial harm to the public health. Our CLIA laboratory, which offers services for sale, is already currently required to report suspected medical device related deaths to both the FDA and the relevant manufacturers of products we purchase and use.

Clinical laboratory tests like our current product offerings are regulated in the U.S. 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 our product candidates will not be subject to such regulation in the future. If we decide to market our product candidates as a diagnostic kit rather than as a LDT, our products would be subject to FDA regulation as a medical device. Further, 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 the FDA, there is no certainty in that respect.

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

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 our product. If pre-market review of our LDTs is required by the FDA, there can be no assurance that our product offerings will be cleared or approved on a timely basis, if at all. Ongoing compliance with FDA regulations, such as the QSR and MDR, would increase the cost of conducting our business and subject us to inspection by 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.

We may be required to conduct clinical studies and we may find it difficult to enroll patients in such clinical studies, which could delay or prevent clinical studies of our product candidates.

If the FDA decides to regulate our LDTs, it may require that we conduct extensive pre-market clinical studies prior to submitting a regulatory application for commercial sales. If we are required to conduct pre-market clinical studies, whether using retrospectively collected and banked samples or prospectively collected samples, delays in the commencement or completion of clinical studies could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement and completion of clinical trials may be delayed by factors such as unforeseen safety issues, lack of effectiveness during clinical trials, inability to monitor patients adequately during or after testing and slower than expected rates of patient recruitment.

Insufficient patient enrollment 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 may 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 failure to adhere to our clinical protocols or FDA requirements, or for other reasons, our clinical studies may have to be extended, delayed or terminated. Many of these factors could 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.

In addition, in the event we are required to conduct clinical trials, it may be very expensive and difficult to design and implement clinical trials due to the rigorous regulatory requirements to which clinical trials are subject. Clinical trials are also time consuming and there is no certainty as to when we may be able to complete the clinical trial process.

The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability and personal injury claims.

To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could materially adversely affect our business, prospects and financial condition. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, we may not be able to renew our existing insurance at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could negatively impact our cash flow and materially adversely affect our business, prospects and financial condition.

Some of our activities may subject us to risks under federal and state laws prohibiting "kickbacks" and false or fraudulent claims.

In addition to FDA marketing restrictions, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the healthcare product and service industry and to regulate billing practices and financial relationships with physicians, hospitals and other healthcare providers. These laws include the Federal False Claims Act and the Anti-Kickback Statute and several similar state laws, which prohibit payments intended to induce physicians or others to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. While the federal law applies only to referrals, products or services for which payment may be made by a federal healthcare program, state laws often apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of medical devices and providers of laboratory services by limiting the kinds of financial arrangements, including sales programs, that may be used with hospitals, physicians, laboratories and other potential purchasers or prescribers of medical devices and laboratory services. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties (including fines) for noncompliance that can be substantial. Interpretations of the applicability of these laws to marketing and billing practices is constantly evolving and even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and therefore could materially adversely affect our business, prospects and financial condition. Our failure to comply with applicable laws could result in various adverse consequences which could harm our business, including the exclusion of our products and services from government programs and the imposition of civil or criminal sanctions.

Our business could be adversely impacted by adoption of new coding for molecular genetic tests.

If our technology were commercially available today, reimbursement would be available under the current procedural terminology, or CPT, codes, for molecular-based testing. The American Medical Association CPT® Editorial Panel is continuing its process of establishing analyte specific billing codes to replace codes that describe procedures used in performing molecular testing. The adoption of analyte specific codes will allow payors to better determine tests being performed. This could lead to limited coverage decisions or payment denials for our product candidates or products we may develop in the future, which could materially adversely affect our business, prospects and financial condition.

Risks Related to Our Intellectual Property

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. We may not be successful in defending challenges made in connection with our patents and patent applications. 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.

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 our employees are also required to 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. Any failure to protect our intellectual property rights could materially adversely affect our business, prospects and financial condition.

Our currently pending or future patent applications may not result in issued patents and any patents issued to us may be challenged, invalidated or held unenforceable. Furthermore, we cannot be certain that we were the first to make the invention claimed in our issued patents or pending patent applications in the U.S., or that we were the first to file for protection of the inventions claimed in our foreign issued patents or pending patent applications. In addition, there are numerous recent changes to the patent laws and proposed changes to the rules of the U.S. Patent and Trademark Office, or the PTO, which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, in September 2011, the U.S. enacted sweeping changes to the U.S. patent system under the Leahy-Smith America Invents Act, including changes that would transition the U.S. from a “first-to-invent” system to a “first-to-file” system and alter the processes for challenging issued patents. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, we may become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine our entitlement to patents, and these proceedings may conclude that other patents or patent applications have priority over our patents or patent applications. It is also possible that a competitor may successfully challenge our patents through various proceedings and those challenges may result in the elimination or narrowing of our patents, and therefore reduce our patent protection. Accordingly, rights under any of our issued patents, patent applications or future patents may not provide us with commercially meaningful protection for our products or afford us a commercial advantage against our competitors or their competitive products or processes.

The patents issued to us may not be broad enough to provide any meaningful protection, one or more of our competitors may develop more effective technologies, designs or methods without infringing our intellectual property rights and one or more of our competitors may 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 our cell-free molecular diagnostic 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 we currently do not generate revenues other than licensing, milestone and royalty income.

We cannot rely solely on our current patents to be successful. The standards that the PTO and foreign patent offices use to grant patents, and the standards that U.S. and foreign courts use to interpret patents, are not the same, 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 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 that 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 cell-free molecular diagnostic 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 attention of our technical and management personnel will be diverted. 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 monetary damages, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights. In our European patent that covers using microRNAs to detect in vivo cell death, an anonymous third party has recently filed an opposition against the claims in the patent. Oppositions against the patentability of claims in a European patent are considered by a panel of examiners at the European Patent Office, and we are considering the full range of options available for defending against the opposition.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications and could further require us to obtain rights to issued patents covering such technologies. There may be third-party patents, patent applications and other intellectual property relevant to our potential products that may block or compete with our potential products or processes. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. 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 that we are ordered to pay, if any, 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 be subject to injunctions against the further development and use of our technology, which could materially adversely affect our business, prospects and financial condition.

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 materially adversely affect our ability to raise the funds necessary to continue our operations.

Risks Related to Ownership of Our Common Stock

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

If we fail to comply with the rules under the Sarbanes-Oxley Act, related to disclosure controls and procedures, or if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important in 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. We previously identified a material weakness in our internal control over financial reporting as of December 31, 2012, which was remedied in the year ended December 31, 2013. We cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

The rights of the holders of our 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 one or more new series of preferred stock. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights that could adversely affect the voting power and equity interests of the holders of our

common stock. Preferred stock, which could be issued with the right to more than one vote per share, could be used to discourage, delay or prevent a change of control of our company, which could materially adversely affect the price of our common stock. Without the consent of the holders of the outstanding shares of our Series A Convertible Preferred Stock, we may not adversely alter or change 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 that is senior to or on 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 historically has been, and we expect will continue to be, subject to significant fluctuations over short periods of time. For example, during the year ended December 31, 2015, the closing price of our common stock ranged from a low of $4.21 to a high of $13.58. These fluctuations may be due to various factors, many of which are beyond our control, including:

- technological innovations or new products and services introduced by us or our competitors;
- clinical trial results relating to our tests or those of our competitors;
- announcements or press releases relating to the industry or to our own business or prospects;
- coverage and reimbursement decisions by third party payors, such as Medicare and other managed care organizations;
- regulation and oversight of our product candidates and services, including by the FDA, Centers for Medicare & Medicaid Services and comparable foreign agencies;
- the establishment of partnerships with clinical reference laboratories;
- healthcare 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.

In addition, market fluctuations, as well as general political and economic conditions, could materially adversely affect the market price of our securities. Because we are a development stage company with no revenue from operations to date, other than licensing, milestone and royalty income, you should consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the foregoing.

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 December 31, 2015, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially owned approximately 33.4% 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 may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- 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.

We have never paid any cash dividends 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 that 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. In addition, under the terms of our Loan and Security Agreement and the Equipment Line of Credit, we are precluded from paying cash dividends without the prior written consent of the Lenders, and the terms of the Series A Convertible Preferred Stock prohibit us from paying dividends to the holders of our common stock so long as any dividends due on the Series A Convertible Preferred Stock remain unpaid. 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 adversely change their recommendations regarding our stock, 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. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, 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 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 of our company or changes in our management. For example, our board of directors has 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 materially adversely affect the market price of our common stock.

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

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

Our common stock is traded on The NASDAQ Capital Market and could be considered "thinly-traded," meaning that the number of investors interested in purchasing our common stock at or near bid prices at any given time may be relatively small or non-existent. Finance transactions resulting in a large amount of newly issued shares that become readily tradable, or

other events that cause current stockholders to sell shares, could place downward pressure on the trading price of our common stock. In addition, the lack of a robust resale market may require a stockholder who desires to sell a large number of shares of common stock to sell the shares in increments over time to mitigate any adverse impact of the sales on the market price of our stock.

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

We may be subject to stockholder litigation, thereby diverting our resources, which could materially adversely affect our profitability and results of operations.

The market for our common stock is characterized by significant price volatility, and we expect that our share price will continue to be at least as volatile for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price for its securities. In addition, stockholders may bring actions against companies relating to past transactions or other matters. Any such actions could give rise to substantial damages and thereby materially adversely affect our consolidated financial position, liquidity or results of operations. Even if an action is not resolved against us, the uncertainty and expense associated with stockholder actions could materially adversely affect our business, prospects and financial condition. Litigation can be costly, time-consuming and disruptive to business operations. The defense of lawsuits could also result in diversion of our management's time and attention away from business operations, which could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We currently lease approximately 22,600 square feet of laboratory and office space for our headquarters in San Diego, California under a lease agreement that expires in December 2021. In November 2015, we also entered into a lease agreement pursuant to which we will lease approximately 2,300 square feet of office space in Torino, Italy. The lease agreement commenced on January 1, 2016 and expires on December 31, 2018. We believe that our facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock has traded on the NASDAQ Capital Market ("NASDAQ") under the symbol "TROV" since May 30, 2012.

Our common stock was traded over the counter on the pink sheets under the symbol TROV.PK from June 15, 2007 until May29, 2012. From July 27, 2004 until June 14, 2007, our common stock was quoted on the OTC Bulletin Board under the symbol "XNOM.OB". Prior to July 27, 2004, our common stock was quoted on the OTC Bulletin Board under the symbol

“UKAR.OB”, but never traded. The following table sets forth the range of high and low per share sales prices of our common stock during the periods indicated, as reported on NASDAQ.

	2015		2014	
	High	Low	High	Low
First Quarter	$ 8.04	$ 4.33	$ 6.74	$ 5.13
Second Quarter	$ 13.58	$ 6.50	$ 6.01	$ 3.50
Third Quarter	$ 10.46	$ 4.85	$ 6.30	$ 3.00
Fourth Quarter	$ 7.18	$ 4.21	$ 5.17	$ 4.01

The closing price of our common stock on NASDAQ on February 29, 2016 was $5.15 per share.

Number of Stockholders

As of February 29, 2016, we had approximately 59 stockholders of record of our common stock.

Dividend Policy

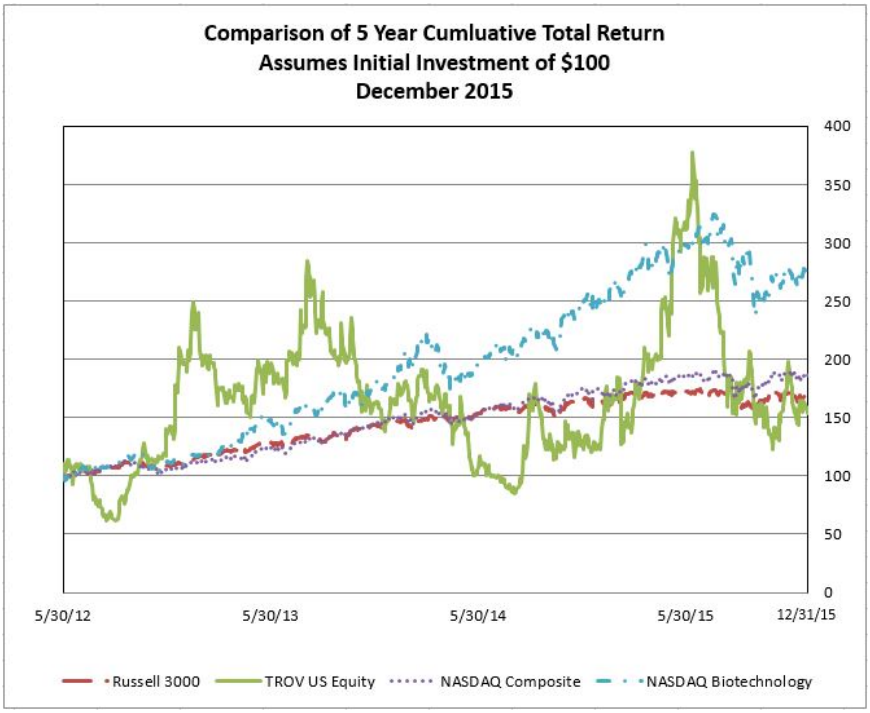
Historically, we have not paid any dividends to the holders of shares of our common stock and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business. Pursuant to the terms of our outstanding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

Corporate Performance Graph

The following corporate performance graph and related information shall not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference into such filing.

The following corporate performance graph compares our total stockholder returns from May 30, 2012 through December 31, 2015 against the NASDAQ Stock Market (U.S.), the NASDAQ Pharmaceutical Index and the Russell 3000 Index, assuming a $100 investment made on May 30, 2012. Each of the comparative measures of cumulative total return assumes reinvestment of dividends. The corporate performance shown on the graph below is not necessarily indicative of future price performance.

COMPARISON OF CUMULATIVE TOTAL RETURN
Among the NASDAQ Stock Market (U.S.),
The NASDAQ Pharmaceutical Index, the Russell 3000 Index
and Trovagene, Inc.



ITEM 6. SELECTED FINANCIAL DATA

The following tables set forth our selected consolidated financial data and have been derived from our audited consolidated financial statements. Consolidated balance sheets as of December 31, 2015 and 2014, as well as consolidated statements of operations for the years ended December 31, 2015, 2014, and 2013, and the reports thereon are included elsewhere in this Annual Report on Form 10-K. The information should be read in conjunction with our audited consolidated financial statements and the notes to such statements, included below in Item 8 “Financial Statements and Supplementary Data”, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7. Historical results are not necessarily indicative of the results to be expected in the future.

	Year ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except for share and per share data)				
Consolidated Statement of Operations Data:					
Revenues	$ 313	$ 280	$ 259	$ 450	$ 258
Costs and Expenses:					
Cost of revenues	629	15	—	—	—
Research and development	10,594	6,665	3,948	1,920	911
Selling and marketing	6,444	2,735	1,530	506	—
General and administrative	7,920	5,810	5,472	2,873	2,324
Total operating expenses	25,587	15,225	10,950	5,299	3,235
Loss from operations	(25,274)	(14,945)	(10,691)	(4,849)	(2,977)
Other (income) loss, net	(3)	25	(23)	4	—
Net interest expense	(1,468)	(831)	(13)	—	(56)
Gain (loss) on change in fair value of derivative instruments-warrants	(726)	1,426	(1,084)	(6,721)	171
Gain on extinguishment of debt	—	—	—	—	623
Net loss and comprehensive loss	(27,471)	(14,325)	(11,811)	(11,566)	(2,239)
Preferred stock dividends	(24)	(23)	(30)	(38)	(38)
Net loss and comprehensive loss attributable to common stockholders	$ (27,495)	$ (14,348)	$ (11,841)	$ (11,604)	$ (2,277)
Net loss per common share - basic	$ (1.05)	$ (0.76)	$ (0.70)	$ (0.89)	$ (0.23)
Net loss per common share - diluted	$ (1.21)	$ (0.88)	$ (0.70)	$ (0.89)	$ (0.23)
Weighted average shares outstanding - basic*	26,201,713	18,904,280	16,978,212	13,066,600 *	9,711,519 *
Weighted average shares outstanding - diluted*	26,452,165	19,071,112	16,978,212	13,066,600 *	9,711,519 *

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

	December 31,				
	2015	2014	2013	2012	2011
	($ in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 67,493	$ 27,294	$ 25,837	$ 10,820	$ 700
Working capital	60,180	23,232	24,060	10,318	(588)
Total assets	71,446	28,897	27,156	11,665	1,039
Total stockholders' equity (deficit)	48,701	8,350	20,392	2,169	(4,231)

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

Forward-Looking Statements

The information in this report contains forward-looking statements. All statements other than statements of historical fact made in this report are forward looking. In particular, the statements herein regarding industry prospects and future results of operations or financial position are forward-looking statements. These forward-looking statements can be identified by the use of words such as "believes," "estimates," "could," "possibly," "probably," "anticipates," "projects," "expects," "may," "will," or "should" or other variations or similar words. No assurance can be given that the future results anticipated by the

forward-looking statements will be achieved. Forward-looking statements reflect management's current expectations and are inherently uncertain. Our actual results may differ significantly from management's expectations.

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

Overview

We are focused on developing and commercializing our precision cancer monitoring technology, which can inform oncologists and guide treatment decisions by determining a tumor's mutational status and enabling physicians to track therapeutic response and resistance over time.

We are expanding the body of clinical evidence supporting our urine-based cell-free molecular diagnostic platform through collaborations with major cancer treatment centers and integrated healthcare networks. We expect that the benefits of our precision cancer monitoring technology will become more apparent in terms of its clinical utility and impact on patient outcomes. Our intellectual property estate protecting our technology includes methods of extracting, purifying, preparing, and detecting cell-free DNA and RNA mutations in urine.

Through December 31, 2015, our cumulative total deficit was $108,887,243. To date, we have generated minimal revenues and expect to incur additional losses to perform further research and development activities and commercial expansion. During 2015, we advanced our business with the following activities:

- We formed the Trovagene Research Institute in Europe with Alberto Bardelli, Ph.D., an internationally recognized leader in cell-free DNA cancer research, and currently affiliated with the Department of Oncology, Torino Medical School and the Candiolo Cancer Institute in Italy. We appointed Dr. Bardelli as the Scientific Director and transferred core technologies from the University of Torino. Trovagene Research Institute intends to improve cancer care through advanced genomic solutions with the mission of accelerating adoption of our PCM platform in translational research and clinical applications.

- Clinical study results were presented by Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the 2015 European Lung Cancer Conference. In that study, our urinary ctDNA assay identified 100% of tissue biopsy confirmed *EGFR T790M* mutations (n=10) in metastatic lung cancer patients. Our assay also detected *T790M* mutations in three subjects that Dr. Husain speculated may have been tissue biopsy false negatives. In addition, data from the study suggest that our assay may be capable of detecting cancer progression earlier than standard imaging and may be useful in determining patient response to novel *EGFR T790M* inhibitors.

- Clinical study results from a second large-scale clinical trial for our urine-based HPV test were presented by Adriana Lorenzi, a research fellow at the Institute of Education and Research and Molecular Oncology Research Center, Barretos Cancer Hospital - Pio XII Foundation, Barretos, Brazil at the 30th International Papillomavirus Conference. In the trial, urine samples collected from women prior to treatment of cervical pre-cancer lesions (referral population) were tested with our HPV HR Test, and results were compared to Roche's cobas® HPV Test results from cervical samples. The trial results were consistent with previously reported Predictors 4 data, which demonstrated that sensitivity with our HPV HR Test for the detection of cervical intraepithelial neoplasia Grade Two or higher ("CIN2+") and Grade Three or higher ("CIN3+") were comparable to other established cervical cancer screening tests. In the Brazilian cohort, 271 cases of CIN2+ and 202 cases of CIN3+ disease were tested.

- Clinical study results for our PCM platform were presented by Julia Johansen, M.D. at Herlev Hospital, Copenhagen, and Hatim Husain, M.D., from the University of California, San Diego Moores Cancer Center at the European Cancer Congress. Results demonstrated that quantitative detection and monitoring of ctDNA and driver mutations can be used to rapidly detect treatment response.

- We completed an underwritten public offering of 4,600,000 shares of common stock with net proceeds of approximately $37.4 million in July 2015.

- We entered into a clinical collaboration with Memorial Sloan Kettering Cancer Center to monitor response to immunotherapy in melanoma patients using our PCM platform.

- We launched our “Yellow Is The New Red” marketing campaign for our PCM service at the 2015 American Society of Clinical Oncology Annual Meeting. The campaign is centered on our Clinical Experience Program, in which qualified oncologists can gain hands on clinical experience with our proprietary urinary liquid biopsy tests.

- We completed an underwritten public offering of 5,111,110 shares of common stock with net proceeds of approximately $21.3 million in February 2015.

- We recruited Matthew Posard to our Executive Management Team as Chief Commercial Officer to lead our commercial operations.

- We entered into a clinical collaboration with University of California, San Diego Moores Cancer Center to determine the utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.

- We entered into a clinical collaboration with City of Hope to conduct studies to determine the clinical utility of detecting and monitoring *EGFR* mutations in lung cancer patients using our PCM platform.

- Two sets of clinical study results were presented at the 2015 Gastrointestinal Cancer Symposium supporting the potential utility of our PCM platform in colorectal and pancreatic cancer patients. Results demonstrated the ability of our PCM platform to detect and quantitate *KRAS* mutations at diagnosis and longitudinally in ctDNA obtained from colorectal and pancreatic cancer patients. We also showed data demonstrating that our proprietary *KRAS* assay may allow physicians to determine mutational status, monitor treatment response, and use genomics to aid in predicting patient prognosis.

- Two sets of clinical study results and one set of analytical data were presented at the 2015 American Association for Cancer Research (“AACR”) Annual Meeting that demonstrated potential clinical utilities and advantages of our PCM platform. Our liquid biopsy technology features single molecule sensitivity and the ability to obtain significantly more ctDNA from urine samples as compared to plasma.

- Clinical results from the PREDICTORS 4 trial were presented by Jack Cuzick, Ph.D., Director, Wolfson Institute of Preventive Medicine and Head, Centre for Cancer Prevention at Queen Mary University of London at the European Research Organization on Genital Infection and Neoplasia 2015 Congress. Based on our analysis of more than 500 samples, the results showed high sensitivity (>90%) for our non-invasive, urine-based HPV assay for the detection of high-risk HPV types and cervical intraepithelial neoplasia (“CIN”) Grade 2 or higher lesions.

- Clinical data from four studies utilizing our PCM platform were presented at the 2015 American Society of Clinical Oncology Annual Meeting in Chicago, Illinois. Results demonstrated that our PCM technology offers advantages over tissue biopsy and demonstrates the ability to monitor tumor dynamics in lung, pancreatic, and colon cancers.

Our product development and commercialization efforts are in their early stages, and we cannot make estimates of the costs or the time our development efforts will take to complete, or the timing and amount of revenues related to the sale of our tests and revenues related to our license agreements. The risk of failing to complete of any program is high because of the many uncertainties involved in bringing new diagnostic products to market, including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols and/or CLIA requirements, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses, and competing technologies being developed by organizations with significantly greater resources.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our accounting policies are described in Item 8. Financial Statements—Note 2 *Basis of Presentation and Summary of Significant Accounting Policies* in this Annual Report on Form 10-K. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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.

Revenue Recognition

Historically, our revenues have been generated from royalty, license and milestones related to agreements we have with other healthcare companies, medical laboratories and biotechnology partners. We also have revenues from our diagnostics services.

We recognize revenues when persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

Milestone, Royalty and License Revenues

We license and sublicense our patent rights to healthcare companies, medical laboratories and biotechnology partners. These agreements may involve multiple elements such as license fees, royalties and milestone payments. Revenue is recognized when the criteria described above have been met as well as the following:

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

Diagnostic Service Revenue

Diagnostic service revenue, which consists of fees for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the U.S., patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, bill third-party payors for testing.

Diagnostic service revenue will be recognized when the criteria described above has been met as well as upon cash collection until we can reliably estimate the amount that will be ultimately collected for our LDTs, at which time we will recognize revenues on an accrual basis.

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 the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 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 stock price, remaining life of the warrant, and risk-free interest rates at each period end. Therefore we 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 Topic 820, *Fair Value Measurements and Disclosures* (“ASC 820”). At December 31, 2015 and 2014, the fair value of such warrants was $3,297,077 and $3,006,021, respectively, which is included in the derivative financial instruments’ liability on our balance sheet.

Cost of Revenue

Cost of revenue represents the cost of materials, personnel costs and costs associated with processing specimens including pathological review, quality control analyses, and delivery charges necessary to render an individualized test result. Costs associated with performing tests are recorded as the tests are processed.

Research and Development

Research and development expense, which includes expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, regulatory and scientific consulting fees and clinical samples, as well as clinical collaborators and insurance, are accounted for in accordance with FASB 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 expense to supplement the more detailed discussions under "Results of Operations" below. Costs are not allocated to projects as the majority of the costs relate to employees and facilities costs and we do not track employees' hours by project or allocate facilities costs on a project basis.

	For the years ended December 31,		
	2015	2014	2013
Salaries and staff costs	$ 5,365,045	$ 3,465,211	$ 2,063,474
Outside services, consultants and lab supplies	4,211,251	2,435,917	1,301,190
Facilities	748,466	628,535	466,138
Other	269,107	135,243	116,787
Total Research and Development	$ 10,593,869	$ 6,664,906	$ 3,947,589

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.

FASB ASC Topic 730, *Research and Development* requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense. There are no non-refundable advance payments that are deferred and capitalized as of December 31, 2015, 2014 and 2013.

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

We account for equity instruments granted to non-employees in accordance with FASB ASC Topic 505-50 "*Equity-Based Payment to Non-Employees"*, where the value of the stock-based compensation is based upon the measurement date as determined at either: (1) the date at which a performance commitment is reached, or (2) the date at which the necessary performance to earn the equity instruments is complete. Accordingly, the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, debt and derivative liabilities. We have adopted 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 fair value due to their short term nature as they reflect current market interest rates. Debt is stated at its respective historical carrying amounts, which approximate fair value as they reflect current market interest rates.

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

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

Off-Balance Sheet Arrangements

As of December 31, 2015, we did not have any off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

See Item 8. Financial Statements—Note 2 *Basis of Presentation and Summary of Significant Accounting Policies* in this Annual Report on Form 10-K for a discussion of recent accounting pronouncements.

Results of Operations

YEARS ENDED DECEMBER 31, 2015 AND 2014

Revenues

Our total revenues were $312,812 and $280,178 for the years ended December 31, 2015 and 2014, respectively. Total revenues consisted of the following:

	For the years ended December 31,		
	2015	2014	(Decrease)/Increase
Royalty income	$ 274,648	$ 270,178	$ 4,470
License fees	—	10,000	(10,000)
Diagnostic service revenue	13,789	—	13,789
Other income	$ 24,375	$ —	$ 24,375
Total revenues	$ 312,812	$ 280,178	$ 32,634

The $4,470 increase in royalty income in the year ended December 31, 2015 is primarily a result of certain licensees' payments exceeding their minimum royalties as compared to the prior year. According to our revenue recognition policy, we do not record royalty revenues in excess of minimum royalty amounts until we have received payment of such royalties.

In the year ended December 31, 2014, we received a $10,000 license fee related to a licensing agreement signed in the second quarter of 2014. There were no license fees earned during the year ended December 31, 2015.

Diagnostic service revenue is recognized when payment is received for the test results. We received $13,789 in diagnostic service revenue in the year ended December 31, 2015, primarily as a result of our clinical laboratory tests. There was no diagnostic service revenue for the year ended December 31, 2014 as no payments were received.

Other revenue consists primarily of revenue from the sale of collection kits. In the year ended December 31, 2015, we entered into supply agreements with our customers to sell specimen collection kits. Revenue was recognized when kits were delivered. There was no such revenue for the year ended December 31, 2014.

We expect our royalty income to fluctuate as the royalties are based on the minimum royalty payments as well as the timing of when payments are received for royalties in excess of minimum royalties. Milestone and license fee revenues are difficult to predict and can vary significantly from period to period. In addition, we expect our diagnostic service revenue to increase in future periods, but as revenue recognition is based on cash receipts, the timing of these revenues is also uncertain. We expect other revenue to fluctuate based on timing of supply agreements.

Cost of Revenues

Our total cost of revenues was $629,191 in the year ended December 31, 2015, compared to $15,441 in the year ended December 31, 2014. The increase in cost of revenues in the year ended December 31, 2015 compared to the prior year is primarily due to an increase in the volume of tests processed. Cost of revenues primarily relates to the costs of our diagnostic service revenue. The costs are recognized at the completion of testing. Due to revenue being recognized when cash is received, costs incurred in one period may relate to revenue recognized in a later period. Gross margins are negative as we begin to build test volume to cover costs associated with running our diagnostic tests as well as inefficiencies in realizing capacity related issues.

Research and Development Expenses

Research and development expenses consisted of the following:

	For the years ended December 31,		
	2015	**2014**	**Increase/(Decrease)**
Salaries and staff costs	$ 3,866,036	$ 2,669,203	$ 1,196,833
Stock-based compensation	1,499,009	796,008	703,001
Outside services, consultants and lab supplies	4,211,251	2,435,917	1,775,334
Facilities	748,466	628,535	119,931
Travel and scientific conferences	228,490	119,562	108,928
Other	40,617	15,681	24,936
Total research and development expenses	$ 10,593,869	$ 6,664,906	$ 3,928,963

Research and development expenses increased by $3,928,963 to $10,593,869 for the year ended December 31, 2015 from $6,664,906 for the year ended December 31, 2014. Substantially all of the increase resulted from an increased number of samples processed and validated in connection with our clinical collaborations. We utilize our clinical collaborations to provide data that summarizes the accuracy of our tests to detect certain types of cancer in urine samples. We also enter into clinical studies to provide data that supports our technology for the monitoring of responsiveness to therapy and the status of diseases. We were party to twenty-six active collaborations or studies during the year ended December 31, 2015, while during the year ended December 31, 2014, we were party to twenty-three collaborations or studies. To support the expansion of our collaboration efforts, we increased the average number of our internal research and development personnel from seventeen to twenty-two, and purchased additional laboratory equipment, lab supplies and clinical samples. To date our research and development expenses have related to validating our tests and supporting clinical collaborations. These costs are expected to increase as we expand current collaborations or enter into new collaborations to support our research and development activities.

Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	For the years ended December 31,		
	2015	2014	Increase/(Decrease)
Salaries and staff costs	$ 2,628,822	$ 1,139,855	$ 1,488,967
Stock-based compensation	768,146	145,240	622,906
Outside services and consultants	932,237	902,181	30,056
Facilities and insurance	283,809	115,713	168,096
Trade shows, conferences and marketing	1,282,059	258,658	1,023,401
Travel	449,294	139,710	309,584
Other	99,211	33,546	65,665
Total selling and marketing expenses	$ 6,443,578	$ 2,734,903	$ 3,708,675

Selling and marketing expenses increased by $3,708,675 to $6,443,578 for the year ended December 31, 2015, from $2,734,903 for the year ended December 31, 2014. The significant components of the increase were primarily increased salaries and staff costs, stock-based compensation, and trade shows, conferences and marketing costs. For the year ended December 31, 2015, we increased our average internal headcount in this functional area from five to thirteen to support our sales and marketing activities, resulting in the increase in salaries and staff costs. In addition to the increased trade shows and conferences costs, costs related to our clinical experience program, where we offer new clinicians a series of tests for no charge, are included in marketing expenses. We expect our selling and marketing expenses to increase as we add new personnel to our commercial team that are focused on increasing market acceptance of our commercially available tests.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	For the years ended December 31,		
	2015	2014	Increase/(Decrease)
Personnel and outside services costs	$ 3,509,844	$ 2,245,801	$ 1,264,043
Stock-based compensation	1,639,196	1,128,948	510,248
Board of Directors' fees	457,865	328,184	129,681
Legal and accounting fees	1,182,427	1,314,960	(132,533)
Facilities and insurance	524,763	336,154	188,609
Travel	266,410	208,651	57,759
Fees, licenses, taxes and other	339,321	247,389	91,932
Total general and administrative expenses	$ 7,919,826	$ 5,810,087	$ 2,109,739

General and administrative expenses increased by $2,109,739 to $7,919,826 for the year ended December 31, 2015 from $5,810,087 for the year ended December 31, 2014. This increase was primarily due to an increase in personnel and outside services costs and stock-based compensation, partially offset by a decrease in legal and accounting fees. We have increased our average internal headcount from four to seven, as well as utilized outside services and consultants, to support our growth in both research and development and sales and marketing, resulting in the increase in personnel and outside services costs during the year ended December 31, 2015 as compared to the prior year. Stock-based compensation, a non-cash expense, will fluctuate based on the timing and amount of options granted, as well as the fair value of the options at the time of grant or remeasurement. In January 2016, our CEO was granted 350,000 non-qualified stock options which have an exercise price of $5.18 per share and vested immediately upon grant. The fair value of the options which is approximately $1.4 million will be expensed in full in the first quarter of 2016. We expect our general and administrative costs to increase to support the growth of our sales and marketing and research and development teams and from the additional costs we will incur in the billing and collection of revenues from the sales of our diagnostic tests.

Interest Expense

Interest expense was $1,525,482 and $843,259 for the years ended December 31, 2015 and 2014, respectively. The increase in the year ended December 31, 2015 resulted primarily from the $15.0 million term loan we entered into in June 2014. We paid twelve months of interest only payments in the year ended December 31, 2015 as compared to six months of interest only payments in the year ended December 31, 2014. If we complete the anticipated refinancing of our debt to include an additional period of interest only payments, our interest expense will increase.

Change in Fair Value of Derivative Instruments - Warrants

We have issued securities that are accounted for as derivative liabilities. As of December 31, 2015, the derivative liabilities related to securities issued were revalued to $3,297,077, resulting in a net increase in value of $291,056 from December 31, 2014, based primarily upon the change in our stock price from $4.30 at December 31, 2014 to $5.40 at December 31, 2015, and the changes in the expected term, volatility and risk-free interest rates for the expected term, offset by fair value of warrants reclassified from a liability to additional paid-in capital upon exercise of warrants. The increase in value was recorded as non-operating loss for the year ended December 31, 2015.

Net Loss

Net loss and per share amounts were as follows:

	For the years ended December 31,		
	2015	2014	Increase/(Decrease)
Net loss and comprehensive loss attributable to common stockholders	$ (27,495,334)	$ (14,348,499)	$ 13,146,835
Net loss per common share - basic	$ (1.05)	$ (0.76)	$ 0.29
Net loss per common share - diluted	$ (1.21)	$ (0.88)	$ 0.33
Weighted-average shares outstanding - basic	26,201,713	18,904,280	7,297,433
Weighted-average shares outstanding - diluted	26,452,165	19,071,112	7,381,053

The increase in net loss and comprehensive loss attributable to common stockholders of $13,146,835 to $27,495,334 for the year ended December 31, 2015 from $14,348,499 for the year ended December 31, 2014 resulted primarily from a slight increase in revenues, offset by an increase in operating expenses, interest expense, and loss from the change in fair value of derivative liabilities. Basic and diluted net loss per share for the year ended December 31, 2015 were impacted by the increase in both basic and diluted weighted-average shares outstanding resulting from the sale and issuance of approximately 10.0 million shares of common stock through underwritten public offerings and a controlled equity offering through our agreement with Cantor Fitzgerald & Co., as well as the issuance of approximately 838,000 shares of common stock in connection with the exercise of stock options and warrants.

YEARS ENDED DECEMBER 31, 2014 AND 2013

Revenues

Our total revenues were $280,178 and $259,246 for the years ended December 31, 2014 and 2013, respectively. Total revenues consisted of the following:

	Years ended December 31,		
	2014	2013	Increase
Royalty income	$ 270,178	$ 259,246	$ 10,932
License fees	10,000	—	10,000
Total revenues	$ 280,178	$ 259,246	$ 20,932

Royalty income increased by $10,932 in the year ended December 31, 2014, primarily as a result of certain licensees exceeding their minimum royalties as compared to the prior year. In accordance with our revenue recognition policy, we do not record royalty revenues in excess of minimum royalty amounts until we have received payment of such royalties.

In the year ended December 31, 2014, we received a $10,000 license fee related to a licensing agreement signed in the second quarter of 2014. There were no license fees earned during the year ended December 31, 2013.

Cost of Revenues

Cost of revenues relates to the costs of our diagnostic services revenues and is recognized at the completion of testing. Gross margins on diagnostic tests are affected by test volumes, the timing of collections and overall reimbursement for the amount paid per test.

Research and Development Expenses

Research and development expenses consisted of the following:

	For the years ended December 31,		
	2014	2013	Increase/(Decrease)
Salaries and staff costs	$ 2,669,203	$ 1,514,009	$ 1,155,194
Stock-based compensation	796,008	549,465	246,543
Outside services, consultants and lab supplies	2,435,917	1,301,190	1,134,727
Facilities	628,535	466,138	162,397
Travel and scientific conferences	119,562	95,399	24,163
Other	15,681	21,388	(5,707)
Total research and development expenses	$ 6,664,906	$ 3,947,589	$ 2,717,317

Research and development expenses increased by $2,717,317 to $6,664,906 for the year ended December 31, 2014 from $3,947,589 for the year ended December 31, 2013. Substantially all of the increase resulted from the expansion of our research and development efforts as we increased the average number of our internal research and development personnel from nine to seventeen, and purchased additional laboratory equipment to support the increase in clinical collaborations for the commercialization of our tests. The clinical collaborations with external parties involve validation of our tests to detect certain types of cancer in urine samples.

Selling and Marketing Expenses

Selling and marketing expenses consisted of the following:

	For the years ended December 31,		
	2014	2013	Increase/(Decrease)
Salaries and staff costs	$ 1,139,855	$ 734,060	$ 405,795
Stock-based compensation	145,240	100,189	45,051
Outside services and consultants	902,181	274,625	627,556
Facilities and insurance	115,713	98,081	17,632
Marketing	258,658	193,701	64,957
Travel	139,710	92,030	47,680
Fees, licenses, taxes and other	33,546	37,474	(3,928)
Total sales and marketing expenses	$ 2,734,903	$ 1,530,160	$ 1,204,743

Selling and marketing expenses increased by $1,204,743 to $2,734,903 for the year ended December 31, 2014 from $1,530,160 for the year ended December 31, 2013. The most significant increase was in outside services and related to reestablishing our corporate and product identity, a commercial update to our website, and market research related to pricing and reimbursement of our tests. We had three commercially available tests as of December 31, 2014. During the year ended

December 31, 2014, we increased our average internal headcount in this functional area from three to five, resulting in an increase in salaries and staff costs and stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses consisted of the following:

	For the years ended December 31,		
	2014	2013	Increase/(Decrease)
Personnel and outside services costs	$ 2,245,801	$ 2,057,986	$ 187,815
Stock-based compensation	1,128,948	1,528,501	(399,553)
Board of Directors' fees	328,184	241,229	86,955
Legal and accounting fees	1,314,960	995,185	319,775
Facilities and insurance	336,154	248,491	87,663
Travel	208,651	220,691	(12,040)
Fees, licenses, taxes and other	247,389	179,955	67,434
Total general and administrative expenses	$ 5,810,087	$ 5,472,038	$ 338,049

General and administrative expenses increased by $338,049 to $5,810,087 for the year ended December 31, 2014 from $5,472,038 for the year ended December 31, 2013. This increase was primarily due to an increase in legal fees related to filings and maintenance of patents. We increased our average internal headcount in these functional areas from two to four, to support the growth in both research and development and sales and marketing, resulting in the increase in salaries and staff costs during the year ended December 31, 2014 as compared to the prior year. In addition, the costs associated with being a public company, such as additional costs for insurance, The NASDAQ Stock Market LLC fees, and compliance with the Sarbanes-Oxley Act of 2002, as amended, added to our general and administrative expenses, as compared to the year ended December 31, 2013. The overall increase was partially offset by decreases in stock-based compensation due to timing and quantity of stock-based awards.

Interest Expense

Interest expense was $843,259 and $17,005 for the years ended December 31, 2014 and 2013, respectively. The increase in the year ended December 31, 2014 resulted from a $15.0 million long term loan that we entered into in June 2014.

Change in Fair Value of Derivative Instruments - Warrants

The change in fair value of derivative instruments resulted in a $1,425,850 gain in the year ended December 31, 2014 compared to a loss of $1,084,114 in the prior year. The gain was a result of the revaluation of warrants based upon the change in our stock price from $5.74 at December 31, 2013 to $4.30 at December 31, 2014, and the changes in the expected term, volatility and risk-free interest rates for the expected term. The decrease in value was recorded as non-operating gain for the year ended December 31, 2014.

Net Loss

Net loss and per share amounts were as follows:

	For the years ended December 31,		
	2014	2013	Increase (Decrease)
Net loss and comprehensive loss attributable to common stockholders	$ (14,348,499)	$ (11,840,778)	$ 2,507,721
Net loss per common share - basic	$ (0.76)	$ (0.70)	$ 0.06
Net loss per common share - diluted	$ (0.88)	$ (0.70)	$ 0.18
Weighted-average shares outstanding - basic	18,904,280	16,978,212	1,926,068
Weighted-average shares outstanding - diluted	19,071,112	16,978,212	2,092,900

The increase in net loss and comprehensive loss attributable to common stockholders of $2,507,721 to $14,348,499 for the year ended December 31, 2014 from $11,840,778 for the year ended December 31, 2013 resulted primarily from a slight increase in revenues, offset by increases in all operating expenses. The net loss per share - basic for the year ended December 31, 2014 increased by $0.06 to a net loss of $0.76 as a result of an overall increase in net loss, slightly offset by an increase in weighted average shares outstanding during the year ended December 31, 2014 compared to the prior year. Weighted-average basic and diluted shares outstanding increased for the year ended December 31, 2014 due to 3.4 million shares issued as a result of shares sold through controlled equity offerings, the exercise of warrants and stock options during the year ended December 31, 2014, and the issuance of approximately 13,000 shares as a result of the net exercise of warrants during the year ended December 31, 2014.

Liquidity and Capital Resources

As of December 31, 2015, we had $67,493,047 in cash and cash equivalents. Net cash used in operating activities for the year ended December 31, 2015 was $22,119,025, compared to $12,727,385 for the year ended December 31, 2014. Our use of cash was primarily a result of the net loss of $27,471,094 for the year ended December 31, 2015, adjusted for non-cash items related to stock-based compensation of $3,946,027, depreciation and amortization of $378,711 and gain from the change in fair value of derivatives of $726,421. The changes in our operating assets and liabilities consisted of higher accounts payable and accrued expenses and an increase in accounts receivable. At our current and anticipated level of operating loss, we expect to continue to incur an operating cash outflow for the next several years. As of December 31, 2015 and 2014, we had working capital of $60,179,971 and $23,231,596, respectively. The increase in working capital is primarily due to the increase in cash and cash equivalents as a result of the sale and issuance of approximately 10.0 million shares of common stock through underwritten public offerings and a controlled equity offering through an agreement with Cantor Fitzgerald & Co.

Investing activities consisted of purchases for capital equipment that used $2,233,466 in cash during the year ended December 31, 2015, compared to $299,790 for the year ended December 31, 2014. We expect to invest approximately $4.6 million in capital equipment during 2016. Any such investment will be predominantly for laboratory equipment.

Net cash provided by financing activities was $64,551,740 during the year ended December 31, 2015, compared to $14,484,036 during the year ended December 31, 2014. Financing activities during the year ended December 31, 2015 included $61,215,399 from the sales of common stock, $2,250,279 from proceeds related to the exercise of warrants and options, and $1,086,062 from new borrowings on equipment lines. As of December 31, 2015, we had approximately $900,000 remaining available for borrowing under our equipment line of credit and we intend to utilize the remaining amount during 2016. Financing activities during the year ended December 31, 2014 consisted of net borrowings of $15.0 million under our debt agreement, offset by $515,964 of repayment on equipment lines.

As of February 29, 2016, our cash balance was approximately $62.9 million and our working capital was approximately $55.8 million.

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 and ramp up of our sales and marketing function. To date, our sources of cash have been primarily limited to the sale of equity securities and debentures and a venture capital loan. 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 (1) significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates; (2) 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 (3) 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.

Controlled Equity Offering and Public Offerings

On January 25, 2013, we filed a Registration Statement on Form S-3 (the “Registration Statement”) to offer and sell in one or more offerings any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price of up to $150,000,000. If issued, the preferred stock, warrants, and units would be convertible, exercisable or exchangeable for common stock, preferred stock or other securities. The Registration Statement was declared effective on February 4, 2013. In addition, in connection with the Registration Statement, we entered into an agreement with Cantor Fitzgerald & Co. (“Agent”) on January 25, 2013 to issue and sell up to $30,000,000 of shares of common stock. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds on sales of our securities. We received gross proceeds

of approximately $4.2 million from the sale of 488,476 shares of our common stock during the year ended December 31, 2013 under the agreement with the Agent. In addition, we received gross proceeds of approximately $15.0 million from the sale of 2,142,857 shares of our common stock through a registered direct offering that occurred in July 2013. During the year ended December 31, 2015, we also received gross proceeds of approximately $2.8 million from the sale of 285,421 shares of our common stock at a weighted-average price of $9.66 under the agreement with the Agent. During the year ended December 31, 2015, we received gross proceeds of approximately $63.2 million from the sale of 9,711,110 shares of our common stock through underwritten public offerings in February 2015 and July 2015.

Contractual Obligations and Commitments

The following table is a summary of contractual obligations that existed as of December 31, 2015, and is based on information appearing in the notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

	Payments Due by period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$ 4,745,113	$ 683,871	$ 1,604,008	$ 1,614,705	$ 842,529
Research agreements (1)	1,666,544	1,666,544	—	—	—
Long-term debt (2)	18,837,720	6,187,388	12,234,475	415,857	—
Purchase obligations - major vendors (3)	133,623	133,623	—	—	—
Total obligations	$ 25,383,000	$ 8,671,426	$ 13,838,483	$ 2,030,562	$ 842,529

(1) Payments under research agreements are based on the completion of activities as specified in the research agreement. The amounts in the table above assume the successful completion of the collaborative research activities contemplated by the agreements.

(2) Represents long-term debt and interest.

(3) Represents amounts that will become due upon future delivery of supplies and services from various suppliers under open purchase orders as of December 31, 2015.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

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

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term money market funds. Due to the short-term duration of our investment portfolio and the relatively low risk profile of our investments, we believe that the fair value of our investment portfolio would not be significantly impacted by either a hypothetical 100 basis point increase or decrease in market interest rates.

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

Effects of Inflation

We do not believe that inflation and changing prices during the years ended December 31, 2015, 2014, and 2013 had a significant impact on our results of operations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2015, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2015, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by BDO USA, LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Trovagene, Inc.
San Diego, California

We have audited Trovagene, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Trovagene, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Trovagene, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Trovagene, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

San Diego, California
March 10, 2016

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of Stockholders to be held in 2016 (the "2016 Proxy Statement"), under the headings "Election of Directors-Information with Respect to Director Nominees," "Section 16(a) Beneficial Ownership Reporting Compliance," "Election of Directors-Information Regarding the Board of Directors and Corporate Governance" and "Executive Officers".

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2016 Proxy Statement under the headings "Executive Compensation," "Summary Compensation Table," "Grants of Plan-Based Awards During Fiscal Year 2015," "Outstanding Equity Awards at Fiscal Year-End," "Option Exercises and Stock Vested," "Pension Benefits-Non-Qualified Defined Contribution and Other Nonqualified Deferred Compensation," "Potential Payments Upon Termination or Change in Control," "Director Compensation" and "Election of Directors-Information Regarding the Board of Directors and Corporate Governance".

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

The information required by this item is incorporated by reference from the information contained in the 2016 Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans".

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

The information required by this item is incorporated by reference from the information contained in the 2016 Proxy Statement under the headings "Certain Relationships and Related Transactions" and "Election of Directors-Information Regarding the Board of Directors and Corporate Governance".

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2016 Proxy Statement under the heading "Proposal 2: Ratification of the Appointment of Our Independent Registered Public Accounting Firm for Fiscal Year Ending December 31, 2016".

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description of Exhibit
	(a)(1)*Financial Statements*
	The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report on Form 10-K.

(b) Exhibits

Exhibit Number	Description
1.2	Controlled Equity Offering[SM] Sales Agreement dated January 25, 2013 by and between Trovagene, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Company's Form S-3 filed on January 25, 2013).
3.1	Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Form 10-12G filed on November 25, 2011).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Trovagene, Inc. (incorporated by reference to Appendix B to the Company's Proxy Statement on Schedule 14A filed on March 20, 2012).
3.3	By-Laws of Trovagene, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Form 10-12G filed on November 25, 2011).
4.1	Form of Common Stock Certificate of Trovagene, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Form 10-12G filed on November 25, 2011).
4.2+	2004 Stock Option Plan (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on July 19, 2004)
4.3	Form of Registration Rights Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K, filed on April 16, 2012).
4.4	Form of Warrant Agency Agreement by and between Trovagene, Inc. and Broadridge Corporate Issuer Solutions, Inc. and Form of Warrant Certificate (incorporated by reference to Exhibit 4.5 to the Company's Amendment No. 3 to Form S-1 filed on May 22, 2012).
4.5	Form of Unit Agency Agreement by and between Trovagene, Inc. and Broadridge Corporate Issuer Solutions, Inc. (incorporated by reference to Exhibit 4.6 to Amendment No. 3 to the Company's Form S-1 filed on May 22, 2012).
4.6	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 28, 2012).
4.7	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 1, 2014).
4.8+	Trovagene, Inc. 2014 Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed on July 23, 2014).

10.1	Summary of Terms of Lease Agreement dated as of October 28, 2009 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.3 to the Company's Form 10-12G/A filed on February 15, 2012).
10.2	Form of First Amendment to Standard Industrial Net Lease dated September 28, 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.4 to the Company's Form 10-12G/A filed on February 15, 2012).
10.3	Form of Second Amendment to Standard Industrial Net Lease dated October 2011 between Trovagene, Inc. and BMR-Sorrento West LLC (incorporated by reference to Exhibit 10.5 to the Company's Form 10-12G/A filed on February 15, 2012).
10.4	Form of Third Amendment to Standard Industrial Net Lease dated October 22, 2012 between Trovagene, Inc. and BMR-Sorrento West, LP. (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.5	Form of Fourth Amendment to Standard Industrial Net Lease dated December 2, 2013 between Trovagene, Inc. and BMR-Coast 9 LP. (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.6	Form of Fifth Amendment to Standard Industrial Net Lease dated May 14, 2014 between Trovagene, Inc. and BMR-Coast 9 LP. (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed on March 12, 2015).
10.7	Sixth Amendment to Standard Industrial Net Lease dated June 11, 2015 between Trovagene, Inc. and BMR-Coast 9 LP (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015).
10.8	Co-Exclusive Sublicense Agreement dated October 22, 2007 between Trovagene, Inc. and Asuragen, Inc. (incorporated by reference to Exhibit 10.6 to the Company's Form 10-12G/A filed on February 15, 2012).
10.9	Amendment to Co-Exclusive Sublicense Agreement dated June 1, 2010 between Trovagene, Inc. and Asuragen, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Form 10-12G/A filed on February 15, 2012).
10.10	Sublicense Agreement dated as of August 27, 2007 between Trovagene, Inc. and Ipsogen SAS (incorporated by reference to Exhibit 10.8 to the Company's Form 10-12G/A filed on February 15, 2012).
10.11	Amendment to Co-Exclusive Sublicense Agreement dated as of September 1, 2010 between Trovagene, Inc. and Ipsogen SAS (incorporated by reference to Exhibit 10.9 to the Company's Form 10-12G/A filed on February 15, 2012).
10.12	Sublicense Agreement dated as of July 20, 2011 between Trovagene, Inc. and Fairview Health Services (incorporated by reference to Exhibit 10.11 to the Company's Form 10-12G/A filed on February 15, 2012).
10.13	Sublicense Agreement dated as of December 1, 2008 by and between Trovagene, Inc. and InVivoScribe Technologies, Inc. (incorporated by reference to Exhibit 10.13 to the Company's Form 10-12G/A filed on February 15, 2012).
10.14	Sublicense Agreement dated as of August 25, 2008 by and between Trovagene, Inc. and Laboratory Corporation of America Holdings (incorporated by reference to Exhibit 10.14 to the Company's Form 10-12G/A filed on February 15, 2012).

10.15	Form of Sublicense Agreement effective as of February 8, 2011 by and between Trovagene, Inc. and MLL Munchner Leukamielabor GmbH (incorporated by reference to Exhibit 10.15 to the Company's Form 10-12G/A filed on February 15, 2012).
10.16	Sublicense Agreement effective as of June 15, 2010 by and between Trovagene, Inc. and Skyline Diagnostics BV (incorporated by reference to Exhibit 10.16 to the Company's Form 10-12G/A filed on February 15, 2012).
10.17	Exclusive License Agreement effective as of December 12, 2011 by and between Columbia University and Trovagene, Inc. (incorporated by reference to Exhibit 10.20 to the Company's Form 10-12G/A filed on February 15, 2012).
10.18	Form of Exclusive License Agreement effective as of October 2011 by and between Gianluca Gaidano, Robert Foa and Davide Rossi and Trovagene, Inc. (incorporated by reference to Exhibit 10.21 to the Company's Form 10-12G/A filed on February 15, 2012).
10.19	Exclusive License Agreement effective as of May 2006 by and between Brunangelo Falini, Cristina Mecucci and Trovagene, Inc. (incorporated by reference to Exhibit 10.23 to the Company's Form 10-12G/A filed on February 15, 2012).
10.20	Form of First Amendment to Exclusive License Agreement effective as of August 2010 by and among Brunangelo Falini, Cristina Mecucci and Trovagene, Inc. (incorporated by reference to Exhibit 10.24 to the Company's Form 10-12G/A filed on February 15, 2012).
10.21	Form of Securities Purchase Agreement dated as of July 30, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 31, 2013).
10.22	Loan and Security Agreement dated as of June 30, 2014 by and among Oxford Finance LLC, Silicon Valley Bank, Trovagene, Inc. and Etherogen, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 1, 2014).
10.23	First Amendment to Loan and Security Agreement dated as of December 18, 2014 by and among Oxford Finance LLC, Silicon Valley Bank, Trovagene, Inc. and Etherogen, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015).
10.24	Second Amendment to Loan and Security Agreement dated as of May 6, 2015 by and among Oxford Finance LLC, Silicon Valley Bank, Trovagene, Inc. and Etherogen, Inc. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015).
10.25	Form of Secured Promissory Note issued by the Company and Etherogen, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 1, 2014).
10.26+	Form of Indemnification Agreement to be entered into between the Company and its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 15, 2015).
10.27*	Patent Assignment and License Agreement dated April 23, 2014 between Trovagene, Inc. and GenSignia IP Ltd. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2014).
10.28+	Employment Agreement, effective January 1, 2016, by and between the Company and Antonius Schuh, Ph.D.
10.29+	Employment Agreement, effective January 1, 2016, by and between the Company and Stephen Zaniboni.

10.30+	Offer Letter and General Employment Terms & Conditions, dated January 14, 2013, by and between the Company and Mark Erlander.
10.31+	Offer Letter and General Employment Terms & Conditions, dated February 9, 2015, by and between the Company and Matthew L. Posard.
10.32	Loan and Security Agreement dated as of November 17, 2015 by and between the Company and Silicon Valley Bank.
21	List of Subsidiaries.
23.1	Consent of BDO USA, LLP
24	Power of Attorney (included on signature page hereto).
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Financial statements from the Annual Report on Form 10-K of Trovagene for the year ended December 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statement of Stockholders' Equity (Deficiency), (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

+ Indicates a management contract or compensatory plan or arrangement.

* The U.S. Securities and Exchange Commission (SEC) has granted confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TROVAGENE, INC.

/s/ Dr. Antonius Schuh

March 10, 2016

Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, Antonius Schuh, Ph.D., and Stephen Zaniboni, and each of them acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Dr. Antonius Schuh Dr. Antonius Schuh	Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2016
/s/ Stephen Zaniboni Stephen Zaniboni	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2016
Thomas H. Adams	Chairman of the Board	
/s/ John P. Brancaccio John P. Brancaccio	Director	March 10, 2016
/s/ Gary S. Jacob Gary S. Jacob	Director	March 10, 2016
/s/ Paul Billings Paul Billings	Director	March 10, 2016
/s/ Stanley Tennant Stanley Tennant	Director	March 10, 2016
/s/ Rodney S. Markin Rodney S. Markin	Director	March 10, 2016

TROVAGENE, INC.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Trovagene, Inc.
San Diego, California

We have audited the accompanying consolidated balance sheets of Trovagene, Inc. and Subsidiaries' ("Trovagene") as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Trovagene, Inc. and Subsidiaries at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Trovagene's internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 10, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP
San Diego, California
March 10, 2016

Trovagene, Inc. and Subsidiaries
Consolidated Balance Sheets

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 67,493,047	$ 27,293,798
Accounts receivable	98,736	56,694
Prepaid expenses and other assets	789,285	369,259
Total current assets	68,381,068	27,719,751
Property and equipment, net	2,690,579	840,387
Other assets	374,004	336,708
Total Assets	$ 71,445,651	$ 28,896,846
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,040,868	$ 747,799
Accrued expenses	1,934,411	1,841,808
Current portion of long-term debt	5,225,818	1,898,548
Total current liabilities	8,201,097	4,488,155
Long-term debt, less current portion	11,246,188	13,053,117
Derivative financial instruments	3,297,077	3,006,021
Total liabilities	22,744,362	20,547,293
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value, 20,000,000 shares authorized, 60,600 shares outstanding at each of December 31, 2015 and 2014, designated as Series A Convertible Preferred Stock with liquidation preference of $606,000 at each of December 31, 2015 and 2014	60	60
Common stock, $0.0001 par value, 150,000,000 shares authorized at December 31, 2015 and 2014; 29,737,601 and 18,915,793 issued and outstanding at December 31, 2015 and 2014, respectively	2,974	1,891
Additional paid-in capital	157,585,498	89,739,511
Accumulated deficit	(108,887,243)	(81,391,909)
Total stockholders' equity	48,701,289	8,349,553
Total Liabilities and Stockholders' Equity	$ 71,445,651	$ 28,896,846

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

Trovagene, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31,		
	2015	2014	2013
Royalty income	$ 274,648	$ 270,178	$ 259,246
License fees	—	10,000	—
Diagnostic service revenue	13,789	—	—
Other revenue	24,375	—	—
Total revenues	312,812	280,178	259,246
Costs and expenses:			
Cost of revenue	629,191	15,441	—
Research and development	10,593,869	6,664,906	3,947,589
Selling and marketing	6,443,578	2,734,903	1,530,160
General and administrative	7,919,826	5,810,087	5,472,038
Total operating expenses	25,586,464	15,225,337	10,949,787
Loss from operations	(25,273,652)	(14,945,159)	(10,690,541)
Interest income	57,261	12,239	3,663
Interest expense	(1,525,482)	(843,259)	(17,005)
Other (income) expense, net	(2,800)	24,845	(22,941)
Gain (loss) from change in fair value of derivative instruments—warrants	(726,421)	1,425,850	(1,084,114)
Net loss and comprehensive loss	(27,471,094)	(14,325,484)	(11,810,938)
Preferred stock dividend	(24,240)	(23,015)	(29,840)
Net loss and comprehensive loss attributable to common stockholders	$ (27,495,334)	$ (14,348,499)	$ (11,840,778)
Net loss per common share — basic	$ (1.05)	$ (0.76)	$ (0.70)
Net loss per common share — diluted	$ (1.21)	$ (0.88)	$ (0.70)
Weighted-average shares outstanding — basic	26,201,713	18,904,280	16,978,212
Weighted-average shares outstanding — diluted	26,452,165	19,071,112	16,978,212

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

Trovagene, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity (Deficit)

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

Trovagene, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity (Deficit)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deficit Accumulated	Total Stockholders' Equity (Deficit)
Stock-based compensation	—	—	—	—	2,070,195	—	2,070,195
Issuance of warrant in connection with debt agreement	—	—	—	—	235,857	—	235,857
Issuance of common stock upon net exercise of warrant	—	—	13,011	1	(1)	—	—
Preferred stock dividend	—	—	—	—	—	(23,015)	(23,015)
Net loss	—	—	—	—	—	(14,325,484)	(14,325,484)
Balance, December 31, 2014	60,600	60	18,915,793	1,891	89,739,511	(81,391,909)	8,349,553
Sale of common stock, net of expenses	—	—	9,996,531	1,000	61,214,399	—	61,215,399
Stock-based compensation	—	—	—	—	3,946,027	—	3,946,027
Derivative liability - Warrants reclassified to additional paid-in capital	—	—	—	—	435,365	—	435,365
Issuance of common stock upon exercise of stock options	—	—	265,166	27	860,825	—	860,852
Issuance of common stock upon net exercise of warrant	—	—	277,136	28	(28)	—	—
Issuance of common stock upon exercise of warrants	—	—	282,975	28	1,389,399	—	1,389,427
Preferred stock dividend	—	—	—	—	—	(24,240)	(24,240)
Net loss	—	—	—	—	—	(27,471,094)	(27,471,094)
Balance, December 31, 2015	60,600	$ 60	29,737,601	$ 2,974	$157,585,498	$(108,887,243)	$48,701,289

Trovagene, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	Year ended December 31,		
	2015	2014	2013
Operating activities			
Net loss	$ (27,471,094)	$ (14,325,484)	$ (11,810,938)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss (gain) on disposal of fixed assets	4,562	(24,845)	22,941
Depreciation and amortization	378,711	234,813	130,520
Stock-based compensation expense	3,946,027	2,070,194	1,979,364
Amortization of debt costs	346,157	248,799	—
Accretion of discount on debt	88,123	57,117	—
Change in fair value of financial instruments	726,421	(1,425,850)	1,084,114
Stock and warrant issued in connection with consulting services	—	—	198,791
Changes in operating assets and liabilities:			
Decrease (increase) in other assets	(37,296)	(258)	25,631
Decrease (increase) in accounts receivable	(42,042)	22,300	89,387
Increase in prepaid expenses	(420,026)	(216,470)	(92,748)
Increase in accounts payable and accrued expenses	361,432	632,299	1,055,690
Net cash used in operating activities	(22,119,025)	(12,727,385)	(7,317,248)
Investing activities:			
Capital expenditures	(2,241,066)	(363,290)	(649,784)
Proceeds from disposals of capital equipment	7,600	63,500	500
Net cash used in investing activities	(2,233,466)	(299,790)	(649,284)
Financing activities			
Proceeds from sale of common stock, net of expenses	61,215,399	—	18,829,644
Proceeds from exercise of warrants	1,389,427	—	3,599,831
Proceeds from exercise of options	860,852	—	38,249
Borrowings under equipment line of credit	1,086,062	—	515,964
Repayments under equipment line of credit	—	(515,964)	—
Borrowings under debt agreement	—	15,000,000	—
Net cash provided by financing activities	64,551,740	14,484,036	22,983,688
Net change in cash and cash equivalents	40,199,249	1,456,861	15,017,156
Cash and cash equivalents—Beginning of period	27,293,798	25,836,937	10,819,781
Cash and cash equivalents—End of period	$ 67,493,047	$ 27,293,798	$ 25,836,937
Supplementary disclosure of cash flow activity:			
Cash paid for taxes	$ 16,934	$ 2,400	$ 7,650
Cash paid for interest	$ 1,061,993	$ 425,256	$ 9,459
Supplemental disclosure of non-cash investing and financing activities:			
Warrants issued in connection with Loan and Security Agreement	$ —	$ 235,857	$ —
Reclassification of derivative financial instruments to additional paid-in capital	$ 435,365	$ —	$ (5,417,871)
Preferred stock dividends accrued	$ 24,240	$ 23,015	$ 29,840

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

Trovagene, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

1. Business Overview and Liquidity

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

To date, Trovagene's efforts have been principally devoted to research and development, securing and protecting patents and raising capital. Through December 31, 2015, the Company sustained cumulative net losses attributed to common stockholders of $108,887,243. The Company's losses have resulted primarily from expenditures incurred in connection with research and development activities, stock-based compensation expense, patent filing and maintenance expenses, outside accounting and legal services and regulatory, scientific and financial consulting fees, amortization and liquidated damages. To date, the Company has generated only limited revenue from operations and expects to incur additional losses to perform further research and development activities as well as expenses related to the commercialization of the diagnostic tests the Company had commercially available as of December 31, 2015.

Liquidity

The Company will need to continue to raise funds until it is able to generate revenues from operations sufficient to fund its development and commercial operations.

Cash used in operating activities was $22,119,025, $12,727,385, and $7,317,248 for the years ended December 31, 2015, 2014, and 2013, respectively. During the years ended December 31, 2015, 2014, and 2013, the Company incurred net loss and comprehensive loss attributable to common stockholders of $27,495,334, $14,348,499, and $11,840,778, respectively. The Company believes that it currently has adequate capital to continue operations for the next twelve months. However, to carry the Company forward beyond the next twelve months, and until it can generate adequate cash flow from operations, additional cash resources will be necessary.

To date, Trovagene's sources of cash have been primarily limited to the sale of debt and equity securities and debt financing. Net cash provided by financing activities for the years ended December 31, 2015, 2014, and 2013 was $64,551,740, $14,484,036 and $22,983,688, respectively. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company can raise additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct its business.

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

- Seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and

- Relinquish licenses or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize itself.

2. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying consolidated financial statements of Trovagene, which include its wholly owned subsidiary Trovagene Srl, a subsidiary formed in Italy, have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances and transactions have been eliminated.

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents consist of operating and money market accounts as of December 31, 2015 and 2014 on deposit with U.S. commercial banks. Cash equivalents are considered by the Company to be highly liquid investments purchased with original maturities of three months or less from the date of purchase.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposit accounts that are not insured by the Federal Deposit Insurance Corporation in federally insured financial institutions. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash due to the financial position of the depository institution in which those deposits are held.

Revenues

Revenue is recognized when persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

Milestone, Royalty and License Revenues

The Company licenses and sublicenses its patent rights to healthcare companies, medical laboratories and biotechnology partners. These agreements may involve multiple elements such as license fees, royalties and milestone payments. Revenue is recognized when the criteria described above have been met as well as the following:

- Up-front nonrefundable license fees pursuant to agreements under which the Company has no continuing performance obligations are recognized as revenues on the effective date of the agreement and when collection is reasonably assured.

- Minimum royalties are recognized as earned, and royalties in excess of minimum amounts are recognized upon receipt of payment when collection is assured.

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

Diagnostic Service Revenues

Revenue for clinical laboratory tests may come from several sources, including commercial third-party payors, such as insurance companies and health maintenance organizations, government payors, such as Medicare and Medicaid in the United States, patient self-pay and, in some cases, from hospitals or referring laboratories who, in turn, might bill third-party payors for testing. The Company is recognizing diagnostic service revenue on the cash collection basis until such time as it is able to properly estimate collections on third party reimbursements.

Allowance for Doubtful Accounts

The Company reviews the collectability of accounts receivable based on an assessment of historic experience, current economic conditions, and other collection indicators. At each of December 31, 2015, 2014 and 2013, the Company had not recorded an allowance for doubtful accounts. When accounts are determined to be uncollectible, they are written off against the reserve balance and the reserve is reassessed. When payments are received on reserved accounts, they are applied to the individual’s account and the reserve is reassessed.

Derivative Financial Instruments—Warrants

The Company has issued common stock warrants in connection with the execution of certain equity financings. Such warrants are classified as derivative liabilities under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 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 the volatility of Trovagene's common stock price, the remaining life of the warrant, and the risk-free interest rates at each period end. The Company thus uses model-derived valuations where inputs are observable in active markets to determine the fair value and accordingly classifies such warrants in Level 3 per FASB ASC Topic 820, *Fair Value Measurements* ("ASC 820"). At December 31, 2015 and 2014, the fair value of these warrants was $3,297,077 and $3,006,021, respectively, and was included in the derivative financial instruments liability on the balance sheet.

Stock-Based Compensation

FASB ASC Topic 718 "*Compensation—Stock Compensation*" ("ASC 718") requires companies to measure the cost of employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is recognized over the period during which an employee is required to provide services in exchange for the award. ASC 718 did not change the way Trovagene accounts for non-employee stock-based compensation. Trovagene continues to account for shares of common stock, stock options and warrants issued to non-employees based on the fair value of the stock, stock option or warrant, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting to non-employees in accordance with FASB ASC Topic 505-50 "*Equity -Based Payment to Non-Employees*", and, accordingly, the value of the stock compensation to non-employees is based upon the measurement date as determined at either (1) the date at which a performance commitment is reached, or (2) the date at which the necessary performance to earn the equity instruments is complete. Therefore, the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

Fair Value of Financial Instruments

Financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, debt and derivative liabilities. The Company has adopted 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 fair value due to their short term nature as they reflect current market interest rates. Debt is stated at its respective historical carrying amounts, which approximate fair value as they reflect current market interest rates.

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

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

Property, Equipment and Depreciation and Amortization

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

Impairment of Indefinite and Long-Lived Assets

The Company reviews its long-lived and indefinite assets to determine if any event has occurred that may indicate its intangible assets with indefinite lives and other long-lived assets are potentially impaired. If indicators of impairment exist, the Company performs an impairment test to assess the recoverability of the affected assets by determining whether the carrying amount of such assets exceeds the undiscounted expected future cash flows. If the affected assets are not recoverable, the Company estimates the fair value of the assets and records an impairment loss if the carrying value of the assets exceeds the fair value. Factors that would indicate potential impairment include a significant decline in the Company's stock price and market capitalization compared to its net book value, significant changes in the ability of a particular asset to generate positive cash flows, and significant changes in the Company's strategic business objectives and utilization of a particular asset. The Company noted no indications of impairment for the years ended December 31, 2015, 2014, and 2013.

Income Taxes

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

Contingencies

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

Cost of Revenue

Cost of revenue represents the cost of materials, personnel costs, costs associated with processing specimens including pathological review, quality control analyses, and delivery charges necessary to render an individualized test result. Costs associated with performing tests are recorded as the tests are processed.

Research and Development

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

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

FASB ASC Topic 730, *Research and Development* requires that non-refundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts are recognized as an expense. There were no non-refundable advance payments as of December 31, 2015, 2014 and 2013.

Net Loss Per Share

Basic and diluted net loss per share is presented in conformity with FASB ASC Topic 260, *Earnings per Share*, for all periods presented. In accordance with this guidance, basic and diluted net loss per common share is determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. Preferred dividends are included in income available to common stockholders in the computation of basic and diluted earnings per share. Shares used in calculating diluted net loss per common share exclude as anti-dilutive the following share equivalents:

	December 31,		
	2015	2014	2013
Options to purchase Common Stock	6,948,630	4,913,472	4,287,545
Warrants to purchase Common stock	4,565,947	5,251,660	6,233,483
Series A Convertible Preferred Stock	63,125	63,125	63,125
	11,577,702	10,228,257	10,584,153

The following table summarizes the Company's diluted net loss per share:

	December 31,		
	2015	2014	2013
Numerator:			
Net loss attributable to common stockholders	$ (27,495,334)	$ (14,348,499)	$ (11,840,778)
Adjustment for change in fair value of derivative instruments - warrants	(4,396,061)	(2,422,337)	—
Net loss used for diluted loss per share	$ (31,891,395)	$ (16,770,836)	$ (11,840,778)
Denominator:			
Weighted-average shares used to compute basic net loss per share	26,201,713	18,904,280	16,978,212
Adjustments to reflect assumed exercise of warrants	250,452	166,832	—
Weighted-average shares used to compute diluted net loss per share	26,452,165	19,071,112	16,978,212
Net loss per share diluted	$ (1.21)	$ (0.88)	$ (0.70)

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, *Leases*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact the adoption of the new standard will have on its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, P*resentation of Financial Statements—Going Concern*, which impacts the accounting guidance related to the evaluation of an entity's ability to continue as a going concern. The amendment establishes management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern in connection with preparing financial statements for each annual and interim reporting period. The amendment also gives guidance to determine whether to disclose information about relevant conditions and events when there is substantial doubt about an entity's ability to continue as a going concern. The amended guidance is effective prospectively for fiscal years beginning after December 15, 2016. The new guidance is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In May 2014, the FASB issued ASU 2014-9, *Revenue from Contracts with Customers* ("ASU 2014-9"). ASU 2014-9 provides companies with a single model for accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the model is to

recognize revenue when control of the goods or services transfers to the customer, as opposed to recognizing revenue when the risks and rewards transfer to the customer under the existing revenue guidance. The guidance permits companies to either apply the requirements retrospectively to all prior periods presented, or apply the requirements in the year of adoption, through a cumulative adjustment. In August 2015, the FASB issued ASU 2015-14, *Deferral of the Effective Date*, which defers the required adoption date of ASU 2014-09 by one year. As a result of the deferred effective date, ASU 2014-09 will be effective for the Company in its first quarter of fiscal year 2018. Early adoption is permitted but not before the original effective date of the first quarter of fiscal year 2017. The Company is in the process of evaluating the transition method that will be elected and the impact of adoption of ASU 2014-09 on its consolidated financial statements.

3. Property and Equipment

Fixed assets consist of laboratory, testing and computer equipment and fixtures stated at cost. Depreciation and amortization expense for the years ended December 31, 2015, 2014, and 2013 was $378,711, $234,813, and $130,520, respectively. Property and equipment consisted of the following:

	As of December 31,	
	2015	2014
Furniture and office equipment	$ 1,483,227	$ 365,955
Leasehold Improvements	39,401	39,401
Laboratory equipment	2,022,733	968,901
	3,545,361	1,374,257
Less—accumulated depreciation and amortization	(854,782)	(533,870)
Property and equipment, net	$ 2,690,579	$ 840,387

4. Stockholders' Equity (Deficit)

Common Stock

On January 25, 2013, the Company filed a Registration Statement on Form S-3 (the "Registration Statement") to offer and sell in one or more offerings, any combination of common stock, preferred stock, warrants, or units having an aggregate initial offering price of up to $150,000,000. If issued, the preferred stock, warrants and units would be convertible, exercisable or exchangeable for common stock, preferred stock or other Trovagene securities. The Registration Statement was declared effective on February 4, 2013. In addition, in connection with the Registration Statement, the Company entered into an agreement with Cantor Fitzgerald & Co. ("Agent") on January 25, 2013 to issue and sell up to $30,000,000 of shares of common stock. As payment for its services, the Agent is entitled to a 3% commission on gross proceeds on sales of the Company's securities. The Company received gross proceeds of approximately $4.2 million from the sale of 488,476 shares of its common stock during the year ended December 31, 2013 under the agreement with the Agent. In addition, the Company received gross proceeds of approximately $15.0 million from the sale of 2,142,857 shares of its common stock through a registered direct offering that occurred in July 2013.

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

During the year ended December 31, 2014, the Company issued a total of 13,011 shares of common stock upon the net exercise of warrants at a weighted-average exercise price of $3.00.

During the year ended December 31, 2015, the Company issued a total of 10,821,808 shares of common stock. The Company received gross proceeds of approximately $63.2 million from the sale of 9,711,110 shares of its common stock through underwritten public offerings in February 2015 and July 2015. The Company also received gross proceeds of approximately $2.8 million from the sale of 285,421 shares of its common stock at a weighted-average price of $9.66 under the agreement with the Agent. In addition, 265,166 shares were issued upon exercise of options for a weighted-average price of

$3.25, 282,975 shares were issued upon exercise of warrants for a weighted-average price of $4.91, and 277,136 shares were issued upon net exercise of 449,403 warrants at a weighted-average exercise price of $3.05.

Warrants

A summary of warrant activity and changes in warrants outstanding, including both liability and equity classifications, is presented below:

	Number of Warrants	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term
Balance outstanding, December 31, 2012	6,985,070	$ 3.96	5.4
Granted	50,000	$ 8.00	
Exercised	(728,488)	$ 4.99	
Expired	(73,099)	$ 4.50	
Balance outstanding, December 31, 2013	6,233,483	$ 3.87	4.5
Granted	85,470	$ 3.51	
Exercised	(36,666)	$ 3.00	
Expired	(16,667)	$ 10.80	
Balance outstanding, December 31, 2014	6,265,620	$ 3.85	3.6
Exercised	(732,378)	$ 3.77	
Balance outstanding, December 31, 2015	5,533,242	$ 3.86	2.5

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

The Company issued warrants to purchase 85,470 shares of common stock at an exercise price of $3.51 per share during the year ended December 31, 2014. The warrants were issued in connection with a $15.0 million debt agreement. The estimated fair value of the warrants was determined on the date of grant using the Black-Scholes option valuation model using the following assumptions: a risk-free interest rate of 2.53%, dividend yield of 0%, expected volatility of 73.8% and expected term of ten years. The resulting fair value of $235,857 was recorded as a debt discount and was amortized to interest expense over the term of the loan using the effective interest method.

Series A Convertible Preferred Stock

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

1) *Dividends.* Holders of the Company's Series A Convertible Preferred Stock are entitled to receive cumulative dividends at the rate per share of 4% per annum, payable quarterly on March 31, June 30, September 30 and December 31, beginning with September 30, 2005. Dividends are payable, at the Company's sole election, in cash or shares of common stock. As of December 31, 2015, 2014, and 2013, the Company had $268,295, $244,055, and $221,040, respectively in accrued cumulative unpaid preferred stock dividends, included in Accrued Expenses in the Company's consolidated balance sheets, and $24,240, $23,015, and $29,840 of accrued dividends was recorded during the years ended December 31, 2015, 2014, and 2013, respectively.

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

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

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

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

6) *Automatic Conversion.* If the price of the Company's common stock equals $25.80 per share for 20 consecutive trading days, and an average of 8,333 shares of common stock per day are traded during the 20 trading days, the Company will have the right to deliver a notice to the holders of the Series A Convertible Preferred Stock, requesting the holders to convert any portion of the shares of Series A Convertible Preferred Stock into shares of common stock at the applicable conversion price. As of the date of these financial statements, such conditions have not been met.

During the year ended December 31, 2013, 35,000 shares of Series A Convertible Preferred Stock were converted into 36,458 shares of common stock, on a net converted basis. As of each of December 31, 2015, 2014, and 2013, there were 60,600 shares of Series A Convertible Preferred Stock outstanding.

5. Stock Option Plan

In June 2004, the Company adopted the Trovagene Stock Option Plan, as amended (the "2004 Plan"), under which up to 6,000,000 shares common stock were reserved for issuance to directors and eligible employees, including executive officers and consultants. Generally, vesting for options granted under the Plan was from three to four years, and options expired after a 10-year period. Options were granted at an exercise price not less than the fair market value at the date of grant. As of December 31, 2014, the 2004 Plan was expired. As of December 31, 2013, there were 1,788,921 shares available for issuance under the 2004 Plan.

During 2013, the Company issued 260,000 options over the authorized number of options in the 2004 Plan. As per FASB ASC Topic 815-40, the options were accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company's statement of operations. Stockholder approval was obtained on July 18, 2013 to increase the number of authorized shares in the 2004 Plan from 3,666,667 to 6,000,000. Accordingly, the options were remeasured as of the date of stockholder approval with the change recorded in stock based compensation expense and the $23,024 liability was reclassified to additional paid-in capital.

In July 2013, an option to purchase 90,000 shares of common stock was granted to a member of the Board for services provided outside of routine Board activities. This option was vested in full upon grant. The fair value of this option was approximately $500,000 and is included in general and administrative expenses.

The Trovagene, Inc. 2014 Equity Incentive Plan (the "2014 EIP'), authorizing up to 2,500,000 shares of common stock for issuance under the 2014 EIP, was approved by the Board in June 2014 and approved by the stockholders of the Company at the September 17, 2014 Annual Meeting of Stockholders. An additional 2,500,000 shares of common stock was authorized for issuance by the Board in March 2015 and was approved by the stockholders at the June 10, 2015 Annual Meeting of Stockholders.

As of December 31, 2015, there were 1,361,832 shares available for issuance under the 2014 EIP.

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

	Years ended December 31,		
	2015	2014	2013
In cost of revenue	$ 39,676	$ —	$ —
In research and development expenses	1,499,009	796,008	549,465
In selling and marketing expense	768,146	145,239	70,626
In general and administrative expenses	1,639,196	1,128,947	1,359,273
Total stock-based compensation	$ 3,946,027	$ 2,070,194	$ 1,979,364

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

	Years ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.35% - 2.15%	1.42% - 2.1%	0.74% - 1.5%
Dividend yield	0%	0%	0%
Expected volatility (range)	73% - 77%	81% - 86%	82% - 100%
Expected volatility (weighted-average)	75%	85%	91%
Expected term (in years)	6.0 years	5.8 years	5.0 years

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

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

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

Expected term — The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* ("SAB No. 107"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under SAB No. 107, options are considered to be "plain vanilla" if they have the following basic characteristics: (1) are granted "at-the-money"; (2) exercisability is conditioned upon service through the vesting date; (3) termination of service prior to vesting results in forfeiture; (4) limited exercise period following termination of service; and (5) are non-transferable and non-hedgeable.

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

The weighted-average fair value per share of all options granted during the years ended December 31, 2015, 2014, and 2013, estimated as of the grant date using the Black-Scholes option valuation model, was $4.60, $3.16 and $4.54 per share, respectively.

The unrecognized compensation cost related to non-vested stock options outstanding at December 31, 2015 and 2014 was $10,430,604 and $4,862,030, respectively. The weighted-average remaining contractual term at December 31, 2015 and 2014 for options outstanding and vested options was 3.1 years and 3.0 years, respectively.

The total intrinsic value of stock options exercised was $1,382,255, $0 and $275,492 during the years ended December 31, 2015, 2014 and 2013, respectively. The total fair value of shares vested during the years ended December 31, 2015, 2014 and 2013 was $2,634,688, $1,960,256 and $1,633,071, respectively.

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

	Number of Options	Weighted-Average Exercise Price Per Share	Intrinsic Value	Weighted-Average Remaining Contractual Life
Balance outstanding, December 31, 2012	3,711,303	$ 4.69	$ 8,301,484	6.3 years
Granted	1,144,760	$ 6.33		
Exercised	(52,500)	$ 4.30		
Forfeited	(516,018)	$ 4.35		
Balance outstanding, December 31, 2013	4,287,545	$ 5.18	$ 5,896,329	6.7 years
Granted	1,410,038	$ 4.42		
Forfeited	(784,111)	$ 7.08		
Balance outstanding, December 31, 2014	4,913,472	$ 4.66	$ 2,808,083	7.6 years
Granted	2,688,500	$ 7.02		
Exercised	(265,166)	$ 3.25		
Forfeited	(388,176)	$ 7.75		
Balance outstanding, December 31, 2015	6,948,630	$ 5.45	$ 5,903,466	7.8 years
Vested and exercisable, December 31, 2015	2,825,398	$ 4.38	$ 4,194,205	6.0 years

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

6. Derivative Financial Instruments — Warrants

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

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

	Year ended December 31		
	2015	2014	2013
Estimated fair value of Trovagene common stock	$5.40 - $10.15	$3.00 - $6.74	$5.74 - $7.18
Expected warrant term	3.0-3.8 years	4.0 years	1 month to 5.8 years
Risk-free interest rate	0.89%-1.31%	1.38%	.03%-1.75%
Expected volatility	73%-77%	86.4%	82%-100%
Dividend yield	—%	—%	—%

Expected volatility is based on the volatility of a peer group of companies with attributes similar to Trovagene. The warrants have a transferability provision and based on guidance provided in SAB No. 107 for instruments issued with such a provision, Trovagene used the full contractual term as the expected term of the warrants. The risk-free interest rate is based on the U.S. Treasury security rates consistent with the expected remaining term of the warrants at each balance sheet date.

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

Date	Description	Number of Warrants	Derivative Instrument Liability
December 31, 2013	Balance of derivative financial instruments liability	1,013,961	$ 4,431,871
	Change in fair value of warrants during the year recognized as a gain in the statement of operations	—	(1,425,850)
December 31, 2014	Balance of derivative financial instruments liability	1,013,961	3,006,021
	Exercised warrants	(46,666)	(435,365)
	Change in fair value of warrants during the year recognized as a loss in the statement of operations	—	726,421
December 31, 2015	Balance of derivative financial instruments liability	967,295	$ 3,297,077

The weighted-average remaining contractual term of all of the Company's warrants outstanding at December 31, 2015 and 2014 was approximately 2.5 and 3.6 years, respectively.

At December 31, 2015 and 2014, the total fair value of the above warrants accounted for as derivative financial instruments, valued using the Black-Scholes option pricing model, was $3,297,077 and $3,006,021, respectively, and is classified as derivative financial instruments liability on the balance sheet.

7. Fair Value Measurements

The following table presents the Company's assets and liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of December 31, 2015 and 2014:

	Fair Value Measurements at December 31, 2015			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$ 65,016,222	$ —	$ —	$ 65,016,222
Total Assets	$ 65,016,222	$ —	$ —	$ 65,016,222
Liabilities:				
Derivative liabilities related to warrants	$ —	$ —	$ 3,297,077	$ 3,297,077
Total Liabilities	$ —	$ —	$ 3,297,077	$ 3,297,077

	Fair Value Measurements at December 31, 2014			
	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Money market fund (1)	$ 27,123,587	$ —	$ —	$ 27,123,587
Total Assets	$ 27,123,587	$ —	$ —	$ 27,123,587
Liabilities:				
Derivative liabilities related to warrants	$ —	$ —	$ 3,006,021	$ 3,006,021
Total Liabilities	$ —	$ —	$ 3,006,021	$ 3,006,021

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

The following table sets forth a summary of changes in the fair value of the Company's Level 3 liabilities for the years ended December 31, 2015 and 2014:

Description	Balance at December 31, 2014	Fair Value of Warrants Reclassified to Additional Paid-in Capital	Unrealized (gains) or losses	Balance at December 31, 2015
Derivative liabilities related to Warrants	$ 3,006,021	$ (435,365)	$ 726,421	$ 3,297,077

Description	Balance at December 31, 2013	Unrealized (gains) or losses	Balance at December 31, 2014
Derivative liabilities related to Warrants	$ 4,431,871	$ (1,425,850)	$ 3,006,021

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

8. Debt

Equipment Line of Credit

In November 2015, the Company entered into a Loan and Security Agreement ("Equipment Line of Credit") with Silicon Valley Bank that provided for cash borrowings for equipment ("Equipment Advances") of up to $2.0 million, secured by the equipment financed. Under the terms of the agreement, interest is equal to 1.25% above the Prime Rate. Interest only payments are due on borrowings through November 30, 2016, with both interest and principal payments commencing in December 2016. Any equipment advances after November 30, 2016 are subject to principal and interest payments immediately over a 36-month period following the advance. All unpaid principal and interest on each Equipment Advance will be due on November 1, 2019. The Company has an obligation to make a final payment equal to 7% of total amounts borrowed at the loan maturity date and the final payment is being accrued over the term of the loans using the effective-interest method.

The Company is also subject to certain affirmative and negative covenants under the Equipment Line of Credit. As of December 31, 2015, the Company was in compliance with all covenants.

As of December 31, 2015, $1,086,062 has been borrowed under the Equipment Line of Credit. As of December 31, 2015, amounts due under the Equipment Line of Credit included $30,168 in current liabilities and $1,058,709 in long-term liabilities, which includes $2,815 of accrued financial payment. The Company recorded $5,702 in interest expense related to the Equipment Line of Credit during the year ended December 31, 2015.

Future maturities of long-term debt at December 31, 2015 are as follows:

2016	$ 30,168
2017	362,021
2018	362,021
2019	331,852
Total principal	1,086,062
Plus final fee premium accretion	2,815
Total long-term obligations	$ 1,088,877

Loan and Security Agreement

In June 2014, the Company entered into a $15,000,000 loan and security agreement ("Agreement") with two banks pursuant to which the lenders provided the Company with a term loan, which was funded at closing. A portion of the proceeds

were used to repay the existing outstanding amount under the Equipment Line of Credit entered into in June 2013. The repayment with the same lender was accounted for as a debt extinguishment under FASB ASC Topic 470-50, *Debt*. The interest rate on the new loan is 7.07% per annum. The Company made interest only payments on the outstanding amount of the loan on a monthly basis through July 2015, after which equal monthly payments of principal and interest were scheduled to become due until the loan maturity date of July 1, 2018. However, included in the Agreement is a provision to extend the interest only payments through January 1, 2016 upon the Company's receipt of unrestricted net cash proceeds from the sale of equity securities of not less than $30 million by June 30, 2015. In June 2015, the Company entered into an amendment to the Agreement ("Amendment"), which reduced the amount of unrestricted net cash proceeds to not less than $21 million from the sale of equity securities to qualify for an interest-only extension. The Company met the conditions in the Amendment related to the interest-only extension and, as a result, the interest only payments that were to expire on August 1, 2015 were extended for six months to February 1, 2016, when both interest and principal payments will commence. The loan is secured by a security interest in all of the Company's assets except intellectual property, which is subject to a negative pledge. In connection with the loan, each of the lenders received a warrant to purchase up to an aggregate of 85,470 shares of the Company's common stock at an exercise price of $3.51 per share, which such warrants are exercisable for ten years from the date of issuance. The original value of the warrants, totaling $235,857, was recorded as debt discount and additional paid-in capital as the warrants were equity classified. As of December 31, 2015, a warrant to purchase 42,735 shares of common stock remains outstanding.

At the Company's option, it may prepay all of the outstanding principal balance, subject to certain pre-payment fees ranging from 1% to 3% of the prepayment amount. In the event of a final payment of the loans under the loan agreement, either in the event of repayment of the loan at maturity or upon any prepayment, the Company is obligated to pay the amortized portion of the final fee of $1,050,000.

The Company is also subject to certain affirmative and negative covenants under the Agreement, including limitations on its ability to: undergo certain change of control events; convey, sell, lease, license, transfer or otherwise dispose of any equipment financed by loans under the loan agreement; create, incur, assume, guarantee or be liable with respect to indebtedness, subject to certain exceptions; grant liens on any equipment financed under the loan agreement; make or permit any payment on specified subordinated debt; and pay dividends. In addition, under the Agreement, subject to certain exceptions, the Company is required to maintain with the lender its primary operating, other deposit and securities accounts. Furthermore, under the Amendment, the Company is required to be in compliance with healthcare laws and regulations and terms and conditions of healthcare permits. The Company was in compliance with all covenants under the Agreement, as amended, as of December 31, 2015.

As of December 31, 2015, amounts due under the Agreement include $5,195,650 in current liabilities and $10,187,479 in long-term liabilities, which include $535,024 of accrued financial payment. The Company recorded $1,590,750 in interest expense related to the Agreement during the year ended December 31, 2015. Closing costs are being accreted over the life of the loan to interest expense.

Future maturities of long-term debt at December 31, 2015 are as follows:

2016	$	5,195,650
2017		6,064,315
2018		3,740,035
Total principal		15,000,000
Less discount		(151,895)
Plus final fee premium accretion		535,024
Total long-term obligations	$	15,383,129

9. Income Taxes

At December 31, 2015, Trovagene had federal net operating loss carryforwards (NOLs) of approximately $72.6 million, which, if not used, expire beginning in 2020. Trovagene also has California NOLs of approximately $52.6 million that will begin to expire in 2021 and New Jersey NOLs of approximately $6.9 million that begin to expire on January 31, 2016. Trovagene also has research and development tax credits available for federal and California purposes of approximately $1.2 million and $0.5 million, respectively. The federal research and development tax credits will begin to expire on January 31, 2025. The California research and development tax credits are not set to expire. The utilization of these NOLs and research and development tax credits is subject to limitations based on past and future changes in ownership of Trovagene pursuant to Section 382 ("Section 382") of the Internal Revenue Code of 1986, as amended (the "Code"). The Company has determined

that ownership changes have occurred for purposes of Section 382 and, therefore, the ability of the Company to utilize its NOLs is limited.

The provision for income taxes based on losses from continuing operations consists of the following at December 31 (in thousands):

	Years ended December 31,		
	2015	2014	2013
Deferred benefit			
Federal	$ (9,602)	$ (5,651)	$ (3,806)
State	(1,742)	(449)	(593)
Total deferred benefit	(11,344)	(6,100)	(4,399)
Valuation allowance	11,344	6,100	4,399
Total income tax provision	$ —	$ —	$ —

Significant components of the Company's taxes and the rates as of December 31 are shown below (in thousands, except percentages):

	Years ended December 31,			
	2015		2014	
Tax computed at the federal statutory rate	$ (9,340)	34 %	$ (4,871)	35 %
State tax, net of federal tax benefit	(1,559)	6 %	(891)	6 %
Permanent Items	258	(1)%	(320)	2 %
Tax credits	(997)	3 %	—	— %
Valuation allowance increase	11,638	(42)%	6,081	(43)%
Other	—	— %	1	— %
Provision for income taxes	$ —	— %	$ —	— %

Significant components of the Company's deferred tax assets and liabilities from federal and state income taxes as of December 31 are shown below:

	Years ended December 31,	
	2015	2014
Deferred tax assets		
Tax loss carryforwards	$ 27,962,000	$ 19,010,900
Research and development credits and other tax credits	1,698,300	698,000
Stock-based compensation	3,225,200	2,193,900
Other	782,000	420,800
Total deferred tax assets	33,667,500	22,323,600
Valuation allowance	(33,667,500)	(22,323,600)
Net deferred tax asset	$ —	$ —

Trovagene records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to Trovagene's ability to utilize its deferred tax assets, the Company recorded a valuation allowance against the deferred tax.

FASB ASC Topic 740-10-30-7, *Accounting for Income Taxes* had no effect on Trovagene's financial position, cash flows or results of operations upon adoption, as Trovagene does not have any unrecognized tax benefits. Trovagene's practice is to recognize interest and/or penalties related to income tax matters in income tax expense, and none have been incurred to date.

10. Commitments and Contingencies

Research and Development and License Agreements

The Company has entered into a variety of collaboration and specimen transfer agreements relating to its development efforts. Included in research and development expense, the Company has incurred and recorded approximately $1,362,000, $712,000, and $217,000 as of December 31, 2015, 2014 and 2013, respectively, relating to services provided by the collaborators in connection with these agreements.

The Company is a party to various agreements under which it licenses technology on an exclusive basis in the field of human diagnostics. License fees are generally calculated as a percentage of product revenues, with rates that vary by agreement. To date, payments have not been material.

Litigation

Trovagene does not believe that the Company has legal liabilities that are probable or reasonably possible that require either accrual or disclosure. From time to time, the Company may become involved in various lawsuits and legal proceedings that 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 the Company's business.

The Company is not currently a party to any material legal proceedings.

Employment and Consulting Agreements

The Company has longer-term contractual commitments with various consultants and employees, including the Company's CEO and CFO. The executive agreements with the CEO, CFO and CCO provide for severance payments. The executive agreement with the CEO also provides for a bonus payment in cash or stock upon the earlier of meeting certain trading volumes and market price of Trovagene's common stock for a minimum period of ninety days or in the event of a change in control where the Company's per share enterprise value equal or exceeds $7.50. If the market price and volume target is realized, the bonus is approximately $3.5 million. If a change of control occurs at the targeted enterprise values, the bonus is equal to 4% of the enterprise value. The executive agreements with the CEO and CFO were replaced by the employment agreements that became effective in January 2016. See Note 14. Subsequent Events.

Lease Agreements

The Company leases laboratory and office spaces under various non-cancelable lease agreements. The Company is headquartered in San Diego, California and leases facilities in San Diego and Italy. The Company currently leases its facilities in San Diego under an operating lease that expires in 2017. On June 11, 2015, the Company entered into an amendment to the lease agreement which expands the square footage leased by the Company to approximately 22,600 square feet at a monthly rental rate of approximately $60,000. The amended lease expires on December 31, 2021. The amended monthly rental rate will be effective when the Company commences business operations in the expanded premises, expected to occur in the second quarter of 2016.

In November 2015, the Company entered into a lease agreement, under the terms of which the Company will lease certain office building in Torino, Italy, consisting of approximately 2,300 square feet at a monthly rental rate of approximately $3,100. The lease is for a period of three years with an effective date of January 1, 2016.

Rent expense for the years ended December 31, 2015, 2014, and 2013 was approximately $471,000, $315,000 and $294,000, respectively. The Company is also a party to various operating lease agreements for office equipment.

Total annual commitments under non-cancelable lease agreements for each of the years ended December 31 are as follows:

2016	$	683,871
2017		792,221
2018		811,797
2019		796,716
2020		817,989
Thereafter		842,529
Total	$	4,745,123

11. Employee Benefit Plan

The Company has a retirement savings plan under Section 401(k) of the Code covering its employees. The plan allows employees to defer, up to the maximum allowed, a percentage of their income on a pre-tax basis through contributions to the plans, plus any employee age 50 and over can participate in the caught-up dollars as allowed by Internal Revenue Service codes. The Company also has a Roth investment plan that is taken after taxes. The Company does not currently make matching contributions.

12. Related Party Transactions

In January 2015, the Company entered into a one year consulting agreement with Thomas H. Adams, Ph.D., the Chairman of the Board, pursuant to which Dr. Adams provides consulting services to the Company in connection with applying the Company's technology in the field of infectious disease with the first application to be detection of John Cunningham virus mutants in the presence of wild type in human urine as a prognostic indicator of the development of progressive multifocal leukoencephalopathy disease. Under the agreement, the Company committed to pay $9,500 per month for the services performed by Dr. Adams. During the year ended December 31, 2015, the Company incurred and recorded $114,000 of consulting fees related to the agreement.

In September 2015, the Company entered into a research agreement with the University of Torino ("University") to collaborate on a program of research to develop, optimize and test molecular profiling tools for plasma and urine ctDNA in cancer. Dr. Alberto Bardelli, the Principal Investigator of the University who oversees this research program, is also a member of the Scientific Advisory Board of the Company. Under the agreement, the Company committed to pay up to $529,000 for the services performed by the University. In addition, the Company may pay royalties to the University on revenue generated by the Company from the commercialization of any tools developed during the collaboration. During the year ended December 31, 2015, the Company incurred and recorded approximately $188,000 of research and development expenses related to the agreement. No royalty expense has been incurred as of December 31, 2015.

13. Selected Quarterly Financial Data (Unaudited)

The following is a summary of the quarterly results of operations of the Company for years ended December 31, 2015 and 2014:

	Quarter Ended(1)			
	March 31	June 30	September 30	December 31
	(dollars in thousands, except per share data)			
2015				
Revenues	$ 127	$ 49	$ 58	$ 79
Operating expenses	$ 4,975	$ 6,682	$ 6,467	$ 7,463
Net loss and comprehensive loss attributable to common stockholders	$ (7,180)	$ (10,186)	$ (2,742)	$ (7,387)
Net loss per common share - basic	$ (0.33)	$ (0.41)	$ (0.10)	$ (0.25)
Net loss per common share - diluted	$ (0.33)	$ (0.41)	$ (0.23)	$ (0.26)
Shares used in the calculation of net loss attributable to common stockholders - basic	21,817,710	24,592,883	28,560,211	29,723,254
Shares used in the calculation of net loss attributable to common stockholders - diluted	21,817,710	24,592,883	29,128,235	30,157,038
2014				
Revenues	$ 111	$ 56	$ 57	$ 56
Operating expenses	$ 3,371	$ 3,297	$ 3,997	$ 4,560
Net loss and comprehensive loss attributable to common stockholders	$ (3,198)	$ (1,079)	$ (5,382)	$ (4,689)
Net loss per common share - basic	$ (0.17)	$ (0.06)	$ (0.28)	$ (0.25)
Net loss per common share - diluted	$ (0.17)	$ (0.17)	$ (0.28)	$ (0.25)
Shares used in the calculation of net loss attributable to common stockholders - basic	18,902,783	18,902,783	18,902,783	18,904,280
Shares used in the calculation of net loss attributable to common stockholders - diluted	18,902,783	19,232,760	18,902,783	19,071,112

(1) Basic and diluted net loss per common share are computed independently for each of the periods presented. Accordingly, the sum of the quarterly net loss per common share amount may not agree to the total for the year.

14. Subsequent Events

Employment Agreements

In January 2016, the Company entered into an employment 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 January 1, 2016 and continues until January 1, 2020 and is automatically renewed for successive one year periods at the end of each term. Dr. Schuh's base compensation is $488,800 per year. Dr. Schuh is eligible to receive an annual bonus of up to 50% of his base compensation based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Dr. Schuh was granted 450,000 non-qualified stock options which have an exercise price of $5.18 per share and vest monthly in equal amounts over a period of four years. Dr. Schuh was also granted 350,000 non-qualified stock options which have an exercise price of $5.18 per share and vested immediately upon grant.

If the employment agreement is terminated by the Company without cause, Dr. Schuh is entitled to receive a severance payment equal to base compensation for twenty-four months and the potential bonus and any benefits Dr. Schuh would be eligible during such twenty-four month period. If the employment agreement is terminated as a result of a change of control, in addition to the severance payment described above, all unvested equity awards would immediately vest and become fully exercisable for a period of six months following the date of termination.

In January 2016, the Company entered into an employment agreement with Stephen Zaniboni in which he agreed to serve as our Chief Financial Officer. The term of the agreement is effective as of January 1, 2016 and continues until January 1, 2020 and is automatically renewed for successive one year periods at the end to each term. Mr. Zaniboni's base compensation

is $357,500 per year. Mr. Zaniboni is eligible to receive an annual bonus of up to 50% of his base compensation based on meeting certain performance objectives and bonus criteria. Upon entering the agreement, Mr. Zaniboni was granted 150,000 non-qualified stock options which have an exercise price of $5.18 per share and vest monthly in equal amounts over a period of four years.

If the employment agreement is terminated by the Company without cause, Mr. Zaniboni is entitled to receive a severance payment equal to base compensation for twelve months and the potential bonus and any benefits Mr. Zaniboni would be eligible during such twelve month period. If the employment agreement is terminated as a result of a change of control, in addition to the severance payment, all unvested equity awards would immediately vest and become fully exercisable for a period of six months following the date of termination.

Debt Agreement

In February 2016, the Company signed a term sheet to refinance its existing term loan entered into on June 2014. Under the term sheet, interest would be equal to 3.75% plus the Wall Street Journal Prime Rate, subject to a floor of 7.25%. Interest only payments would be for 12 months, followed by equal monthly payments of principal and interest over the following 30 months. The Company would also have an obligation to make a final payment equal to 7.50% of total funded amounts at the loan maturity date. In addition, the lenders would receive a warrant to purchase such number of shares of the Company’s common stock as is equal to 1% of the funded amount divided by an average closing price of the Company’s common stock.

Registration Statement

Effective February 4, 2016, the Registration Statement expired and the Company therefore will no longer be able to issue securities pursuant to the Registration Statement, including pursuant to its agreement with the Agent.

Exhibit 10.28

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made and entered into effective as of January 1, 2016 (the "Effective Date"), by and between Antonius Schuh, Ph.D. (the "Executive") and Trovagene, Inc., a Delaware corporation (the "Company").

R E C I T A L S

WHEREAS, Executive serves as the Chief Executive Officer of the Company;

WHEREAS, Executive is a Managing Partner of Global Source Ventures LLC, an investment and consulting firm (together with its successors and assigns, "GSV"), and serves as director, officer and/or consultant of or to various entities;

WHEREAS, the Executive previously entered into an executive agreement with the Company as of October 11, 2011 (the "Executive Agreement"); and

WHEREAS, the parties wish to enter into a new Agreement between the Executive and the Company in its entirety, on the terms and conditions contained in this Agreement, which will supersede, amend and restate the Executive Agreement and all prior agreements and understandings between the parties, oral or written.

AGREEMENT

In consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of a material act of fraud, embezzlement or misappropriation, which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) a material breach of Executive's proprietary information agreement that is materially injurious to the Company; or (iv) Executive's (1) material failure to perform his duties as set forth in this Agreement, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i) the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), obtains "beneficial ownership" (as defined in Rule 13d 3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("Voting Stock");

(ii) the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly more than fifty percent (50%) or more of the voting stock of the resulting entity or a parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii) there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "Disability" means totally and permanently disabled as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof.

(d) "Good Reason" shall mean without Executive's express written consent any of the following: (i) a material reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) the relocation of Executive to a facility or a location more than twenty-five (25) miles from the Company's then current principal location; (iv) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (v) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 13 below.

2. Duties and Scope of Position. During the Term (as defined below), Executive will serve as Chief Executive Officer of the Company, reporting to the Board of Directors, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing his investments, other business affairs and other matters or serving on civic or charitable boards or committees, provided that no such activities unduly interfere with the performance of his obligations under this Agreement, provided that Executive shall honor the non-competition and non-solicitation terms as per Section 16 below. During the Term, Executive agrees to disclose to the Company those other companies of which he is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of January 1, 2016 (the "Effective Date") and shall continue until January 1, 2020, unless earlier terminated in accordance with Section 10 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the other party a written notice of their intent not to renew such employment, such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Term as that term is defined below. The period commencing as of the Effective Date and ending on Executive's last date of employment with the Company under this Agreement is the "Term" and the end of the Term is referred to herein as the "Expiration Date."

4. Base Compensation. The Company shall pay to Executive a base compensation (the "Base Compensation") of $488,800 per year (prorated for any partial year), payable at such times as the Company customarily pays its other senior executives (but in any event no less often than monthly). In addition, each year during the Term, Executive shall be reviewed for purposes of determining the appropriateness of his Base Compensation hereunder. The Base Compensation shall be subject to all federal, state and local payroll tax withholding and any other withholdings required by law. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4.

5. Benefits; Expense Reimbursement.

(a) Benefits. During the Term, Executive shall be entitled to participate in all company employee benefit plans. In the event Executive elects to pay to a self-funded health insurance program, Executive shall be reimbursed by the Company for such costs up to the maximum amount the Company would be obligated to pay for similar benefits pursuant to its health insurance plans.

(b) Expenses. During the Term, the Company shall promptly reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company.

6. Target Bonus. In addition to his Base Compensation, during the Term Executive shall be given the opportunity to earn an annual bonus (the "Bonus") of up to 50% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "Target Year") to be mutually agreed upon by the Executive and the Board or its compensation committee. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 6, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365. The determinations of the Board or its compensation committee with respect to Bonuses will be final and binding.

7. Stock Option Grant. The Company shall grant 450,000 non-qualified stock options (the "Options") to Executive pursuant to the Company's 2014 Equity Incentive Plan in January 2016. Such Options will have an exercise price equal to the closing price of the Common Stock of the Company, as reported on The Nasdaq Stock Market, LLC, on the date of grant. The Options will vest monthly in equal amounts over a period of 4 years from the date of grant. Except as provided in the foregoing sentences, the Option shall have the same terms as the stock option grant agreement for the option granted on December 11, 2014, by the Company to Executive. The Options shall be deemed to have been earned by Executive effective as of the Effective Date.

8. Prior Stock Options. The Company and Executive hereby acknowledge and agree that all of the stock options granted by the Company to Executive prior to the Effective Date are deemed transferred in their entirety by Executive to GSV, and the Company hereby consents to each such transfer. In addition, the Company agrees that the incentive stock option agreement granted October 15, 2012, by the Company to Executive was intended to provide non-qualified stock options to Executive on the date of grant. As such, Company hereby agrees to amend such incentive stock option agreement to reflect that the options granted thereunder are non-incentive stock options, and that all such granted options (whether vested or unvested) shall transfer to GSV effective as of the Effective Date.

9. Additional Options. In lieu of the Realization Bonus in the Executive Agreement, the Company shall grant an additional 350,000 non-qualified stock options to Executive pursuant to the Company's 2014 Equity Incentive Plan in January 2016 (the "Additional Options"). The Additional Options will have an exercise price equal to the closing price of the Common Stock of the Company, as reported on The Nasdaq Stock Market, LLC, on the date of grant, and will vest immediately upon grant. Except as provided in the foregoing sentences, the Additional Options shall have the same terms as the stock option grant agreement for the option granted on December 11, 2014, by the Company to Executive. The Additional Options shall be deemed to have been earned by Executive effective as of the Effective Date.

10. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in Section 11 below, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Term upon sixty (60) days' prior written notice for any reason or no reason.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in Section 11 below, Executive's employment shall terminate automatically upon his death. Subject to the obligations of the Company set forth in Section 11 below, in the event Executive is unable to perform his duties as a result of Disability during the Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

11. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability or Termination by Executive. In the event that Executive's employment hereunder is terminated during the Term by the Company for Cause, as a result of Executive's death or Disability, or voluntarily by Executive without Good Reason, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: on the date of termination, the Company shall pay Executive a lump sum amount equal to (i) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (ii) any Bonus, Options and Additional Options earned and not yet paid or granted, as applicable, through the date of termination; and (iii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination.

(b) Termination by Company Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, the Company shall compensate Executive as follows:

(i) on the date of termination, the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus, Options and Additional Options earned and not yet paid or granted, as applicable, through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and, provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, the Company shall pay Executive the Base Compensation for twenty four (24) months from the date of termination, the potential Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twenty-four (24) month period following the termination and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twenty-four (24) month period. Without limiting the foregoing, Executive also shall be entitled to the severance benefits set forth under Section 11(c) below.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 11(a) or 11(b) herein to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause at any time within twelve (12) months prior to the consummation of a Change of Control if, prior to, or as of such termination, a Change of Control transaction was Pending (as defined in Section 11(d) below) at any time during such twelve (12)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time upon or within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i) on the date of termination (except as specified in clause (C)), the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination;

(ii) on the date of termination, the Company shall pay to Executive a lump sum amount equal to twenty-four (24) months of Executive's Base Compensation then in effect as of the day of termination, the maximum Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twenty-four (24) month period and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twenty-four (24) month period;

(iii) notwithstanding any provision of any stock incentive plan, stock option agreement, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares and equity awards held by Executive or transferred by Executive to GSV that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive or transferred by Executive to GSV, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending (as defined in Section 11(d) below) or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv) Severance benefits under this Section 11(c) and Section 11(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

In order to effectuate the provisions of Section 11(c)(iii) hereof, in the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, no equity award held by Executive or transferred by Executive to GSV shall expire or terminate prior to the earlier to occur of (a) ten (10) years after the date of the award and (b) fifteen (15) months after Executive's termination of employment with the Company.

(d) Definition of "Pending." For purposes of Section 11(c) herein, a Change of Control transaction shall be deemed to be "Pending" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction; or (C) a third party has publicly announced, through a filing with the Securities and Exchange Commission, its intent to commence a tender offer or similar transaction to acquire 50% or more of the outstanding voting interests of the Company.

12. 280G Excise Tax. Notwithstanding any other provisions in this Agreement, in the event that any payment or benefit received or to be received by Executive under this Agreement or under any other agreement between Executive and the Company or otherwise (collectively, the "Total Payments") would be subject (in whole or part), to any excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), or any successor provision thereto (the "Excise Tax"), then the Company will reduce the Total Payments to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax (but in no event to less than zero); *provided, however, that* the Total Payments will only be reduced if the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state, municipal and local income taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state, municipal and local income taxes on such Total Payments and the amount of Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments). In the case of a reduction in the Total Payments, the Total Payments will be reduced in the following order (unless reduction in another order is required to avoid adverse consequences under Section 409A of the Code, in which case, reduction will be in such other order): (i) payments that are payable in cash that are valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a) will be reduced (if necessary, to zero), with amounts that are payable last reduced first; (ii) payments and benefits due in respect of any equity valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a), with the highest values reduced first

(as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; (iii) payments that are payable in cash that are valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with amounts that are payable last reduced first, will next be reduced; (iv) payments and benefits due in respect of any equity valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; and (v) all other non-cash benefits not otherwise described in clauses (ii) or (iv) will be next reduced pro-rata. Any reductions made pursuant to each of clauses (i)-(v) above will be made in the following manner: first, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity not subject to Section 409A of the Code, and second, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity subject to Section 409A of the Code as deferred compensation.

13. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing delivered to Executive, at or prior to such Change of Control, to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a Change of Control. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by contract, operation of law or otherwise.

14. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given (a) when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or (b) three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

15. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit B, and incorporated herein by this reference.

16. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered

Area. For the purpose of this Section 16(a), (i) "Competing Business" means any medical diagnostic company, any contract manufacturer, any research laboratory or other company or entity (whether or not organized for profit) that has, or is seeking to develop, one or more products or therapies that is related to trans renal DNA and (ii) "Covered Area" means all geographical areas of the United States and other foreign jurisdictions where Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly traded, so long as ownership of such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

(b) Non-Solicitation. Executive further agrees that during the Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by Executive of his covenants and agreements set forth herein. Accordingly, Executive agrees and acknowledges that any such violation of this Section 16 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to seek injunctive relief against the breach of this Section 16 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

17. Employment Relationship. Executive's employment with the Company will be "at will," meaning that either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time-to-time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

18. Miscellaneous Provisions.

(a) Survival. Sections 1, 5, 6, 11, 12, 14, 15, 16 and 18 herein, including this Section 18(a), shall survive the termination of Executive's employment with the Company, the expiration of this Agreement and the termination of this Agreement for any reason.

(b) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Entire Agreement. This Agreement supersedes, amends and restates all prior agreements and understandings between the parties, oral or written, including, without limitation, the Executive Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(g) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(h) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

Trovagene, Inc.

By: /s/ Thomas H. Adams

Name: Thomas H. Adams

Title: Chairman

EXECUTIVE:

/s/ Antonius Schuh

Antonius Schuh, Ph.D.

Exhibit A

Form of Release Agreement

Exhibit B

Confidentiality and Inventions Agreement

Exhibit 10.29

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is made and entered into effective as of January 1, 2016 (the "Effective Date"), by and between Stephen Zaniboni (the "Executive") and Trovagene, Inc., a Delaware corporation (the "Company").

R E C I T A L S

WHEREAS, Executive serves as the Chief Financial Officer of the Company;

WHEREAS, Executive is a Managing Partner of Global Source Ventures LLC, an investment and consulting firm (together with its successors and assigns, "GSV"), and serves as director, officer and/or consultant of or to various entities;

WHEREAS, the Executive previously entered into an executive agreement with the Company as of February 1, 2012 (the "Executive Agreement"); and

WHEREAS, the parties wish to enter into a new Agreement between the Executive and the Company in its entirety, on the terms and conditions contained in this Agreement, which will supersede, amend and restate the Executive Agreement and all prior agreements and understandings between the parties, oral or written.

AGREEMENT

In consideration of the mutual covenants herein contained and the employment of Executive by the Company, the parties agree as follows:

1. Definition of Terms. The following terms referred to in this Agreement shall have the following meanings:

(a) "Cause" shall mean any of the following: (i) the commission of a material act of fraud, embezzlement or misappropriation, which is intended to result in substantial personal enrichment of Executive in connection with Executive's employment with the Company; (ii) Executive's conviction of, or plea of *nolo contendere*, to a crime constituting a felony (other than traffic-related offenses); (iii) a material breach of Executive's proprietary information agreement that is materially injurious to the Company; or (iv) Executive's (1) material failure to perform his duties as set forth in this Agreement, and (2) failure to "cure" any such failure within thirty (30) days after receipt of written notice from the Company delineating the specific acts that constituted such material failure and the specific actions necessary, if any, to "cure" such failure.

(b) "Change of Control" shall mean the occurrence of any of the following events:

(i) the date on which any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")), obtains "beneficial ownership" (as defined in Rule 13d-3 of the Exchange Act) or a pecuniary interest in fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities ("Voting Stock");

(ii) the consummation of a merger, consolidation, reorganization, or similar transaction involving the Company, other than a transaction: (1) in which substantially all of the holders of the Voting Stock immediately prior to such transaction hold or receive directly or indirectly more than fifty percent (50%) or more of the voting stock of the resulting entity or a parent company thereof, in substantially the same proportions as their ownership of the Company immediately prior to the transaction; or (2) in which the holders of the Company's capital stock immediately before such transaction will, immediately after such transaction, hold as a group on a fully diluted basis the ability to elect at least a majority of the authorized directors of the surviving entity (or a parent company); or

(iii) there is consummated a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries, other than a sale, lease, license or disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company in substantially the same proportions as their ownership of the Company immediately prior to such sale, lease, license or disposition.

(c) "Disability" means totally and permanently disabled as defined in the Company's disability benefit plan applicable to senior executive officers as in effect on the date thereof.

(d) "Good Reason" shall mean without Executive's express written consent any of the following: (i) a material reduction of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction, or the removal of Executive from such position, duties or responsibilities; (ii) a reduction of Executive's compensation as in effect immediately prior to such reduction; (iii) the relocation of Executive to a facility or a location more than twenty-five (25) miles from the Company's then current principal location; (iv) a material breach by the Company of this Agreement or any other agreement with Executive that is not corrected within fifteen (15) days after written notice from Executive (or such earlier date that the Company has notice of such material breach); or (v) the failure of the Company to obtain the written assumption of this Agreement by any successor contemplated in Section 12 below.

2. Duties and Scope of Position. During the Term (as defined below), Executive will serve as Chief Financial Officer of the Company, reporting to the Chief Executive Officer and the Board of Directors, and assuming and discharging such responsibilities as are commensurate with Executive's position. During the Term, Executive will provide services in a manner that will faithfully and diligently further the business of the Company and will devote a substantial portion of Executive's business time, attention and energy thereto. Notwithstanding the foregoing, nothing in this Agreement shall restrict Executive from managing his investments, other business affairs and other matters or serving on civic or charitable boards or committees, provided that no such activities unduly interfere with the performance of his obligations under this Agreement, provided that Executive shall honor the non-competition and non-solicitation terms as per Section 15 below. During the Term, Executive agrees to disclose to the Company those other companies of which he is a member of the Board of Directors, an executive officer, or a consultant.

3. Term. The term of Executive's employment under this Agreement shall commence as of January 1, 2016 (the "Effective Date") and shall continue until January 1, 2020, unless earlier terminated in accordance with Section 9 hereof. The term of Executive's employment shall be automatically renewed for successive one (1) year periods until the Executive or the Company delivers to the other party a written notice of their intent not to renew such employment, such written notice to be delivered at least sixty (60) days prior to the expiration of the then-effective Term as that term is defined below. The period commencing as of the Effective Date and ending on Executive's last date of employment with the Company under this Agreement is the "Term" and the end of the Term is referred to herein as the "Expiration Date."

4. Base Compensation. The Company shall pay to Executive a base compensation (the "Base Compensation") of $357,500 per year (prorated for any partial year), payable at such times as the Company customarily pays its other senior executives (but in any event no less often than monthly). In addition, each year during the Term, Executive shall be reviewed for purposes of determining the appropriateness of his Base Compensation hereunder. The Base Compensation shall be subject to all federal, state and local payroll tax withholding and any other withholdings required by law. For purposes of the Agreement, the term "Base Compensation" as of any point in time shall refer to the Base Compensation as adjusted pursuant to this Section 4.

5. Benefits; Expense Reimbursement.

(a) Benefits. During the Term, Executive shall be entitled to participate in all company employee benefit plans. In the event Executive elects to pay to a self-funded health insurance program, Executive shall be reimbursed by the Company for such costs up to the maximum amount the Company would be obligated to pay for similar benefits pursuant to its health insurance plans.

(b) Expenses. During the Term, the Company shall promptly reimburse Executive for all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company.

6. Target Bonus. In addition to his Base Compensation, during the Term Executive shall be given the opportunity to earn an annual bonus (the "Bonus") of up to 50% of Base Compensation. The Bonus shall be earned by Executive upon the Company's achievement of performance milestones for a fiscal year (in each case, the "Target Year") to be mutually agreed upon by the Executive and the Board or its compensation committee. In the event Executive is employed by the Company for less than the full Target Year for which a Bonus is earned pursuant to this Section 6, Executive shall be entitled to receive a pro-rated Bonus for such Target Year based on the number of days Executive was employed by the Company during such Target Year divided by 365. The determinations of the Board or its compensation committee with respect to Bonuses will be final and binding.

7. Stock Option Grant. The Company shall grant 150,000 non-qualified stock options (the "Options") to Executive pursuant to the Company's 2014 Equity Incentive Plan in January 2016. Such Options will have an exercise price equal to the closing price of the Common Stock of the Company, as reported on The Nasdaq Stock Market, LLC, on the date of grant. The Options will vest monthly in equal amounts over a period of 4 years from the date of grant. Except as provided in the foregoing sentences, the Option shall have the same terms as the stock option grant agreement for the option granted on December 11, 2014, by the Company to Executive. The Options shall be deemed to have been earned by Executive effective as of the Effective Date.

8. Prior Stock Options. The Company and Executive hereby acknowledge and agree that all of the stock options granted by the Company to Executive prior to the Effective Date are deemed transferred in their entirety by Executive to GSV, and the Company hereby consents to each such transfer.

9. Termination.

(a) Termination by the Company. Subject to the obligations of the Company set forth in Section 10 below, the Company may terminate Executive's employment at any time and for any reason (or no reason), and with or without Cause, and without prejudice to any other right or remedy to which the Company or Executive may be entitled at law or in equity or under this Agreement. Notwithstanding the foregoing, in the event the Company desires to terminate the Executive's employment without Cause, the Company shall give the Executive not less than sixty (60) days advance written notice. Executive's employment shall terminate automatically in the event of his death.

(b) Termination by Executive. Executive may voluntarily terminate the Term upon sixty (60) days' prior written notice for any reason or no reason.

(c) Termination for Death or Disability. Subject to the obligations of the Company set forth in Section 10 below, Executive's employment shall terminate automatically upon his death. Subject to the obligations of the Company set forth in Section 10 below, in the event Executive is unable to perform his duties as a result of Disability during the Term, the Company shall have the right to terminate the employment of Executive by providing written notice of the effective date of such termination.

10. Payments Upon Termination of Employment.

(a) Termination for Cause, Death or Disability or Termination by Executive. In the event that Executive's employment hereunder is terminated during the Term by the Company for Cause, as a result of Executive's death or Disability, or voluntarily by Executive without Good Reason, the Company shall compensate Executive (or in the case of death, Executive's estate) as follows: on the date of termination, the Company shall pay Executive a lump sum amount equal to (i) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (ii) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (iii) within 2-1/2 months following submission of proper expense reports by Executive or Executive's estate, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination.

(b) Termination by Company Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, the Company shall compensate Executive as follows:

(i) on the date of termination, the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus and Options earned and not yet paid or granted, as applicable, through the date of termination; and (C) within 2-1/2 months following submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination; and, provided that Executive executes a written release, substantially in the form attached hereto as Exhibit A, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, the Company shall pay Executive the Base Compensation for twelve (12) months from the date of termination, the potential Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period following the termination and any benefits (or benefits reimbursement payments) pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period. Without limiting the foregoing, Executive also shall be entitled to the severance benefits set forth under Section 10(c) below.

(c) Termination in the Context of a Change of Control. Notwithstanding anything in Section 10(a) or 10(b) herein to the contrary, in the event of Executive's termination of employment with the Company either (i) by the Company without Cause at any time within twelve (12) months prior to the consummation of a Change of Control if, prior to, or as of such termination, a Change of Control transaction was Pending (as defined in Section 10(d) below) at any time during such twelve (12)-month period, (ii) by Executive for Good Reason at any time within twelve (12) months after the consummation of a Change of Control, or (iii) by the Company without Cause at any time upon or within twelve (12) months after the consummation of a Change of Control, then, Executive shall be entitled to the following payments and other benefits:

(i) on the date of termination (except as specified in clause (C)), the Company shall pay Executive a lump sum amount equal to (A) any portion of unpaid Base Compensation then due for periods prior to the effective date of termination; (B) any Bonus earned and not yet paid through the date of termination; and (C) within 2-1/2 months following

submission of proper expense reports by Executive, all expenses reasonably and necessarily incurred by Executive in connection with the business of the Company prior to the date of termination;

(ii) on the date of termination, the Company shall pay to Executive a lump sum amount equal to twelve (12) months of Executive's Base Compensation then in effect as of the day of termination, the maximum Bonus the Executive is or would be eligible for pursuant to Section 6 herein during such twelve (12) month period and any benefits pursuant to Section 5 herein that the Executive is or would be eligible for during such twelve (12) month period;

(iii) notwithstanding any provision of any stock incentive plan, stock option agreement, restricted stock agreement or other agreement relating to capital stock of the Company, all of the shares and equity awards held by Executive or transferred by Executive to GSV that are then unvested shall immediately vest and, with respect to all options, warrants and other convertible securities of the Company beneficially held by Executive or transferred by Executive to GSV, become fully exercisable for (A) a period of six months following the date of termination only if at the time of such termination there is a Change of Control transaction Pending (as defined in Section 10(d) below) or (B) if clause (A) does not apply, then such period of time set forth in the agreement evidencing the security; and

(iv) Severance benefits under this Section 10(c) and Section 10(b) above shall be mutually exclusive and severance under one such section shall prohibit severance under the other.

In order to effectuate the provisions of Section 10(c)(iii) hereof, in the event that Executive's employment is terminated during the Term by the Company without Cause or by Executive for Good Reason, no equity award held by Executive or transferred by Executive to GSV shall expire or terminate prior to the earlier to occur of (a) ten (10) years after the date of the award and (b) fifteen (15) months after Executive's termination of employment with the Company.

(d) Definition of "Pending." For purposes of Section 10(c) herein, a Change of Control transaction shall be deemed to be "Pending" each time any of the following circumstances exist: (A) the Company and a third party have entered into a confidentiality agreement that has been signed by a duly-authorized officer of the Company and that is related to a potential Change of Control transaction; (B) the Company has received a written expression of interest from a third party, including a binding or non-binding term sheet or letter of intent, related to a potential Change of Control transaction; or (C) a third party has publicly announced, through a filing with the Securities and Exchange Commission, its intent to commence a tender offer or similar transaction to acquire 50% or more of the outstanding voting interests of the Company.

11. 280G Excise Tax. Notwithstanding any other provisions in this Agreement, in the event that any payment or benefit received or to be received by Executive under this Agreement or under any other agreement between Executive and the Company or otherwise (collectively, the "Total Payments") would be subject (in whole or part), to any excise tax imposed under Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), or any successor provision thereto (the "Excise Tax"), then the Company will reduce the Total Payments to the extent necessary so that no portion of the Total Payments is subject to the Excise Tax (but in no event to less than zero); *provided, however, that* the Total Payments will only be reduced if the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state, municipal and local income taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state, municipal and local income taxes on such Total Payments and the amount of Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments). In the case of a reduction in the Total Payments, the Total Payments will be reduced in the following order (unless reduction in another order is required to avoid adverse consequences under Section 409A of the Code, in which case, reduction will be in such other order): (i) payments that are payable in cash that are valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a) will be reduced (if necessary, to zero), with amounts that are payable last reduced first; (ii) payments and benefits due in respect of any equity valued at full value under Treasury Regulation Section 1.280G-1, Q&A 24(a), with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; (iii) payments that are payable in cash that are valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with amounts that are payable last reduced first, will next be reduced; (iv) payments and benefits due in respect of any equity valued at less than full value under Treasury Regulation Section 1.280G-1, Q&A 24, with the highest values reduced first (as such values are determined under Treasury Regulation Section 1.280G-1, Q&A 24) will next be reduced; and (v) all other non-cash benefits not otherwise described in clauses (ii) or (iv) will be next reduced pro-rata. Any reductions made pursuant to each of clauses (i)-(v) above will be made in the following manner: first, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity not subject to Section 409A of the Code, and second, a pro-rata reduction of cash payments and payments and benefits due in respect of any equity subject to Section 409A of the Code as deferred compensation.

12. Successors. Any successor to the Company (whether direct or indirect and whether by purchase, lease, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company's business and/or assets or otherwise pursuant to a Change of Control shall assume the Company's obligations under this Agreement and agree expressly in writing delivered to Executive, at or prior to such Change of Control, to perform the Company's obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a Change of Control. For all purposes under this Agreement, the term "Company" shall include any successor to the Company's business and/or assets (including any parent company to the Company), whether or not in connection with a Change of Control, which becomes bound by the terms of this Agreement by contract, operation of law or otherwise.

13. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given (a) when personally delivered (if to the Company, addressed to its Secretary at the Company's principal place of business on a non-holiday weekday between the hours of 9 a.m. and 5 p.m.; if to Executive, via personal service to his last known residence) or (b) three business days following the date it is mailed by U.S. registered or certified mail, return receipt requested and postage prepaid.

14. Confidential Information. Executive recognizes and acknowledges that by reason of Executive's employment by and service to the Company before, during and, if applicable, after the Term, Executive will have access to certain confidential and proprietary information relating to the Company's business, which may include, but is not limited to, trade secrets, trade "know-how," product development techniques and plans, formulas, customer lists and addresses, financing services, funding programs, cost and pricing information, marketing and sales techniques, strategy and programs, computer programs and software and financial information (collectively referred to herein as "Confidential Information"). Executive acknowledges that such Confidential Information is a valuable and unique asset of the Company and Executive covenants that he will not, unless expressly authorized in writing by the Company, at any time during the course of Executive's employment use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Executive also covenants that at any time after the termination of such employment, directly or indirectly, he will not use any Confidential Information or divulge or disclose any Confidential Information to any person, firm or corporation, unless such information is in the public domain through no fault of Executive or except when required to do so by a court of law, by any governmental agency having supervisory authority over the business of the Company or by any administrative or legislative body (including a committee thereof) with apparent jurisdiction to order Executive to divulge, disclose or make accessible such information. All written Confidential Information (including, without limitation, in any computer or other electronic format) which comes into Executive's possession during the course of Executive's employment shall remain the property of the Company. Unless expressly authorized in writing by the Company, Executive shall not remove any written Confidential Information from the Company's premises, except in connection with the performance of Executive's duties for and on behalf of the Company and in a manner consistent with the Company's policies regarding Confidential Information. Upon termination of Executive's employment, the Executive agrees to immediately return to the Company all written Confidential Information (including, without limitation, in any computer or other electronic format) in Executive's possession. As a condition of Executive's employment with the Company and in order to protect the Company's interest in such proprietary information, the Company shall require Executive's execution of a Confidentiality Agreement and Inventions Agreement in the form attached hereto as Exhibit B, and incorporated herein by this reference.

15. Non-Competition; Non-Solicitation.

(a) Non-Compete. The Executive hereby covenants and agrees that during the Term and for a period of one year following the Expiration Date, the Executive will not, without the prior written consent of the Company, directly or indirectly, on his own behalf or in the service or on behalf of others, whether or not for compensation, engage in any business activity, or have any interest in any person, firm, corporation or business, through a subsidiary or parent entity or other entity (whether as a shareholder, agent, joint venturer, security holder, trustee, partner, Executive, creditor lending credit or money for the purpose of establishing or operating any such business, partner or otherwise) with any Competing Business in the Covered Area. For the purpose of this Section 15 (a), (i) "Competing Business" means any medical diagnostic company, any contract manufacturer, any research laboratory or other company or entity (whether or not organized for profit) that has, or is seeking to develop, one or more products or therapies that is related to trans renal DNA and (ii) "Covered Area" means all geographical areas of the United States and other foreign jurisdictions where Company then has offices and/or sells its products directly or indirectly through distributors and/or other sales agents. Notwithstanding the foregoing, the Executive may own shares of companies whose securities are publicly traded, so long as ownership of such securities do not constitute more than one percent (1%) of the outstanding securities of any such company.

(b) Non-Solicitation. Executive further agrees that during the Term and for a period of one (1) year from the Expiration Date, the Executive will not divert any business of the Company and/or its affiliates or any customers or suppliers

of the Company and/or the Company's and/or its affiliates' business to any other person, entity or competitor, or induce or attempt to induce, directly or indirectly, any person to leave his or her employment with the Company and/or its affiliates; provided, however, that the foregoing provisions shall not apply to a general advertisement or solicitation program that is not specifically targeted at such employees.

(c) Remedies. Executive acknowledges and agrees that his obligations provided herein are necessary and reasonable in order to protect the Company and its affiliates and their respective business and Executive expressly agrees that monetary damages would be inadequate to compensate the Company and/or its affiliates for any breach by Executive of his covenants and agreements set forth herein. Accordingly, Executive agrees and acknowledges that any such violation of this Section 15 will cause irreparable injury to the Company and that, in addition to any other remedies that may be available, in law, in equity or otherwise, the Company and its affiliates shall be entitled to seek injunctive relief against the breach of this Section 15 or the continuation of any such breach by the Executive without the necessity of proving actual damages.

16. Employment Relationship. Executive's employment with the Company will be "at will," meaning that either Executive or the Company may terminate Executive's employment at any time and for any reason, with or without Cause or Good Reason. Any contrary representations that may have been made to Executive are superseded by this Agreement. This is the full and complete agreement between Executive and the Company on this term. Although Executive's duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time-to-time, the "at will" nature of Executive's employment may only be changed in an express written agreement signed by Executive and a duly authorized officer of the Company (other than Executive).

17. Miscellaneous Provisions.

(a) Survival. Sections 1, 5, 6, 10, 11, 13, 14, 15 and 17 herein, including this Section 17(a), shall survive the termination of Executive's employment with the Company, the expiration of this Agreement and the termination of this Agreement for any reason.

(b) Modifications; No Waiver. No provision of this Agreement may be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Entire Agreement. This Agreement supersedes, amends and restates all prior agreements and understandings between the parties, oral or written, including, without limitation, the Executive Agreement. No modification, termination or attempted waiver shall be valid unless in writing, signed by the party against whom such modification, termination or waiver is sought to be enforced.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the internal substantive laws, but not the conflicts of law rules, of the State of California.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, and may be delivered by facsimile or other electronic means, but all of which shall be deemed originals and taken together will constitute one and the same Agreement.

(g) Headings. The headings of the Articles and Sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

(h) Construction of Agreement. In the event of a conflict between the text of the Agreement and any summary, description or other information regarding the Agreement, the text of the Agreement shall control.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year first above written.

COMPANY:

Trovagene, Inc.

By: /s/ Antonius Schuh

Name: Antonius Schuh

Title: Chief Executive Officer

EXECUTIVE:

/s/ Stephen Zaniboni

Stephen Zaniboni

Exhibit A

Form of Release Agreement

Exhibit B

Confidentiality and Inventions Agreement

Exhibit 10.30

January 23, 2013

Mark Erlander
[…***…]
[…***…]

Dear **Mark:**

We are pleased to present the following offer of employment. This letter will summarize and confirm the details of our offer for you to join Trovagene, Inc., in the position of Chief Scientific Officer, at the San Diego office commencing on a date mutually agreed between you and the CEO, reporting to Antonius Schuh, CEO.

Here are the specific details of our offer:

TriNet HR Corporation: Our benefits, payroll, and human resource management services are provided through TriNet HR Corporation, a professional employer organization. As a result of Trovagene's arrangement with TriNet, TriNet will be considered your employer of record for these purposes. Your managers here at Trovagene will be responsible for directing your work, reviewing your performance, setting your schedule, and otherwise directing your work.

Base Compensation: Your compensation will be $200,000 annually, less payroll deductions and required taxes and withholdings, and will be paid on a bi-weekly basis. This is an exempt position and you are expected to work during the core hours of 8:00 a.m. to 5:00 p.m., Monday through Friday as well as those hours necessary to get the job done. We understand that you will also be employed by Gensignia. This Compensation is set based on the allocation of your effort between the two companies currently estimated to be 2/3's to Trovagene and 1/3 to Gensignia. This allocation and related compensation allocation will be reviewed annually on your anniversary date of employment with Trovagene and may be adjusted accordingly.

Benefits: Trovagene offers a full range of benefits for you and your qualified dependents as outlined in the attached Summary of Benefits. A presentation of our benefits program will be given to you during your first week of employment. Information about these benefits is included with this letter. Additional information will be provided online in the End User License Agreement (EULA) that you are required to accept in order to become a TriNet employee.

Bonus: In addition to your annual salary the company will offer you an incentive target bonus of 50% of your base salary based on mutually agreed goals between you, the CEO and the Board of Directors.

This offer of employment is contingent upon you fulfilling each of the following terms:

Acknowledgement of Company Handbook and Confidentiality Agreement: As a Trovagene employee, you are required to follow its rules and regulations. Therefore you will be asked to acknowledge in writing that you have read the Trovagene employee handbook, and sign and comply with the attached Proprietary Information and Inventions Agreement (the "Proprietary Information Agreement"), which prohibits, among other things, the unauthorized use or disclosure of Trovagene's confidential and proprietary information. In order to retain necessary flexibility in the administration of policies and procedures, Trovagene and TriNet reserve the right to change or revise policies, procedures, and benefits at any time.

Required Documentation: To comply with the government-mandated confirmation of employment eligibility, please review the enclosed I-9 Form and "Lists of Acceptable Documents" as approved by the United States Department of Justice for establishing identity and employment eligibility. Please bring the required I-9 documents with you on your first day of employment; failure to submit proof of your employment eligibility will postpone your start date or result in termination of your employment. Also enclosed are additional new hire forms that you should complete and bring with you on your first day of work.

At Will Employment: Please understand, as stated in all job offers, Trovagene is an employment-at-will company. That means that you or the Company may terminate your employment at any time, with or without cause and with or without prior notice. Accordingly, this letter is not a contract and should not be construed as creating contractual obligations.

This offer letter, together with your Proprietary Information Agreement and EULA, forms the complete and exclusive statement of your employment with Trovagene. It supersedes any other agreements or promises made to you by anyone, whether oral or

written. Changes to the terms of this letter require a written modification signed by an authorized employee of Trovagene. Additionally, Trovagene reserves the right to revoke this offer should it not receive a satisfactory reference check for you.

If you wish to accept employment at Trovagene under the terms described above, please sign and date this letter and the Proprietary Information Agreement, and return both in the enclosed self-addressed stamped envelope by 01/31/13. Please retain copies for your records.

Mark, we are excited that you are joining Trovagene's team and feel that you have a great deal to contribute. If you have any questions, please feel free to call Stephen Zaniboni**.**

Sincerely,

/s/ Stephen Zaniboni

Stephen Zaniboni
Chief Financial Officer

I understand and accept the terms of this employment offer.

/s/ Mark Erlander
Mark Erlander

01/28/2013
Date

03/04/2013
Start Date

cc: HR
Recruiting

Enclosures: Proprietary Information and Inventions Agreement

Confidential

Trovagene, Inc.

GENERAL EMPLOYMENT TERMS & CONDITIONS

Name: Mark Erlander Position: Chief Scientific Officer

Date of Offer: 01/14/13 Scheduled Reporting Date: TBD

1.a Compensation: Your base salary is $16,666.66 per month, $200,000, annualized. As an incentive, it is currently anticipated that you may receive stock options to purchase 200,000 shares of Trovagene (the "Company") common stock (in addition to the already issued 15,000 options for your SAB grant) subject to the vesting schedule, terms and conditions of the company's Stock Option Plan, option agreement, and subject to approval of the Company's Board of Directors.

b. Benefits, payroll, and other human resource management services are provided through TriNet Employer Group, Inc. TriNet is a professional employer organization contracted by the company to perform selected employer responsibilities on our behalf. As a result of Trovagene's arrangement with TriNet, TriNet will be considered your employer of record for payroll, benefits, and other functions involving employer related administration.

2. Expenses. The company will reimburse you for reasonable and necessary expenses incurred by you in furtherance of Trovagene's business. All expenses claimed are subject to the review and approval of your supervisor. Records must be maintained and submitted for any expenses to be reimbursed - including destination for auto mileage totals and receipts for all other items. Use of personal automobile for company business will be reimbursed at the applicable IRS rate in effect per mile.

3. Trade Secrets. During and after your employment, you will hold all Trade Secrets of Trovagene in confidence; you will not disclose these Trade Secrets to any one. This does not apply to information disclosed in the ordinary course of business to other persons who are employees of the company at the time.

"Trade Secrets" means the information described in the Description of Trade Secrets (Attachment A) and any other information that from time to time may be identified by Trovagene as confidential or is otherwise known to you as being confidential, whether embodied in memoranda, manuals, letters, or other documents, computer disks, tapes or other information storage devices, hardware, or other media or vehicles. Trade Secrets do not include information generally known or that is or becomes public domain information through no fault of yours. You will also hold confidential any confidential information of any customer, prospective customer, vendor or other person, if you are told or if you know that the information is confidential.

You will not use any Trade Secrets of Trovagene other than for the benefit of the Company; and you will not use any confidential information of any customer, prospective customer, vendor or other person other than for the benefit of such customer, vendor or other person if such disclosure is required in the performance of your normal work duties.

These terms and conditions of this paragraph 3 are subject to further definition and requirements in the separate *Proprietary Information & Inventions Agreement* ("PIIA") which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

4. Invention Assignment. In consideration of your employment with Trovagene, you hereby represent to, and agree with the Company as follows:

a. Company Business. You understand that the Company is engaged in a continuous program of research, development, production, and marketing in connection with its business and that, as an essential part of your employment with the Company, you may be expected to make new contributions to and create inventions of value for the Company.

b. Disclosure of Inventions. From and after the date you become employed with the Company, you will promptly disclose in confidence to the Company all inventions, improvements, designs, original works of authorship, formulas, processes, compositions of matter, computer software programs, databases, mask works, and trade secrets ("Invention(s)"), whether or not patentable, copyrightable or protractible as trade secrets, that are made or conceived or first reduced to practice or created by you, either alone or jointly with others, during the period of your employment, whether or not in the course of your employment.

c. Work for Hire; Assignment of Inventions. You acknowledge that copyrightable works prepared by you within the scope of your employment are "works for hire" under the Copyright Act and that the Company will be considered the author thereof. You agree

that all inventions that (a) are developed using equipment, supplies, facilities, or trade secrets of the Company, (b) result from work performed by you for the Company, or (c) relate to the Company's business or current or anticipated research and development, will be the sole and exclusive property of the Company and are hereby assigned by you to the Company.

d. Assignment of Other Rights. You hereby irrevocably transfer and assign to the Company: (a) all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Invention; and (b) any and all "Moral Rights" (as defined below) that you may have in or with respect to any Invention. You also hereby forever waive and agree never to assert any and all Moral Rights you have in or with respect to any Invention, even after termination of your work on behalf of the Company. "Moral Rights" mean any rights to claim authorship of an Invention, to object to or prevent the modification of any Invention, or to withdraw from circulation or control the publication or distribution of any Invention, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right."

e. Assistance. You agree to assist the Company in very proper way to obtain for the Company and enforce patents, copyrights, mask work rights, trade secret rights, and other legal protection for the company's Inventions in any and all countries. You will execute any documents that the Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Your obligations under this paragraph will continue beyond the termination of your employment with the Company, provided that the Company will compensate you at a reasonable rate after such termination for time or expenses actually spent by you at the Company's request on such assistance. You appoint the Secretary of the Company as your attorney-in-fact to execute documents on your behalf for this purpose.

f. Other Requirements. These terms and conditions of this paragraph 4 are subject to further definition and requirements in the separate Proprietary Information & Inventions Agreement (“PIIA”) which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

5. Proprietary Information. You understand that your employment by the Company creates a relationship of confidence and trust with respect to any information of a confidential or secret nature that may be disclosed to you by the Company or to the business of any parent, subsidiary, affiliate, customer or supplier of the Company or any other party with whom the Company agrees to hold information of such party in confidence ("Proprietary Information"). Such Proprietary Information includes but is not limited to Inventions, marketing plans, product plans, business strategies, financial information, forecasts, personnel information, and customer lists. These terms and conditions of this paragraph 5 are subject to further definition and requirements in the separate Proprietary Information & Inventions Agreement (“PIIA”) which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

6. Company Property. During and after your employment, you will not use any Company Property for any purpose other than for the benefit of the Company. Except for business uses related to the performance of your job, you will not remove from the Company premises any Company Property without written consent of your supervisor. In the event of your termination of employment, or at any time at the request of the Company, you will return all Company Property. You will also return all copies of Company Property, and any Work Product derived from Company Property.

"Company Property" means Trade Secrets of Trovagene Work Product, customer lists, prospect lists, forms, manuals, records, correspondence, contracts, notes, memoranda, notebooks and other documents of the Company, software media, equipment, and other intangible and tangible property owned by the Company.

7. Confidentiality. At all times, both during you employment and after its termination, you will keep and hold all such Proprietary Information in strict confidence and trust, and you will not use or disclose any of such Proprietary Information without the prior written consent of the Company, except as may be necessary to perform your duties as an employee of the Company for the benefit of the Company. Upon termination of your employment with the Company, you will promptly deliver to the Company all documents and materials of any nature pertaining to you work with the Company and you will not take with you any documents or materials or copies thereof containing any Proprietary Information.

8. No Breach of Prior Agreement. You represent that your performance of all the terms of this Agreement and your duties as an employee of the Company will not breach any invention assignment, proprietary information or similar agreement with any former employer or other party. You represent that you will not bring with you to Company or use in the performance of your duties for the Company any documents or materials of a former employer that are not generally available to the public or have not been legally transferred to the Company.

9. Duty not to Compete. You understand that your employment with the Company requires your undivided attention and effort. As a result, during your employment, you will not, without the Company's express written consent, engage in any employment

or business other than for the Company, or invest in or assist in any manner any business which directly or indirectly competes with the business or future business plans of the Company.

10. Non-solicitation. During, and for a period of one (1) year after termination of your employment with the Company, you will not directly or indirectly solicit or take away suppliers, customers, employees or consultants of the Company for your own benefit or for the benefit of any other party.

11. Name & Likeness Rights, etc. You hereby authorize the Company to use, reuse, and to grant others the right to use and reuse your name, photograph, likeness (including caricature), voice, and biographical information, and any reproduction or simulation thereof, in any media now known or hereafter developed (including but not limited to film, video, and digital, or other electronic media), both during and after my employment, for whatever purposes the Company deems necessary.

12. Injunctive Relief. You understand that in the event of a breach or threatened breach of this Agreement by you, the Company will suffer irreparable harm and will therefore be entitled to injunctive relief to enforce this Agreement.

13. Governing Law. This Agreement will be governed and interpreted in accordance with the internal laws of the State of {Worksite State}, without regard to or application of choice of law rules or principles.

14. Severability. In the event that any provision of this Agreement is found by a court, arbitrator, or other tribunal to be illegal, invalid, or unenforceable, then such maximum extent permissible under applicable law, and the remainder of this Agreement shall remain in full force and effect.

15. Termination of Employment. As Trovagene is the company for which you will perform service, we will retain the right to control and direct your work, its results, and the manner and means by which your work is accomplished. Your employment with the Company is at will, and therefore, may be terminated by you or the Company at any time and for any reason, with or without cause, and with or without notice. This “at will” employment relationship may not be modified by any oral or implied agreement. If the company terminates the employee without cause, you are entitled to severance benefits equal to 6 months of your base salary, provided a written release between the company and the employee is executed.

16. No Duty to Employ. This agreement does not constitute a contract of employment or obligate the Company to employ you for any stated period of time.

17. Subsequent Employers. If your employment is terminated, the Company has the right to inform any subsequent employer of your obligations under Sections 3 - 10 above, and can send a copy of these terms of employment to that employer.

Entire Agreement. This document and its related attachments contain the entire agreement between you and Trovagene regarding the terms of your employment. Any amendment to these terms must be in writing and must be signed by you and the Company’s President.

I accept the above terms of employment as stated:

/s/ Mark Erlander 01/28/2013
Mark Erlander Date

Approved by Trovagene (Following receipt of signed acceptance by employee)

/s/ Stephen Zaniboni 01/28/2013
Stephen Zaniboni, CFO Date

TROVAGENE, INC.
GENERAL EMPLOYMENT TERMS AND CONDITIONS
ATTACHMENT A

DESCRIPTION OF TRADE SECRETS

* Employee list and all information contained in employee records

* Vendor list and all information contained in vendor records

* Customer list and all information contained in customer/company records

* Prospective Customer list and all information contained in prospective customer/company records

* Stockholder list and all information contained in stockholder records

* All information concerning the financial condition of the Company, including information contained in any income statement, balance sheet or other internal financial report.

* Marketing plans and strategies of the Company, including information pertaining to prospective customers.

* Financing plans and strategies of the Company

* Staffing plans and strategies of the Company

* Expansion plans and business strategies of the Company

* Negotiations for financing, merger, acquisition, new customers, new vendors or otherwise

* Technical research projects, methodologies and results

* Other research and development projects

* Drawings and specifications

* Software and hardware documentation

* Forms, manuals, handbooks and guidelines written for internal staff use

* Any materials for which the Company has copyright protection or are marked confidential

* The Company's proprietary operating procedures and systems

Exhibit 10.31

February 6, 2015

Matthew L. Posard
[…***…]
[…***…]

Dear Matt,

We are pleased to present the following offer of employment. This letter will summarize and confirm the details of our offer for you to join Trovagene, Inc., in the position of Chief Commercial Officer**,** commencing on March, 2015 and reporting to the CEO. In this position, you will play a key supporting role performing and acting as Chief Commercial Officer.

Orientation Information: On your first day of work, you should plan to report to the CEO at 9:30 am.

Here are the specific details of our offer:

TriNet HR Corporation: Our benefits, payroll, and human resource management services are provided through TriNet HR Corporation, a professional employer organization. As a result of Trovagene's arrangement with TriNet, TriNet will be considered your employer of record for these purposes. Your managers here at Trovagene will be responsible for directing your work, reviewing your performance, setting your schedule, and otherwise directing your work.

Base Compensation: Your compensation will be $325,000.00 per year, less payroll deductions and required taxes and withholdings, and will be paid on a bi-weekly basis. This position is eligible for a discretionary annual bonus of up to 50% of your base salary. This is an exempt position and your schedule will be 40 hours per week as well as those hours necessary to get the job done. The company's core hours of business are 8:00 a.m. to 5:00 p.m., Monday through Friday.

Benefits: Trovagene offers a full range of benefits for you and your qualified dependents as outlined in the attached Summary of Benefits. A presentation of our benefits program will be given to you during your first week of employment. Information about these benefits is included with this letter. Additional information will be provided online in the End User License Agreement (EULA) that you are required to accept in order to become a TriNet employee.

This offer of employment is contingent upon you fulfilling each of the following terms:

Acknowledgement of Company Handbook and Confidentiality Agreement: As a Trovagene employee, you are required to follow its rules and regulations. Therefore you will be asked to acknowledge in writing that you have read the Trovagene employee handbook, and sign and comply with the attached Proprietary Information and Inventions Agreement (the "Proprietary Information Agreement"), which prohibits, among other things, the unauthorized use or disclosure of Trovagene's confidential and proprietary information. In order to retain necessary flexibility in the administration of policies and procedures, Trovagene and TriNet reserve the right to change or revise policies, procedures, and benefits at any time.

Required Documentation: To comply with the government-mandated confirmation of employment eligibility, please review the enclosed I-9 Form and "Lists of Acceptable Documents" as approved by the United States Department of Justice for establishing identity and employment eligibility. Please bring the required I-9 documents with you on your first day of employment; failure to submit proof of your employment eligibility will postpone your start date or result in termination of your employment. Also enclosed are additional new hire forms that you should complete and bring with you on your first day of work.

At Will Employment: Please understand, as stated in all job offers, Trovagene is an employment-at-will company. That means that you or the Company may terminate your employment at any time, with or without cause and with or without prior notice. Accordingly, this letter is not a contract and should not be construed as creating contractual obligations.

This offer letter, together with your Proprietary Information Agreement and EULA, forms the complete and exclusive statement of your employment with Trovagene. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes to the terms of this letter require a written modification signed by an authorized employee of Trovagene. Additionally, Trovagene reserves the right to revoke this offer should it not receive a satisfactory reference check for you.

If you wish to accept employment at Trovagene under the terms described above, please sign and date this letter and the Proprietary Information Agreement, and return both via email by **Monday, February 9th at 5:00pm.** Please retain copies for your records.

Matt, we are excited that you are joining Trovagene's team and feel that you have a great deal to contribute. If you have any questions, please feel free to contact our Controller, Brigitte Lindsay at blindsay@trovagene.com**.**

Sincerely,

/s/ Antonius Schuh

Antonius Schuh
CEO

I understand and accept the terms of this employment offer.

/s/ Matthew L. Posard
Matthew L. Posard

_____
Date

_____
Start Date

cc: HR
Recruiting

Enclosures: Proprietary Information and Inventions Agreement

Confidential

Trovagene, Inc.

GENERAL EMPLOYMENT TERMS & CONDITIONS

Name: Matthew L. Posard Position: CCO

Date of Offer: 2/9/2015 Scheduled Reporting Date: 3/9/2015

1.a Compensation: Your base salary is $325,000.00 per year. This position is eligible for a discretionary annual bonus of up to 50% of your base salary. As an incentive, management will recommend that you receive stock options to purchase 500,000 of Trovagene's (the "Company") common stock. The options will be subject to the vesting schedule, terms and conditions of the company's Stock Option Plan, and option agreement. The option agreement will contain provisions to the effect that change of control will trigger full vesting.

b. Benefits, payroll, and other human resource management services are provided through TriNet Employer Group, Inc. TriNet is a professional employer organization contracted by the company to perform selected employer responsibilities on our behalf. As a result of Trovagene's arrangement with TriNet, TriNet will be considered your employer of record for payroll, benefits, and other functions involving employer related administration.

2. Expenses. The company will reimburse you for reasonable and necessary expenses incurred by you in furtherance of Trovagene's business. All expenses claimed are subject to the review and approval of your supervisor. Records must be maintained and submitted for any expenses to be reimbursed - including destination for auto mileage totals and receipts for all other items. Use of personal automobile for company business will be reimbursed at the applicable IRS rate in effect per mile.

3. Trade Secrets. During and after your employment, you will hold all Trade Secrets of Trovagene in confidence; you will not disclose these Trade Secrets to any one. This does not apply to information disclosed in the ordinary course of business to other persons who are employees of the company at the time.

"Trade Secrets" means the information described in the Description of Trade Secrets (Attachment A) and any other information that from time to time may be identified by Trovagene as confidential or is otherwise known to you as being confidential, whether embodied in memoranda, manuals, letters, or other documents, computer disks, tapes or other information storage devices, hardware, or other media or vehicles. Trade Secrets do not include information generally known or that is or becomes public domain information through no fault of yours. You will also hold confidential any confidential information of any customer, prospective customer, vendor or other person, if you are told or if you know that the information is confidential.

You will not use any Trade Secrets of Trovagene other than for the benefit of the Company; and you will not use any confidential information of any customer, prospective customer, vendor or other person other than for the benefit of such customer, vendor or other person if such disclosure is required in the performance of your normal work duties.

These terms and conditions of this paragraph 3 are subject to further definition and requirements in the separate *Proprietary Information & Inventions Agreement* ("PIIA") which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

4. Invention Assignment. In consideration of your employment with Trovagene, you hereby represent to, and agree with the Company as follows:

a. Company Business. You understand that the Company is engaged in a continuous program of research, development, production, and marketing in connection with its business and that, as an essential part of your employment with the Company, you may be expected to make new contributions to and create inventions of value for the Company.

b. Disclosure of Inventions. From and after the date you become employed with the Company, you will promptly disclose in confidence to the Company all inventions, improvements, designs, original works of authorship, formulas, processes, compositions of matter, computer software programs, databases, mask works, and trade secrets ("Invention(s)"), whether or not patentable, copyrightable or protractible as trade secrets, that are made or conceived or first reduced to practice or created by you, either alone or jointly with others, during the period of your employment, whether or not in the course of your employment.

c. Work for Hire; Assignment of Inventions. You acknowledge that copyrightable works prepared by you within the scope of your employment are "works for hire" under the Copyright Act and that the Company will be considered the author thereof. You agree that all inventions that (a) are developed using equipment, supplies, facilities, or trade secrets of the Company, (b) result from work performed by you for the Company, or (c) relate to the Company's business or current or anticipated research and development, will be the sole and exclusive property of the Company and are hereby assigned by you to the Company.

d. Assignment of Other Rights. You hereby irrevocably transfer and assign to the Company: (a) all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Invention; and (b) any and all "Moral Rights" (as defined below) that you may have in or with respect to any Invention. You also hereby forever waive and agree never to assert any and all Moral Rights you have in or with respect to any Invention, even after termination of your work on behalf of the Company. "Moral Rights" mean any rights to claim authorship of an Invention, to object to or prevent the modification of any Invention, or to withdraw from circulation or control the publication or distribution of any Invention, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right."

e. Assistance. You agree to assist the Company in very proper way to obtain for the Company and enforce patents, copyrights, mask work rights, trade secret rights, and other legal protection for the company's Inventions in any and all countries. You will execute any documents that the Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Your obligations under this paragraph will continue beyond the termination of your employment with the Company, provided that the Company will compensate you at a reasonable rate after such termination for time or expenses actually spent by you at the Company's request on such assistance. You appoint the Secretary of the Company as your attorney-in-fact to execute documents on your behalf for this purpose.

f. Other Requirements. These terms and conditions of this paragraph 4 are subject to further definition and requirements in the separate Proprietary Information & Inventions Agreement (“PIIA”) which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

5. Proprietary Information. You understand that your employment by the Company creates a relationship of confidence and trust with respect to any information of a confidential or secret nature that may be disclosed to you by the Company or to the business of any parent, subsidiary, affiliate, customer or supplier of the Company or any other party with whom the Company agrees to hold information of such party in confidence ("Proprietary Information"). Such Proprietary Information includes but is not limited to Inventions, marketing plans, product plans, business strategies, financial information, forecasts, personnel information, and customer lists. These terms and conditions of this paragraph 5 are subject to further definition and requirements in the separate Proprietary Information & Inventions Agreement (“PIIA”) which you may be required to execute. Your signature below constitutes your consent that the obligations herein may be expanded or otherwise modified by virtue of said PIIA.

6. Company Property. During and after your employment, you will not use any Company Property for any purpose other than for the benefit of the Company. Except for business uses related to the performance of your job, you will not remove from the Company premises any Company Property without written consent of your supervisor. In the event of your termination of employment, or at any time at the request of the Company, you will return all Company Property. You will also return all copies of Company Property, and any Work Product derived from Company Property.

"Company Property" means Trade Secrets of Trovagene Work Product, customer lists, prospect lists, forms, manuals, records, correspondence, contracts, notes, memoranda, notebooks and other documents of the Company, software media, equipment, and other intangible and tangible property owned by the Company.

7. Confidentiality. At all times, both during you employment and after its termination, you will keep and hold all such Proprietary Information in strict confidence and trust, and you will not use or disclose any of such Proprietary Information without the prior written consent of the Company, except as may be necessary to perform your duties as an employee of the Company for the benefit of the Company. Upon termination of your employment with the Company, you will promptly deliver to the Company all documents and materials of any nature pertaining to you work with the Company and you will not take with you any documents or materials or copies thereof containing any Proprietary Information.

8. No Breach of Prior Agreement. You represent that your performance of all the terms of this Agreement and your duties as an employee of the Company will not breach any invention assignment, proprietary information or similar agreement with any former employer or other party. You represent that you will not bring with you to Company or use in the performance of your duties for the Company any documents or materials of a former employer that are not generally available to the public or have not been legally transferred to the Company.

9. Duty not to Compete. You understand that your employment with the Company requires your undivided attention and effort. As a result, during your employment, you will not, without the Company's express written consent, engage in any employment or business other than for the Company, or invest in or assist in any manner any business which directly or indirectly competes with the business or future business plans of the Company.

10. Non-solicitation. During, and for a period of one (1) year after termination of your employment with the Company, you will not directly or indirectly solicit or take away suppliers, customers, employees or consultants of the Company for your own benefit or for the benefit of any other party.

11. Name & Likeness Rights, etc. You hereby authorize the Company to use, reuse, and to grant others the right to use and reuse your name, photograph, likeness (including caricature), voice, and biographical information, and any reproduction or simulation thereof, in any media now known or hereafter developed (including but not limited to film, video, and digital, or other electronic media), both during and after my employment, for whatever purposes the Company deems necessary.

12. Injunctive Relief. You understand that in the event of a breach or threatened breach of this Agreement by you, the Company will suffer irreparable harm and will therefore be entitled to injunctive relief to enforce this Agreement.

13. Governing Law. This Agreement will be governed and interpreted in accordance with the internal laws of the State of {Worksite State}, without regard to or application of choice of law rules or principles.

14. Severability. In the event that any provision of this Agreement is found by a court, arbitrator, or other tribunal to be illegal, invalid, or unenforceable, then such maximum extent permissible under applicable law, and the remainder of this Agreement shall remain in full force and effect.

15. Termination of Employment. As Trovagene is the company for which you will perform service, we will retain the right to control and direct your work, its results, and the manner and means by which your work is accomplished. Your employment with the Company is at will, and therefore, may be terminated by you or the Company at any time and for any reason, with or without cause, and with or without notice. This “at will” employment relationship may not be modified by any oral or implied agreement.

If you are terminated without cause, you will be entitled to severance pay for a severance period of up to 12 months or 50% of the time you were employed with Trovagene, whatever period is less ('Severance Period'). Severance payments will be made consistent with the Company's payroll. You will be entitled to receive severance payment during the Severance Period and as long as you remain unemployed.

16. No Duty to Employ. This agreement does not constitute a contract of employment or obligate the Company to employ you for any stated period of time.

17. Subsequent Employers. If your employment is terminated, the Company has the right to inform any subsequent employer of your obligations under Sections 3 - 10 above, and can send a copy of these terms of employment to that employer.

Entire Agreement. This document and its related attachments contain the entire agreement between you and Trovagene regarding the terms of your employment. Any amendment to these terms must be in writing and must be signed by you and the Company’s President.

I accept the above terms of employment as stated:

/s/ Matthew Posard _____
Matthew L. Posard Date

Approved by Trovagene (Following receipt of signed acceptance by employee)

/s/ Antonius Schuh _____
Antonius Schuh, CEO Date

TROVAGENE, INC.
GENERAL EMPLOYMENT TERMS AND CONDITIONS
ATTACHMENT A

DESCRIPTION OF TRADE SECRETS

* Employee list and all information contained in employee records

* Vendor list and all information contained in vendor records

* Customer list and all information contained in customer/company records

* Prospective Customer list and all information contained in prospective customer/company records

* Stockholder list and all information contained in stockholder records

* All information concerning the financial condition of the Company, including information contained in any income statement, balance sheet or other internal financial report.

* Marketing plans and strategies of the Company, including information pertaining to prospective customers.

* Financing plans and strategies of the Company

* Staffing plans and strategies of the Company

* Expansion plans and business strategies of the Company

* Negotiations for financing, merger, acquisition, new customers, new vendors or otherwise

* Technical research projects, methodologies and results

* Other research and development projects

* Drawings and specifications

* Software and hardware documentation

* Forms, manuals, handbooks and guidelines written for internal staff use

* Any materials for which the Company has copyright protection or are marked confidential

* The Company's proprietary operating procedures and systems

Exhibit 10.32

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (this "**Agreement**") dated as of November 17, 2015 (the "**Effective Date**") between **SILICON VALLEY BANK**, a California corporation ("**Bank**"), and **TROVAGENE, INC.**, a Delaware corporation ("**Borrower**"), provides the terms on which Bank shall lend to Borrower and Borrower shall repay Bank. The parties agree as follows:

1 ACCOUNTING AND OTHER TERMS

Accounting terms not defined in this Agreement shall be construed following GAAP. Calculations and determinations must be made following GAAP. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein.

2 LOAN AND TERMS OF PAYMENT

6.2 **Promise to Pay**. Borrower hereby unconditionally promises to pay Bank the outstanding principal amount of all Credit Extensions and accrued and unpaid interest thereon as and when due in accordance with this Agreement.

2.1.1 **Equipment Advances**.

(a) Availability. Subject to the terms and conditions of this Agreement, during the Draw Period, Bank shall make advances (each, an "**Equipment Advance**" and, collectively, "**Equipment Advances**") not exceeding the Equipment Line. Equipment Advances may only be used to finance Eligible Equipment purchased within one hundred eighty (180) days (determined based upon the applicable invoice date of such Eligible Equipment) before the date of each Equipment Advance; provided, however, the initial tranche of the Equipment Advance may be used to finance Eligible Equipment purchased from January 1, 2015 through the Effective Date. All Eligible Equipment must have been new when purchased by Borrower, except for such Eligible Equipment that is disclosed in writing to Bank by Borrower, and that Bank in its sole discretion has agreed to finance, prior to being financed by Bank. No Equipment Advance may exceed one hundred percent (100%) of the total invoice for Eligible Equipment (excluding taxes, shipping, warranty charges, freight discounts and installation expenses relating to such Eligible Equipment except to the extent such are allowed to be financed pursuant hereto as Other Equipment). Unless otherwise agreed to by Bank, not more than thirty five percent (35%) of the proceeds of the Equipment Line shall be used to finance Other Equipment. The Equipment Advances shall be available in two (2) tranches. The initial tranche of the Equipment Advance shall be advanced to Borrower on or about the Effective Date in a single advance in an amount equal to Five Hundred Thousand Dollars ($500,000). Bank may make advances to Borrower under the second tranche of the Equipment Advances during the Draw Period in an aggregate amount up to One Million Five Hundred Thousand Dollars ($1,500,000). Each Equipment Advance under the second tranche must be in an amount equal to the lesser of Two Hundred Fifty Thousand Dollars ($250,000) or the amount that has not yet been drawn under the Equipment Line. After repayment, no Equipment Advance may be reborrowed.

(b) Repayment. Equipment Advances outstanding on November 17, 2016 are payable in (i) thirty six (36) consecutive equal monthly installments of principal plus (ii) monthly payments of accrued interest, beginning on December 1, 2016 and continuing on the first of each month thereafter and ending on the Equipment Maturity Date. All unpaid principal and interest on each Equipment Advance shall be due on the Equipment Maturity Date.

(c) Prepayment Upon an Event of Loss. Borrower shall bear the risk of any loss, theft, destruction, or damage of or to the Financed Equipment. If, during the term of this Agreement, any item of Financed Equipment becomes obsolete or is lost, stolen, destroyed, damaged beyond repair, rendered permanently unfit for use, or seized by a governmental authority for any reason for a period ending beyond the Equipment Maturity Date with respect to such Financed Equipment (an "**Event of Loss**"), then, within ten (10) days following such Event of Loss, Borrower shall (i) pay to Bank on account of the Obligations all accrued interest to the date of the prepayment, plus all outstanding principal owing with respect to the Financed Equipment subject to the Event of Loss plus the Final Payment; or (ii) if no Event of Default has occurred and is continuing, at Borrower's option, repair or replace any Financed Equipment subject to an Event of Loss provided the repaired or replaced Financed Equipment is of equal or like value to the Financed Equipment subject to an Event of Loss and provided further that Bank has a first priority perfected security interest in such repaired or replaced Financed Equipment. Any partial prepayment of an Equipment Advance paid by Borrower on account of an Event of Loss shall be applied to prepay amounts owing for such Equipment Advance in inverse order of maturity.

(d) Prepayment.

(i) Voluntary Prepayment. So long as an Event of Default has not occurred and is not continuing, Borrower shall have the option to prepay all, but not less than all, of the Equipment Advances advanced by Bank under this Agreement, provided Borrower (i) delivers written notice to Bank of its election to prepay the Equipment Advances at least thirty (30) days prior to such prepayment and (ii) pays, on the date of such prepayment, (a) all outstanding principal with respect to the Term Loans, plus accrued but unpaid interest, (b) the Final Payment, (c) the Prepayment Fee, plus (d) all other sums, including Bank Expenses, if any, that shall have become due and payable.

(ii) Mandatory Prepayment Upon an Acceleration. If the Equipment Advances are accelerated following the occurrence and continuance of an Event of Default or otherwise, Borrower shall immediately pay to Bank an amount equal to the sum of (i) all outstanding principal with respect to the Equipment Advances, plus accrued but unpaid interest, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other sums, including Bank Expenses, if any, that shall have become due and payable, including interest at the Default Rate with respect to any past due amounts.

2.2 **Intentionally Omitted**.

2.3 **Payment of Interest on the Credit Extensions**.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding for each Equipment Advance shall accrue interest at a floating per annum rate equal to one and one quarter percentage points (1.25%) above the Prime Rate, which interest shall be payable monthly.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall bear interest at a rate per annum which is five percentage points (5.00%) above the rate that is otherwise applicable thereto (the "**Default Rate**"). Fees and expenses which are required to be paid by Borrower pursuant to the Loan Documents (including, without limitation, Bank Expenses) but are not paid when due shall bear interest until paid at a rate equal to the highest rate applicable to the Obligations. Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Bank.

(c) Adjustment to Interest Rate. Changes to the interest rate of any Credit Extension based on changes to the Prime Rate shall be effective on the effective date of any change to the Prime Rate and to the extent of any such change.

(d) Payment; Interest Computation. Interest is payable monthly on the first calendar day of each month and shall be computed on the basis of a 360-day year for the actual number of days elapsed. In computing interest, (i) all payments received after 12:00 p.m. Pacific time on any day shall be deemed received at the opening of business on the next Business Day, and (ii) the date of the making of any Credit Extension shall be included and the date of payment shall be excluded; provided, however, that if any Credit Extension is repaid on the same day on which it is made, such day shall be included in computing interest on such Credit Extension.

2.4 **Fees**. Borrower shall pay to Bank:

(a) Commitment Fee. A fully earned, non-refundable commitment fee of Five Thousand Dollars ($5,000), on the Effective Date;

(b) Final Payment. The Final Payment, when due hereunder;

(c) Bank Expenses. All Bank Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due (or, if no stated due date, upon demand by Bank); and

(d) Fees Fully Earned. Unless otherwise provided in this Agreement or in a separate writing by Bank, Borrower shall not be entitled to any credit, rebate, or repayment of any fees earned by Bank pursuant to this Agreement notwithstanding any termination of this Agreement or the suspension or termination of Bank's obligation to make loans and advances hereunder. Bank may deduct amounts owing by Borrower under the clauses of this Section 2.4 pursuant to the terms of Section 2.5(c). Bank shall provide Borrower written notice of deductions made from the Designated Deposit Account pursuant to the terms of the clauses of this Section 2.4.

2.5 **Payments; Application of Payments; Debit of Accounts.**

(a) All payments to be made by Borrower under any Loan Document shall be made in immediately available funds in Dollars, without setoff or counterclaim, before 12:00 p.m. Pacific time on the date when due. Payments of principal and/or interest received after 12:00 p.m. Pacific time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment shall be due the next Business Day, and additional fees or interest, as applicable, shall continue to accrue until paid.

(b) Bank has the exclusive right to determine the order and manner in which all payments with respect to the Obligations may be applied. Borrower shall have no right to specify the order or the accounts to which Bank shall allocate or apply any payments required to be made by Borrower to Bank or otherwise received by Bank under this Agreement when any such allocation or application is not specified elsewhere in this Agreement.

(c) Bank may debit any of Borrower's deposit accounts, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Bank when due. These debits shall not constitute a set-off. Bank shall use commercially reasonable efforts to notify Borrower of any amounts (other than principal and interest payments) debited from Borrower's deposit accounts with respect to this Agreement.

2.6 **Withholding.** Payments received by Bank from Borrower under this Agreement will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any Governmental Authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to Bank, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, Bank receives a net sum equal to the sum which it would have received had no withholding or deduction been required, and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish Bank with proof reasonably satisfactory to Bank indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

3 **CONDITIONS OF LOANS**

3.1 **Conditions Precedent to Initial Credit Extension**. Bank's obligation to make the initial Credit Extension is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, such documents, and completion of such other matters, as Bank may reasonably deem necessary or appropriate, including, without limitation:

(a) duly executed original signatures to the Loan Documents;

(b) the Operating Documents and long-form good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(c) duly executed original signatures to the completed Borrowing Resolutions for Borrower;

(d) certified copies, dated as of a recent date, of financing statement searches, as Bank may request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(e) the Perfection Certificate of each Borrower, together with the duly executed original signatures thereto;

(f) a copy of Borrower's Investors' Rights Agreement and any amendments thereto;

(g) evidence satisfactory to Bank that the insurance policies and endorsements required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing lender loss payable and/or additional insured clauses or endorsements in favor of Bank; and

(h) payment of the fees and Bank Expenses then due as specified in Section 2.4 hereof.

3.2 **Conditions Precedent to all Credit Extensions**. Bank's obligations to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) timely receipt of an executed Payment/Advance Form and Loan Supplement;

(b) the representations and warranties in this Agreement shall be true, accurate, and complete in all material respects on the date of the Payment/Advance Form and Loan Supplement and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in this Agreement remain true, accurate, and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; and

(c) Bank determines to its satisfaction that there has not been a Material Adverse Change.

3.3 **Covenant to Deliver**. Borrower agrees to deliver to Bank each item required to be delivered to Bank under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Bank of any such item shall not constitute a waiver by Bank of Borrower's obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Bank's sole discretion.

3.4 **Procedures for Borrowing**. Subject to the prior satisfaction of all other applicable conditions to the making of an Equipment Advance set forth in this Agreement, to obtain an Equipment Advance, Borrower must notify Bank (which notice shall be irrevocable) by electronic mail or facsimile no later than 12:00 p.m. Pacific time one (1) Business Day before the proposed Funding Date. The notice shall be a Payment/Advance Form, must be signed by a Responsible Officer or designee, and shall include a copy of the invoice for the Equipment being financed. Borrower shall also deliver to Bank by electronic mail or facsimile a completed Loan Supplement, executed by a Responsible Officer or his or her designee, copies of invoices for the Financed Equipment and such additional information as Bank may reasonably request at least five (5) Business Days before the proposed Funding Date. At Bank's discretion, Bank shall have the opportunity to confirm that, upon filing the UCC-1 financing statement covering the Equipment described on the Loan Supplement, Bank shall have a first priority perfected security interest in such Equipment. If Borrower satisfies the conditions of each Equipment Advance, Bank shall disburse such Equipment Advance by transfer to the Designated Deposit Account.

4 CREATION OF SECURITY INTEREST

4.1 **Grant of Security Interest**. Borrower hereby grants Bank, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Bank, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

Borrower acknowledges that it previously has entered, and/or may in the future enter, into Bank Services Agreements with Bank. Regardless of the terms of any Bank Services Agreement, Borrower agrees that any amounts Borrower owes Bank thereunder shall be deemed to be Obligations hereunder and that it is the intent of Borrower and Bank to have all such Obligations secured by the first priority perfected security interest in the Collateral granted herein (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien in this Agreement).

If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Bank's obligation to make Credit Extensions has terminated, Bank shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower. In the event (x) all Obligations (other than inchoate indemnity obligations), except for Bank Services, are satisfied in full, and (y) this Agreement is terminated, Bank shall terminate the security interest granted herein upon Borrower providing cash collateral acceptable to Bank in its good faith business judgment for Bank Services, if any. In the event such Bank Services consist of outstanding Letters of Credit, Borrower shall provide to Bank cash collateral in an amount equal to (x) if such Letters of Credit are denominated in Dollars, then at least one hundred five percent (105.0%); and (y) if such Letters of Credit are denominated in a Foreign Currency,

then at least one hundred ten percent (110.0%), of the Dollar Equivalent of the face amount of all such Letters of Credit plus all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its business judgment), to secure all of the Obligations relating to such Letters of Credit.

4.2 **Priority of Security Interest**. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien under this Agreement). If Borrower shall acquire a commercial tort claim, Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof and grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank.

4.3 **Authorization to File Financing Statements**. Borrower hereby authorizes Bank to file financing statements, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral, by either Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all in Bank's discretion.

5 REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants as follows:

5.1 **Due Organization, Authorization; Power and Authority**. Borrower is duly existing and in good standing as a Registered Organization in its jurisdiction of formation and is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its business or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business. In connection with this Agreement, Borrower has delivered to Bank a completed certificate signed by Borrower, entitled "Perfection Certificate". Borrower represents and warrants to Bank that (a) Borrower's exact legal name is that indicated on the Perfection Certificate and on the signature page hereof; (b) Borrower is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (c) the Perfection Certificate accurately sets forth Borrower's organizational identification number or accurately states that Borrower has none; (d) the Perfection Certificate accurately sets forth Borrower's place of business, or, if more than one, its chief executive office as well as Borrower's mailing address (if different than its chief executive office); (e) Borrower (and each of its predecessors) has not, in the past five (5) years, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificate pertaining to Borrower and each of its Subsidiaries is accurate and complete (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement). If Borrower is not now a Registered Organization but later becomes one, Borrower shall promptly notify Bank of such occurrence and provide Bank with Borrower's organizational identification number.

The execution, delivery and performance by Borrower of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's organizational documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Borrower is bound. Borrower is not in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Borrower's business.

5.2 **Collateral**. Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens. Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Bank in connection herewith. The Accounts are bona fide, existing obligations of the Account Debtors.

The Collateral is not in the possession of any third party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate (other than movable items of personal property including laptop computers and telephonic devices used and moved in the ordinary course of business, having an aggregate book value not exceed One Hundred Thousand Dollars

($100,000). None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 7.2.

All Financed Equipment is new, except for such Financed Equipment that has been disclosed in writing to Bank by Borrower as "used" and that Bank, in its sole discretion, has agreed to finance. All Inventory is in all material respects of good and marketable quality, free from material defects.

Borrower is the sole owner of the Intellectual Property which it owns or purports to own except for (a) non-exclusive licenses granted to its customers in the ordinary course of business, (b) over-the-counter software that is commercially available to the public, and (c) material Intellectual Property licensed to Borrower and noted on the Perfection Certificate. Each Patent which it owns or purports to own and which is material to Borrower's business is valid and enforceable, and no part of the Intellectual Property which Borrower owns or purports to own and which is material to Borrower's business has been judged invalid or unenforceable, in whole or in part. To the best of Borrower's knowledge, no claim has been made that any part of the Intellectual Property violates the rights of any third party except to the extent such claim would not reasonably be expected to have a material adverse effect on Borrower's business.

Except as noted on the Perfection Certificate, Borrower is not a party to, nor is it bound by, any Restricted License.

5.3 **Litigation**. There are no actions or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Borrower or any of its Subsidiaries involving more than, individually or in the aggregate, Two Hundred Fifty Thousand Dollars ($250,000).

5.4 **Financial Statements; Financial Condition**. All consolidated financial statements for Borrower and any of its Subsidiaries delivered to Bank fairly present in all material respects Borrower's consolidated financial condition and Borrower's consolidated results of operations. There has not been any material deterioration in Borrower's consolidated financial condition since the date of the most recent financial statements submitted to Bank.

5.5 **Solvency**. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower is able to pay its debts (including trade debts) as they mature.

5.6 **Regulatory Compliance**. Borrower is not an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Borrower is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower (a) has complied in all material respects with all Requirements of Law, and (b) has not violated any Requirements of Law the violation of which could reasonably be expected to have a material adverse effect on its business. None of Borrower's or any of its Subsidiaries' properties or assets has been used by Borrower or any Subsidiary or, to the best of Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than legally. Borrower and each of its Subsidiaries have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

5.7 **Subsidiaries; Investments**. Borrower does not own any stock, partnership, or other ownership interest or other equity securities except for Permitted Investments.

5.8 **Tax Returns and Payments; Pension Contributions**. Borrower has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except (a) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (b) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Twenty Five Thousand Dollars ($25,000).

To the extent Borrower defers payment of any contested taxes, Borrower shall (i) notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the governmental authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Borrower is unaware of any claims or adjustments proposed for any of Borrower's prior tax years which could result in additional taxes becoming due and payable by Borrower. Borrower has paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and Borrower has not withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with

respect to, any such plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

5.9 **Use of Proceeds**. Borrower shall use the proceeds of the Credit Extensions solely to purchase Eligible Equipment.

5.10 **Full Disclosure**. No written representation, warranty or other statement of Borrower in any certificate or written statement given to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Bank, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized by Bank that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 **Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

5.12 **Healthcare and Regulatory Matters**. Without limiting the generality of any other representation or warranty made in this Agreement, Borrower hereby represents and warrants that the following statements are true, complete and correct, and Borrower hereby covenants and agrees to notify Bank within three (3) Business Days following the occurrence of any facts, events or circumstances, whether threatened, existing or pending, that would make any of the following representations and warranties untrue, incomplete or incorrect (together with such supporting data and information as shall be necessary to fully explain to Bank the scope and nature of the fact, event or circumstance), and shall provide to Bank within two (2) Business Days of Bank's request, such additional information as Bank shall request regarding such disclosure:

(a) Reimbursement; Nongovernmental Account Debtors. Borrower and each Subsidiary has provided to Bank copies of all participation agreements required by Bank with HMOs, insurers, Third-Party Payors, and preferred provider organizations with respect to the business operations of Borrower and each Subsidiary. Borrower and each Subsidiary is in compliance in all material respects with contracts with Account Debtors and is entitled to reimbursement under such contracts.

(b) Compliance with Healthcare Regulations.

(i) Borrower and each Subsidiary has timely filed or caused to be timely filed, all cost reports and other reports of every kind whatsoever required by a Third-Party Payor Program, to have been filed or made with respect to the business operations of Borrower or such Subsidiary. There are no claims, actions or appeals pending (and neither Borrower nor any Subsidiary has filed any claims or reports which should result in any such claims, actions or appeals) before any Governmental Authority pertaining to Borrower's or such Subsidiary's business operations, including, without limitation, any intermediary or carrier, the Provider Reimbursement Review Board or the Administrator of CMS, with respect to any state or federal Medicare or Medicaid cost reports or claims filed by Borrower or such Subsidiary, or any disallowance by any Governmental Authority in connection with any audit of such cost reports;

(ii) Borrower and each Subsidiary has obtained all necessary accreditations to operate its business as now conducted, and currently is in compliance with all statutory and regulatory requirements applicable to it, the failure of which would have a material adverse effect;

(iii) Neither Borrower nor any Subsidiary is currently or has in the past been subject to: (1) any state or local governmental investigation, inspection or inquiry related to any license or licensure standards applicable to Borrower or such Subsidiary; (2) any federal, state, local governmental or private payor civil or criminal investigations, inquiries or audits involving and/or related to any federal, state or private payor healthcare fraud and abuse provisions or contractual prohibition of healthcare fraud and abuse; or (3) any federal, state or private payor inquiry, investigation, inspection or audit regarding Borrower or any Subsidiary or their activities, including, without limitation, any federal, state or private payor inquiry or investigation of any Person having "ownership, financial or control interest" in Borrower or any Subsidiary (as that term is defined in 42 C.F.R. § 420.201 et seq.) involving and/or related to healthcare fraud and abuse, false claims under 31 U.S.C. §§ 3729-3731 or any similar contractual prohibition, or any qui tam action brought pursuant to 31 U.S.C. § 3729 et seq.;

(iv) No director, officer, shareholder, employee or Person with a "direct or indirect ownership interest" (as that phrase is defined in 42 C.F.R. § 420.201) in Borrower or any Subsidiary: (1) has had a civil monetary penalty assessed against him or her pursuant to 42 U.S.C. § 1320a-7a; (2) has been excluded from participation in a Federal Health Care Program (as that term is defined in 42 U.S.C. § 1320a-7b); (3) has been convicted (as that term is defined in 42 C.F.R. § 1001.2)

of any of those offenses described in 42 U.S.C. § 1320a-7b or 18 U.S.C. §§ 669, 1035, 1347 or 1518, including without limitation any of the following categories of offenses: (A) criminal offenses relating to the delivery of an item or service under any Federal Health Care Program (as that term is defined in 42 U.S.C. § 1320a-7b) or healthcare benefit program (as that term is defined in 18 U.S.C. § 24b); (B) criminal offenses under federal or state law relating to patient neglect or abuse in connection with the delivery of a healthcare item or service; (C) criminal offenses under federal or state law relating to fraud and abuse, theft, embezzlement, false statements to third parties, money laundering, kickbacks, breach of fiduciary responsibility or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in a program operated by or financed in whole or in part by any federal, state or local governmental agency; (D) federal or state laws relating to the interference with or obstruction of any investigations into any criminal offenses described in (1) through (3) above; or (E) criminal offenses under federal or state law relating to the unlawful manufacturing, distribution, prescription or dispensing of a controlled substance; or (4) has been involved or named in a U.S. Attorney complaint made or any other action taken pursuant to the False Claims Act under 31 U.S.C. §§ 3729-3731 or qui tam action brought pursuant to 31 U.S.C. § 3729 et seq.;

(v) Borrower and each Subsidiary is and shall continue to be in compliance with all applicable laws relating to its relationships with physicians;

(vi) Borrower and each Subsidiary, and their employees and contractors, in the exercise of their duties on behalf of Borrower or any Subsidiary, is and shall continue to be in compliance with all laws, rules, regulations, orders, decrees and directions of any Governmental Authority (including, without limitation, the Social Security Act, as amended, the rules and regulations promulgated by CMS), and any state laws applicable to the collections on Accounts, any contracts relating thereto or any other Collateral, or otherwise applicable to its business and properties, a violation of which could materially adversely affect its ability to collect on its Accounts or repay the Obligations;

(vii) All persons providing professional healthcare services for or on behalf of Borrower or any Subsidiary (either as an employee or independent contractor) are appropriately licensed in every jurisdiction in which they hold themselves out as professional health care providers; and

(viii) None of Borrower's nor any Subsidiary's state and local licenses, permits, registrations, certifications and other approvals relating to providing healthcare services and other services provided by Borrower or such Subsidiary have been suspended, revoked, limited or denied renewal at any time.

(c) Healthcare Permits. Borrower has (i) each Healthcare Permit and other rights from, and have made all declarations and filings with, all applicable Governmental Authorities, all self-regulatory authorities and all courts and other tribunals necessary to engage in the ownership, management and operation of the assets of Borrower, and (ii) no knowledge that any Governmental Authority is considering limiting, suspending or revoking any Healthcare Permit. All such Healthcare Permits are valid and in full force and effect and Borrower is in material compliance with the terms and conditions of all such Healthcare Permits, except where failure to be in such compliance or for a Healthcare Permit to be valid and in full force and effect would not have a material adverse effect.

(d) HIPAA Compliance. To the extent that and for so long as Borrower or any Subsidiary is a "covered entity" or "business associate" as either such term is defined under the requirements and implementing regulations at 45 Code of Federal Regulations ("C.F.R.") Parts 160-64 for the Administrative Simplification provisions of Title II, Subtitle F of HIPAA, Borrower and each Subsidiary (i) has undertaken or will promptly undertake all necessary surveys, audits, inventories, reviews, analyses and/or assessments (including any necessary risk assessments) of all areas of its business and operations required by HIPAA and/or that could be adversely affected by the failure of Borrower or such Subsidiary to be HIPAA Compliant; (ii) has developed a detailed plan and time line for becoming HIPAA Compliant (a "HIPAA Compliance Plan"); and (iii) has implemented those provisions of such HIPAA Compliance Plan in all material respects necessary to ensure that Borrower and each Subsidiary becomes HIPAA Compliant.

6 AFFIRMATIVE COVENANTS

Borrower shall do all of the following:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower shall comply, and have each Subsidiary comply, in all material respects, with all laws, ordinances and regulations to which it is subject.

(b) Obtain all of the Governmental Approvals necessary for the performance by Borrower of its obligations under the Loan Documents to which it is a party and the grant of a security interest to Bank in all of its property. Borrower shall promptly provide copies of any such obtained Governmental Approvals to Bank.

6.2 **Financial Statements, Reports, Certificates**. Provide Bank with the following:

(a) Quarterly Financial Statements. As soon as available, but no later than thirty (30) days after the last day of each quarter, a company prepared consolidated and consolidating balance sheet and income statement covering Borrower's and each of its Subsidiary's operations for such quarter certified by a Responsible Officer and in a form acceptable to Bank (the "**Quarterly Financial Statements**");

(b) Quarterly Compliance Certificate. Within thirty (30) days after the last day of each quarter and together with the Quarterly Financial Statements, a duly completed Compliance Certificate signed by a Responsible Officer, certifying that as of the end of such quarter, Borrower was in full compliance with all of the terms and conditions of this Agreement, and setting forth calculations showing compliance with the financial covenants set forth in this Agreement and such other information as Bank may reasonably request;

(c) Annual Operating Budget and Financial Projections. As soon as available after approval thereof by Borrower's Board of Directors, but no later than sixty (60) days after the last day of each of Borrower's fiscal years, (i) annual operating budgets (including income statements, balance sheets and cash flow statements, by month) for the current fiscal year of Borrower, and (ii) annual financial projections for such fiscal year (on a monthly basis) as approved by Borrower's board of directors, together with any related business forecasts used in the preparation of such annual financial projections; provided that, any revisions of the such annual projections approved by Borrower's board of directors shall be delivered to Bank no later than seven (7) days after such approval);

(d) Annual Audited Financial Statements. As soon as available, but no later than one hundred eighty (180) days after the last day of Borrower's fiscal year, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm reasonably acceptable to Bank;

(e) Other Statements. Within five (5) days of delivery, copies of all statements, reports and notices made available to Borrower's security holders or to any holders of Subordinated Debt;

(f) SEC Filings. In the event that Borrower becomes subject to the reporting requirements under the Exchange Act within five (5) days of filing, copies of all periodic and other reports, proxy statements and other materials filed by Borrower with the SEC, any Governmental Authority succeeding to any or all of the functions of the SEC or with any national securities exchange, or distributed to its shareholders, as the case may be. Documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the Internet at Borrower's website address; provided, however, Borrower shall promptly notify Bank in writing (which may be by electronic mail) of the posting of any such documents;

(g) Legal Action Notice. A prompt report of any legal actions pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, Two Hundred Fifty Thousand Dollars ($250,000) or more;

(h) Immediately upon Borrower's receipt thereof, (x) notice of any investigation or audit, or pending or threatened proceedings relating to, any violation by a Borrower of any Healthcare Law, including, (i) any investigation or audit or proceeding involving violation of any of the Medicare and/or Medicaid fraud and abuse provisions and (ii) any criminal or civil investigation initiated, claim filed or disclosure required by the Office of Inspector General, the Department of Justice, CMS or any other Governmental Authority; and (y) notice of any written recommendation from any Governmental Authority or other regulatory body that a Borrower should have its licensure, provider or supplier number or accreditation suspended, revoked or limited in any way, or have its eligibility to participate in Medicare, Medicaid or any other government program to accept assignments or rights to reimbursement under Medicaid, Medicare or any other government program regulations suspended, revoked or limited in any way; and

(i) Other Financial Information. Other financial information reasonably requested by Bank.

6.3 **Inventory; Returns**. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower and its Account Debtors shall follow Borrower's customary practices as they exist at the Effective Date. Borrower must promptly notify Bank of all returns, recoveries, disputes and claims that involve more than One Hundred Thousand Dollars ($100,000).

6.4 **Taxes; Pensions**. Timely file, and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower and each of its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Bank, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms.

6.5 **Insurance**.

(a) Keep its business and the Collateral insured for risks and in amounts standard for companies in Borrower's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Borrower, and in amounts that are satisfactory to Bank. All property policies shall have a lender's loss payable endorsement showing Bank as an additional lender loss payee. All liability policies shall show, or have endorsements showing, Bank as an additional insured. Bank shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral.

(b) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Two Hundred Fifty Thousand Dollars ($250,000) with respect to any loss, but not exceeding Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(c) At Bank's request, Borrower shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 6.5 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. If Borrower fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Bank deems prudent.

6.6 **Operating Accounts**.

(a) Maintain all of its and all of its Subsidiaries' operating and other deposit accounts and securities accounts with Bank and Bank's Affiliates.

(b) Borrower shall cause all Medicare and Medicaid payments, and only such payments, owing to Borrower to be wire transferred or sent via ACH directly to Borrower's operating account held at Bank (the "**Medicare/Medicaid Receivables Account**") to which such payments are being directed and/or remitted. Bank hereby disclaims any right or interest (including any security interest or right of off set (or set-off)) in or to such Medicare/Medicaid Receivables Account. If at any time, such payments are no longer wire transferred or sent via ACH directly to the Medicare/Medicaid Receivables Account, Borrower shall cause all Medicare and/or Medical payments to be mailed or delivered to a post office box designated by Bank, and Borrower shall enter into a lockbox agreement with Bank on Bank's standard form with respect to such payments. No other amounts shall be directed or remitted, by or for the benefit of Borrower, to the Medicare/Medicaid Receivables Account. All items or amounts which are remitted to the Medicare/Medicaid Receivables Account shall, on a daily basis, be swept to Borrower's Designated Deposit Account, and Borrower shall cause all payments other than those directed or remitted to the Medicare/Medicaid Receivables Account, to be directed or remitted to such Designated Deposit Account. Borrower shall not change the instructions related to the sweep of funds from the Medicare/Medicaid Receivables Account to the Designated Deposit Account.

6.7 **Intentionally Omitted**.

6.8 **Protection of Intellectual Property Rights**.

(a) (i) Protect, defend and maintain the validity and enforceability of its Intellectual Property; (ii) promptly advise Bank in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value of its Intellectual Property; and (iii) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Bank's written consent.

(b) Provide written notice to Bank within ten (10) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Borrower shall take such steps as Bank requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any Restricted License to be deemed "Collateral" and for Bank to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

6.9 **Litigation Cooperation**. From the date hereof and continuing through the termination of this Agreement, make available to Bank, without expense to Bank, Borrower and its officers, employees and agents and Borrower's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Borrower.

6.10 **Access to Collateral; Books and Records**. Allow Bank, or its agents, to inspect the Collateral and audit and copy Borrower's Books. Such inspections or audits shall be conducted no more often than once every twelve (12) months unless an Event of Default has occurred and is continuing in which case such inspections and audits shall occur as often as Bank shall determine is necessary. The foregoing inspections and audits shall be at Borrower's expense, and the charge therefor shall be Eight Hundred Fifty Dollars ($850) per person per day (or such higher amount as shall represent Bank's then-current standard charge for the same), plus reasonable out-of-pocket expenses. In the event Borrower and Bank schedule an audit more than ten (10) days in advance, and Borrower cancels or seeks to reschedule the audit with less than ten (10) days written notice to Bank, then (without limiting any of Bank's rights or remedies), Borrower shall pay Bank a fee of One Thousand Dollars ($1,000) plus any out-of-pocket expenses incurred by Bank to compensate Bank for the anticipated costs and expenses of the cancellation or rescheduling.

6.11 **Formation or Acquisition of Subsidiaries**. Notwithstanding and without limiting the negative covenants contained in Sections 7.3 and 7.7 hereof, at the time that Borrower forms any direct or indirect Subsidiary or acquires any direct or indirect Subsidiary after the Effective Date, Borrower shall (a) cause such new Subsidiary to provide to Bank a joinder to the Loan Agreement to cause such Subsidiary to become a co-borrower hereunder, together with such appropriate financing statements, all in form and substance satisfactory to Bank (including being sufficient to grant Bank a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Subsidiary), (b) provide to Bank appropriate certificates and powers and financing statements, pledging all of the direct or beneficial ownership interest in such new Subsidiary, in form and substance satisfactory to Bank, and (c) provide to Bank all other documentation in form and substance satisfactory to Bank, including one or more opinions of counsel satisfactory to Bank, which in its opinion is appropriate with respect to the execution and delivery of the applicable documentation referred to above. Any document, agreement, or instrument executed or issued pursuant to this Section 6.13 shall be a Loan Document.

6.12 **Further Assurances**. Execute any further instruments and take further action as Bank reasonably requests to perfect or continue Bank's Lien in the Collateral or to effect the purposes of this Agreement. Deliver to Bank, within five (5) days after the same are sent or received, copies of all correspondence, reports, documents and other filings with any Governmental Authority regarding compliance with or maintenance of Governmental Approvals or Requirements of Law or that could reasonably be expected to have a material effect on any of the Governmental Approvals or otherwise on the operations of Borrower or any of its Subsidiaries.

6.13 **Healthcare Laws; Participation Agreements**. Borrower will (i) maintain in full force and effect, and free from restrictions, probations, conditions or known conflicts all Permits necessary under Healthcare Laws to continue to receive reimbursement under all Third-Party Payor Programs in which Borrower participates as of the date of this Agreement, and (ii) provide to Bank upon request, an accurate, complete and current list of all participation agreements with Third-Party Payors with respect to the business of Borrower (collectively, "**Participation Agreements**"). Borrower will at all times comply with all requirements, contracts, conditions and stipulations applicable to Borrower in order to maintain in good standing and without default or limitation all such Participation Agreements.

7 NEGATIVE COVENANTS

Borrower shall not do any of the following without Bank's prior written consent:

7.1 **Dispositions**. Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out or obsolete Equipment that does not constitute Financed Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of Borrower; (c) consisting of Permitted Liens and Permitted Investments; (d) consisting of the sale or issuance of any stock of Borrower permitted under Section 7.2 of this Agreement; (e) consisting of Borrower's use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; and (f) of non-exclusive licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business and licenses that could not result in a legal transfer of title of the licensed property but that may be exclusive in respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States.

7.2 **Changes in Business, Management, Ownership, or Business Locations**. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such Subsidiary, as applicable, or reasonably related thereto; (b) liquidate or dissolve; (c) (i) fail to provide notice to Bank of any Key Person departing from or ceasing to be employed by Borrower within five (5) days after his departure from Borrower; or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Bank the venture capital investors prior to the closing of the transaction).

Borrower shall not, without at least thirty (30) days prior written notice to Bank: (1) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than One Hundred Thousand Dollars ($100,000) in Borrower's assets or property) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of One Hundred Thousand Dollars ($100,000) to a bailee at a location other than to a bailee and at a location already disclosed in the Perfection Certificate, (2) change its jurisdiction of organization, (3) change its organizational structure or type, (4) change its legal name, or (5) change any organizational number (if any) assigned by its jurisdiction of organization. If Borrower intends to deliver any portion of the Collateral valued, individually or in the aggregate, in excess of Two Hundred Thousand Dollars ($200,000) to a bailee, and Bank and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Borrower intends to deliver the Collateral, then Borrower will first receive the written consent of Bank, and such bailee shall execute and deliver a bailee agreement in form and substance satisfactory to Bank.

7.3 **Mergers or Acquisitions**. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person (including, without limitation, by the formation of any Subsidiary). A Subsidiary may merge or consolidate into another Subsidiary or into Borrower.

7.4 **Indebtedness**. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 **Encumbrance**. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, permit any Collateral not to be subject to the first priority security interest granted herein, or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or any Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

7.6 **Distributions; Investments**. (a) Pay any dividends or make any distribution or payment or redeem, retire or purchase any capital stock provided that Borrower may repurchase the stock of former employees or consultants pursuant to stock repurchase agreements so long as an Event of Default does not exist at the time of such repurchase and would not exist after giving effect to such repurchase, provided that the aggregate amount of all such repurchases does not exceed One Hundred Thousand Dollars ($100,000) per fiscal year; or (b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.7 **Transactions with Affiliates**. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower, except for transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person.

7.8 **Subordinated Debt**. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

7.9 **Compliance**. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to (a) meet the minimum funding requirements of ERISA, (b) prevent a Reportable Event or Prohibited Transaction, as defined in ERISA, from occurring, or (c) comply with the Federal Fair Labor Standards Act, the failure of any of the conditions described in clauses (a) through (c) which could reasonably be expected to have a material adverse effect on Borrower's business; or violate any other law or regulation, if the violation could reasonably be expected to have a material adverse effect on Borrower's business, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

8 EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 **Payment Default**. Borrower fails to (a) make any payment of principal or interest on any Credit Extension when due, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day cure period shall not apply to payments due on the Equipment Maturity Date). During the cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

8.2 **Covenant Default**.

(a) Borrower fails or neglects to perform any obligation in Sections 6.2, 6.4, 6.5, 6.6, 6.8(b), 6.10, 6.11, 6.12 or violates any covenant in Section 7; or

(b) Borrower fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Cure periods provided under this section shall not apply, among other things, to financial covenants or any other covenants set forth in clause (a) above;

8.3 **Material Adverse Change**. A Material Adverse Change occurs;

8.4 **Attachment; Levy; Restraint on Business**.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or of any entity under the control of Borrower (including a Subsidiary), or (ii) a notice of lien or levy is filed against any of Borrower's assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; or

(b) (i) any material portion of Borrower's assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower from conducting all or any material part of its business;

8.5 **Insolvency**. (a) Borrower or any of its Subsidiaries is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and is not dismissed or stayed within thirty (30) days (but no Credit Extensions shall be made while any of the conditions described in clause (a) exist and/or until any Insolvency Proceeding is dismissed);

8.6 **Other Agreements**. There is, under any agreement to which Borrower or any Guarantor is a party with a third party or parties, (a) any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of Two Hundred Fifty Thousand Dollars ($250,000); or (b) any breach or default by Borrower or Guarantor, the result of which could have a material adverse effect on Borrower's or any Guarantor's business;

8.7 **Judgments; Penalties**. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars ($250,000) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower by any Governmental Authority, and the same are not, within ten (10) days after the entry, assessment or issuance thereof, discharged, satisfied, or paid, or after execution thereof, stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the satisfaction, payment, discharge, stay, or bonding of such fine, penalty, judgment, order or decree);

8.8 **Misrepresentations**. Borrower or any Person acting for Borrower makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

8.9 **Subordinated Debt**. Any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, any Person shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder, or the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement;

8.10 **Guaranty**. (a) Any guaranty of any Obligations terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any guaranty of the Obligations; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor; or (d) the liquidation, winding up, or termination of existence of any Guarantor; or

8.11 **Governmental Approvals.** Any Governmental Approval shall have been (a) revoked, rescinded, suspended, modified in an adverse manner or not renewed in the ordinary course for a full term or (b) subject to any decision by a Governmental Authority that designates a hearing with respect to any applications for renewal of any of such Governmental Approval or that could result in the Governmental Authority taking any of the actions described in clause (a) above, and such decision or such revocation, rescission, suspension, modification or non-renewal (i) cause, or could reasonably be expected to cause, a Material Adverse Change, or (ii) adversely affects the legal qualifications of Borrower or any of its Subsidiaries to hold such Governmental Approval in any applicable jurisdiction and such revocation, rescission, suspension, modification or non-renewal could reasonably be expected to affect the status of or legal qualifications of Borrower or any of its Subsidiaries to hold any Governmental Approval in any other jurisdiction.

9 BANK'S RIGHTS AND REMEDIES

9.1 **Rights and Remedies**. Upon the occurrence and during the continuance of an Event of Default, Bank may, without notice or demand, do any or all of the following:

(a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Bank;

(c) demand that Borrower (i) deposit cash with Bank in an amount equal to at least one hundred ten percent (110%) of the Dollar Equivalent of the aggregate face amount of all Letters of Credit remaining undrawn (plus all interest, fees, and costs due or to become due in connection therewith (as estimated by Bank in its good faith business judgment)), to secure all of the Obligations relating to such Letters of Credit, as collateral security for the repayment of any future drawings under such Letters of Credit, and Borrower shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any Letters of Credit;

(d) terminate any FX Contracts;

(e) verify the amount of, demand payment of and performance under, and collect any Accounts and General Intangibles, settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Bank considers advisable, and notify any Person owing Borrower money of Bank's security interest in such funds;

(f) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies;

(g) apply to the Obligations (i) any balances and deposits of Borrower it holds, or (ii) any amount held by Bank owing to or for the credit or the account of Borrower;

(h) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. Bank is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section, Borrower's rights under all licenses and all franchise agreements inure to Bank's benefit;

(i) place a "hold" on any account maintained with Bank;

(j) demand and receive possession of Borrower's Books; and

(k) exercise all rights and remedies available to Bank under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

9.2 **Power of Attorney**. Borrower hereby irrevocably appoints Bank as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Bank determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Bank or a third party as the Code permits. Borrower hereby appoints Bank as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Bank's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations have been satisfied in full and Bank is under no further obligation to make Credit Extensions hereunder. Bank's foregoing appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until all Obligations have been fully repaid and performed and Bank's obligation to provide Credit Extensions terminates.

9.3 **Protective Payments**. If Borrower fails to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Bank may obtain such insurance or make such payment, and all amounts so paid by Bank are Bank Expenses and immediately due and payable, bearing interest at the then highest rate applicable to the Obligations, and secured by the Collateral. Bank will make reasonable efforts to provide Borrower with notice of Bank obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Bank are deemed an agreement to make similar payments in the future or Bank's waiver of any Event of Default.

9.4 **Application of Payments and Proceeds Upon Default**. If an Event of Default has occurred and is continuing, Bank shall have the right to apply in any order any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations. Bank shall pay any surplus to Borrower by credit to the Designated Deposit Account or to other Persons legally entitled thereto; Borrower shall remain liable to Bank for any deficiency. If Bank, directly or indirectly, enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Bank shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Bank of cash therefor.

9.5 **Bank's Liability for Collateral**. So long as Bank complies with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Bank, Bank shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 **No Waiver; Remedies Cumulative**. Bank's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Bank thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Bank's rights and remedies under this Agreement and the other Loan Documents are cumulative. Bank has all rights and remedies provided under the Code, by law, or in equity. Bank's exercise of one right or remedy is not an election and shall not preclude Bank from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Bank's waiver of any Event of Default is not a continuing waiver. Bank's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 **Demand Waiver**. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

10 NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Bank or Borrower may change its mailing or electronic mail address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

Trovagene, Inc.
11055 Flintkote Avenue, Suite B
San Diego, CA 92121
Attn: Stephen Zaniboni, Chief Financial Officer
Fax: (858) 952-7570
Email: szaniboni@trovagene.com

If to Bank:

Silicon Valley Bank
4370 La Jolla Village Drive, Suite 1050
San Diego, CA 92122
Attn: Anthony Flores
Fax: (858) 784-3308
Email: aflores@svb.com

11 CHOICE OF LAW, VENUE, JURY TRIAL WAIVER, AND JUDICIAL REFERENCE

California law governs the Loan Documents without regard to principles of conflicts of law. Borrower and Bank each submit to the exclusive jurisdiction of the State and Federal courts in Santa Clara County, California; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER AND BANK EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR BOTH PARTIES TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

WITHOUT INTENDING IN ANY WAY TO LIMIT THE PARTIES' AGREEMENT TO WAIVE THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY, if the above waiver of the right to a trial by jury is not enforceable, the parties hereto agree that any and all disputes or controversies of any nature between them arising at any time shall be decided by a reference to a private judge, mutually selected by the parties (or, if they cannot agree, by the Presiding Judge of the Santa Clara County, California Superior Court) appointed in accordance with California Code of Civil Procedure Section 638 (or pursuant to comparable provisions of federal law if the dispute falls within the exclusive jurisdiction of the federal courts), sitting without a jury, in Santa Clara County, California; and the parties hereby submit to the jurisdiction of such court. The reference proceedings shall be conducted pursuant to and in accordance with the provisions of California Code of Civil Procedure §§ 638 through 645.1, inclusive. The private judge shall have the power, among others, to grant provisional relief, including without limitation, entering temporary restraining orders, issuing preliminary and permanent injunctions and appointing receivers. All such proceedings shall be closed to the public and confidential and all records relating thereto shall be permanently sealed. If during the course of any dispute, a party desires to seek provisional relief, but a judge has not been appointed at that point pursuant to the judicial reference procedures, then such party may apply to the Santa Clara County, California Superior Court for such relief. The proceeding before the private judge shall be conducted in the same manner as it would be before a court under the rules of evidence applicable to judicial proceedings. The parties shall be entitled to discovery which shall be conducted in the same manner as it would be before a court under the rules of discovery applicable to judicial proceedings. The private judge shall oversee discovery and may enforce all discovery rules and orders applicable to judicial proceedings in the same manner as a trial court judge. The parties agree that the selected or appointed private judge shall have the power to decide all issues in the action or proceeding, whether of fact or of law, and shall report a statement of decision thereon pursuant to California Code of Civil Procedure § 644(a). Nothing in this paragraph shall limit the right of any party at any time to exercise self-help remedies, foreclose against collateral, or obtain provisional remedies. The private judge shall also determine all issues relating to the applicability, interpretation, and enforceability of this paragraph.

This Section 11 shall survive the termination of this Agreement.

12 GENERAL PROVISIONS

12.1 **Termination Prior to Equipment Maturity Date; Survival**. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations, and any other obligations which, by their terms, are to survive the termination of this Agreement, and any Obligations under Bank Services Agreements that are cash collateralized in accordance with Section 4.1 of this Agreement), this Agreement may be terminated prior to the Equipment Maturity Date by Borrower, in accordance with Section 2.1.1. Those obligations that are expressly specified in this Agreement as surviving this Agreement's termination shall continue to survive notwithstanding this Agreement's termination.

12.2 **Successors and Assigns**. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not assign this Agreement or any rights or obligations under it without Bank's prior written consent

(which may be granted or withheld in Bank's discretion). Bank has the right, without the consent of or notice to Borrower, to sell, transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents.

12.3 **Indemnification**. Borrower agrees to indemnify, defend and hold Bank and its directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Bank (each, an "**Indemnified Person**") harmless against: (i) all obligations, demands, claims, and liabilities (collectively, "**Claims**") claimed or asserted by any other party in connection with the transactions contemplated by the Loan Documents; and (ii) all losses or expenses (including Bank Expenses) in any way suffered, incurred, or paid by such Indemnified Person as a result of, following from, consequential to, or arising from transactions between Bank and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct.

This Section 12.3 shall survive until all statutes of limitation with respect to the Claims, losses, and expenses for which indemnity is given shall have run.

12.4 **Time of Essence**. Time is of the essence for the performance of all Obligations in this Agreement.

12.5 **Severability of Provisions**. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.6 **Correction of Loan Documents**. Bank may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties so long as Bank provides Borrower with written notice of such correction and allows Borrower at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by an amendment signed by both Bank and Borrower.

12.7 **Amendments in Writing; Waiver; Integration**. No purported amendment or modification of any Loan Document, or waiver, discharge or termination of any obligation under any Loan Document, shall be enforceable or admissible unless, and only to the extent, expressly set forth in a writing signed by the party against which enforcement or admission is sought. Without limiting the generality of the foregoing, no oral promise or statement, nor any action, inaction, delay, failure to require performance or course of conduct shall operate as, or evidence, an amendment, supplement or waiver or have any other effect on any Loan Document. Any waiver granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver. The Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of the Loan Documents merge into the Loan Documents.

12.8 **Counterparts**. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.9 **Confidentiality**. In handling any confidential information, Bank shall exercise the same degree of care that it exercises for its own proprietary information, but disclosure of information may be made: (a) to Bank's Subsidiaries or Affiliates (such Subsidiaries and Affiliates, together with Bank, collectively, "**Bank Entities**"); (b) to prospective transferees or purchasers of any interest in the Credit Extensions (provided, however, Bank shall use its best efforts to obtain any prospective transferee's or purchaser's agreement to the terms of this provision); (c) as required by law, regulation, subpoena, or other order; (d) to Bank's regulators or as otherwise required in connection with Bank's examination or audit; (e) as Bank considers appropriate in exercising remedies under the Loan Documents; and (f) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. Confidential information does not include information that is either: (i) in the public domain or in Bank's possession when disclosed to Bank, or becomes part of the public domain (other than as a result of its disclosure by Bank in violation of this Agreement) after disclosure to Bank; or (ii) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

Bank Entities may use anonymous forms of confidential information for aggregate datasets, for analyses or reporting, and for any other uses not expressly prohibited in writing by Borrower. The provisions of the immediately preceding sentence shall survive termination of this Agreement.

12.10 **Attorneys' Fees, Costs and Expenses**. In any action or proceeding between Borrower and Bank arising out of or relating to the Loan Documents, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

12.11 **Electronic Execution of Documents**. The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act.

12.12 **Captions**. The headings used in this Agreement are for convenience only and shall not affect the interpretation of this Agreement.

12.13 **Construction of Agreement**. The parties mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties caused the uncertainty to exist.

12.14 **Relationship**. The relationship of the parties to this Agreement is determined solely by the provisions of this Agreement. The parties do not intend to create any agency, partnership, joint venture, trust, fiduciary or other relationship with duties or incidents different from those of parties to an arm's-length contract.

12.15 **Third Parties**. Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights or remedies under or by reason of this Agreement on any persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any person not an express party to this Agreement; or (c) give any person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

13 DEFINITIONS

13.1 **Definitions**. As used in the Loan Documents, the word "shall" is mandatory, the word "may" is permissive, the word "or" is not exclusive, the words "includes" and "including" are not limiting, the singular includes the plural, and numbers denoting amounts that are set off in brackets are negative. As used in this Agreement, the following capitalized terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"**Affiliate**" is, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Agreement**" is defined in the preamble hereof.

"**Bank**" is defined in the preamble hereof.

"**Bank Entities**" is defined in Section 12.9.

"**Bank Expenses**" are all audit fees and expenses, costs, and expenses (including reasonable attorneys' fees and expenses) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to Borrower.

"**Bank Services**" are any products, credit services, and/or financial accommodations previously, now, or hereafter provided to Borrower or any of its Subsidiaries by Bank or any Bank Affiliate, including, without limitation, any letters of credit, cash management services (including, without limitation, merchant services, direct deposit of payroll, business credit cards, and check cashing services), interest rate swap arrangements, and foreign exchange services as any such products or services may be identified in Bank's various agreements related thereto (each, a "**Bank Services Agreement**").

"**Borrower**" is defined in the preamble hereof.

"**Borrower's Books**" are all Borrower's books and records including ledgers, federal and state tax returns, records regarding Borrower's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Borrowing Resolutions**" are, with respect to any Person, those resolutions substantially in the form attached hereto as Exhibit B.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which Bank is closed.

"**Cash Equivalents**" means (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) Bank's certificates of deposit issued maturing no more than one (1) year after issue; and (d) money market funds at least ninety-five percent (95%) of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition.

"**Claims**" is defined in Section 12.3.

"**CMS**" means the Centers for Medicare & Medicaid Services.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of California; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Bank's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of California, the term "**Code**" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A and, upon any Equipment Advance, any additional Equipment described in the Loan Supplement for such Equipment Advance.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Compliance Certificate**" is that certain certificate in the form attached hereto as Exhibit C.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation, in each case, directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Credit Extension**" is any Equipment Advance or any other extension of credit by Bank for Borrower's benefit.

"**Default Rate**" is defined in Section 2.3(b).

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Designated Deposit Account**" is the multicurrency account denominated in Dollars, account number XXXXXX6635, maintained by Borrower with Bank.

"**Dollars**," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"**Dollar Equivalent**" is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

"**Draw Period**" is the period of time from the Effective Date through the earlier to occur of (a) August 31, 2016 or (b) an Event of Default.

"**Effective Date**" is defined in the preamble hereof.

"**Eligible Equipment**" is the following to the extent it complies with all of Borrower's representations and warranties to Bank, is acceptable to Bank in all respects, is located at 11055 Flintkote Avenue, Suite B, San Diego, CA 92121 or such other location of which Bank has approved in writing, and is subject to a first priority Lien in favor of Bank: (a) general purpose equipment computer equipment, office equipment, test and laboratory equipment, furnishings, subject to the limitations set forth herein, and (b) Other Equipment.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**Equipment Advance**" is defined in Section 2.1.1(a).

"**Equipment Line**" is an Equipment Advance or Equipment Advances in an aggregate amount of up to Two Million Dollars ($2,000,000).

"**Equipment Maturity Date**" is November 1, 2019.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, and its regulations.

"**Event of Default**" is defined in Section 8.

"**Event of Loss**" is defined in Section 2.1.1(c).

"**Exchange Act**" is the Securities Exchange Act of 1934, as amended.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earlier of (a) the final Payment Date for such Equipment Advance or (b) the acceleration of such Equipment Advance, equal to the Loan Amount for such Equipment Advance multiplied by the Final Payment Percentage.

"**Final Payment Percentage**" is, for each Equipment Advance, seven percent (7.00%).

"**Financed Equipment**" is all present and future Eligible Equipment in which Borrower has any interest which is financed by an Equipment Advance.

"**Foreign Currency**" means lawful money of a country other than the United States.

"**Funding Date**" is any date on which a Credit Extension is made to or for the account of Borrower which shall be a Business Day.

"**FX Contract**" is any foreign exchange contract by and between Borrower and Bank under which Borrower commits to purchase from or sell to Bank a specific amount of Foreign Currency on a specified date.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" is all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all Intellectual Property, claims, income and other tax refunds, security and other deposits, payment intangibles, contract rights, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Guarantor**" is any Person providing a Guaranty in favor of Bank.

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Healthcare Laws**" means all applicable laws relating to the possession, control, warehousing, marketing, sale and distribution of pharmaceuticals, the operation of medical or senior housing facilities (such as, but not limited to, nursing homes, skilled nursing facilities, rehabilitation hospitals, intermediate care facilities and adult care facilities), patient healthcare, patient healthcare information, patient abuse, the quality and adequacy of medical care, rate setting, equipment, personnel, operating policies, fee splitting, including, without limitation, (a) all federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(6)), the Stark Law (42 U.S.C. §1395nn), the civil False Claims Act (31 U.S.C. §3729 et seq.), (b) TRICARE, (c) HIPAA, (d) Medicare, (e) Medicaid, (f) quality of medical care and accreditation standards and requirements of all applicable state Laws or regulatory bodies, (g) all laws, policies, procedures, requirements and regulations pursuant to which Healthcare Permits are issued, and (h) any and all other applicable health care laws, regulations, manual provisions, policies and administrative guidance, each of (a) through (h) as may be amended from time to time.

"**Healthcare Permit**" means a Permit (a) issued or required under Healthcare Laws applicable to the business of any Borrower or any of its Subsidiaries or necessary in the possession, ownership, warehousing, marketing, promoting, sale, labeling, furnishing, distribution or delivery of goods or services under Healthcare Laws applicable to the business of a Borrower or any of its Subsidiaries, and/or (b) issued by any Person from which any Borrower has, as of the Effective Date, received an accreditation (including, without limitation, JCAHO).

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, as the same may be amended, modified or supplemented from time to time, and any successor statute thereto, and any and all rules or regulations promulgated from time to time thereunder.

"**HIPAA Compliant**" shall mean that the applicable Person (a) has adopted and implemented policies and procedures, and has trained its personnel, in compliance with each of the applicable requirements of the so-called "Administrative Simplification" provisions of HIPAA, and (b) is not and could not reasonably be expected to become subject to any deficiency with respect to HIPAA.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

"**Indemnified Person**" is defined in Section 12.3.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"**Intellectual Property**" means, with respect to any Person, all of such Person's right, title, and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to such Person;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**Key Person**" is each of Borrower's (i) Chief Executive Officer, who is Antonius Schuh, Ph.D. as of the Effective Date, (ii) Chief Financial Officer, who is Stephen Zaniboni, CPA as of the Effective Date and (iii) Chief Science Officer, who is Mark Earlander, Ph.D. as of the Effective Date.

"**Letter of Credit**" is a standby or commercial letter of credit issued by Bank upon request of Borrower based upon an application, guarantee, indemnity, or similar agreement.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Amount**" in respect of each Equipment Advance is the original principal amount of such Equipment Advance.

"**Loan Documents**" are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, any Bank Services Agreement, any subordination agreement, any note, or notes or guaranties executed by Borrower or any Guarantor, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank in connection with this Agreement or Bank Services, all as amended, restated, or otherwise modified.

"**Loan Supplement**" is the form attached hereto as Schedule 1.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Bank's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations, or condition (financial or otherwise) of Borrower; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"**Obligations**" are Borrower's obligations to pay when due any debts, principal, interest, fees, Bank Expenses, and other amounts Borrower owes Bank now or later, whether under this Agreement, the other Loan Documents, or otherwise, including, without limitation, all obligations relating to letters of credit (including reimbursement obligations for drawn and undrawn letters of credit), cash management services, and foreign exchange contracts, if any, and including interest accruing after Insolvency Proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank, and to perform Borrower's duties under the Loan Documents.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Other Equipment**" is leasehold improvements, intangible property such as computer software and software licenses, equipment specifically designed or manufactured for Borrower, other intangible property, limited use property and other similar property and soft costs approved by Bank, including taxes, shipping, warranty charges, freight discounts and installation expenses.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"**Payment/Advance Form**" is that certain form attached hereto as Exhibit D.

"**Perfection Certificate**" is defined in Section 5.1.

"**Permits**" means all governmental licenses, authorizations, provider numbers, supplier numbers, registrations, permits, certificates, franchises, qualifications, accreditations, consents and approvals required under all applicable laws and required in order to carry on its business as now conducted, including, without limitation, Healthcare Permits.

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to Bank under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and shown on the Perfection Certificate;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(f) Indebtedness secured by Liens permitted under clauses (a) and (c) of the definition of "Permitted Liens" hereunder;

(g) other Indebtedness not enumerated above not to exceed Ten Thousand Dollars ($10,000) at any time; and

(h) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (f) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments (including, without limitation, Subsidiaries) existing on the Effective Date and shown on the Perfection Certificate;

(b) (i) Investments consisting of Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Bank;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of deposit accounts in which Bank has a perfected security interest;

(e) Investments accepted in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of the creation of a Subsidiary for the purpose of consummating a merger transaction permitted by Section 7.3 of this Agreement, which is otherwise a Permitted Investment;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed One Hundred Thousand Dollars ($100,000) in the aggregate for (i) and (ii) in any fiscal year;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;

(j) non-cash joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support; and

(k) other Investments not otherwise permitted by Section 7.7 not exceeding Ten Thousand Dollars ($10,000) in the aggregate outstanding at any time.

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date and shown on the Perfection Certificate or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) purchase money Liens (i) on Equipment (other than Financed Equipment) acquired or held by Borrower incurred for financing the acquisition of the Equipment securing no more than Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate amount outstanding, or (ii) existing on Equipment (other than Financed Equipment) when acquired, if the Lien is confined to the property and improvements and the proceeds of the Equipment;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Twenty Five Thousand Dollars ($25,000) and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Bank a security interest therein;

(h) non-exclusive license of Intellectual Property granted to third parties in the ordinary course of business, and licenses of Intellectual Property that could not result in a legal transfer of title of the licensed property that may be exclusive in

respects other than territory and that may be exclusive as to territory only as to discreet geographical areas outside of the United States; and

(i) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under Sections 8.4 and 8.7.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Fee**" is, with respect to any Equipment Advance subject to prepayment prior to the Equipment Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Equipment Advance through and including the first anniversary of the Funding Date of such Equipment Advance, three percent (3.00%) of the principal amount of such Equipment Advance prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Equipment Advance through and including the second anniversary of the Funding Date of such Equipment Advance, two percent (2.00%) of the principal amount of the Equipment Advance prepaid; and

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Equipment Advance and prior to the Equipment Maturity Date, one percent (1.00%) of the principal amount of the Equipment Advance prepaid.

"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors).

"**Quarterly Financial Statements**" is defined in Section 6.2(a).

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Regulatory Change**" means, with respect to Bank, any change on or after the date of this Agreement in United States federal, state, or foreign laws or regulations, including Regulation D, or the adoption or making on or after such date of any interpretations, directives, or requests applying to a class of lenders including Bank, of or under any United States federal or state, or any foreign laws or regulations (whether or not having the force of law) by any court or governmental or monetary authority charged with the interpretation or administration thereof.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the Chief Executive Officer, President, Chief Financial Officer and Controller of Borrower.

"**Restricted License**" is any material license or other agreement with respect to which Borrower is the licensee (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such license or agreement or any other property, or (b) for which a default under or termination of could interfere with the Bank's right to sell any Collateral.

"**SEC**" shall mean the Securities and Exchange Commission, any successor thereto, and any analogous Governmental Authority.

"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Subordinated Debt**" is indebtedness incurred by Borrower subordinated to all of Borrower's now or hereafter indebtedness to Bank (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Bank entered into between Bank and the other creditor), on terms acceptable to Bank.

"**Subsidiary**" is, as to any Person, a corporation, partnership, limited liability company or other entity of which shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the board of directors or other managers of such corporation, partnership or other entity are at the time owned, or the management of which is otherwise controlled, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of Borrower.

"**Third-Party Payor**" means Medicare, Medicaid, TRICARE, and other state or federal health care program, Blue Cross and/or Blue Shield, private insurers, managed care plans and any other Person or entity which presently or in the future maintains Third-Party Payor Programs.

"**Third-Party Payor Programs**" means all payment and reimbursement programs, sponsored by a Third-Party Payor, in which a Borrower or any Subsidiary participates.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 7.1.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

TROVAGENE, INC.

By /s/ Stephen Zaniboni

Name: Stephen Zaniboni

Title: CFO

BANK:

SILICON VALLEY BANK

By /s/ Anthony Flores

Name: Anthony Flores

Title: Vice President

EXHIBIT A - COLLATERAL DESCRIPTION

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All Equipment financed by Bank, including the following:

Equipment listed on Annex A

and all Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

EXHIBIT B

CORPORATE BORROWING certificatE

Borrower: **Trovagene, Inc.** **Date**: November 17, 2015
Bank: Silicon Valley Bank

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto are true, correct and complete copies of Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth above. Such Certificate of Incorporation have not been amended, annulled, rescinded, revoked or supplemented, and remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and Silicon Valley Bank ("Bank") may rely on them until Bank receives written notice of revocation from Borrower.

Resolved, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories
			☐
			☐
			☐
			☐

Resolved Further, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

Resolved Further, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from Bank.
Execute Loan Documents. Execute any loan documents Bank requires.
Grant Security. Grant Bank a security interest in any of Borrower's assets.
Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Apply for Letters of Credit. Apply for letters of credit from Bank.
Enter Derivative Transactions. Execute spot or forward foreign exchange contracts, interest rate swap agreements, or other derivative transactions.
Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effect these resolutions.

Resolved Further, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name: _____
Title: _____

*** *If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the _____ of Borrower, hereby certify as to paragraphs 1 through 5 above, as of the date set forth above.

By: _____
Name: _____
Title: _____

EXHIBIT C

COMPLIANCE CERTIFICATE

TO: SILICON VALLEY BANK Date:
FROM: TROVAGENE, INC.

The undersigned authorized officer of TROVAGENE, INC. ("Borrower") certifies that under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"):

(1) Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below; (2) there are no Events of Default; (3) all representations and warranties in the Agreement are true and correct in all material respects on this date except as noted below; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date; (4) Borrower, and each of its Subsidiaries, has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 5.8 of the Agreement; and (5) no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

Attached are the required documents supporting the certification. The undersigned certifies that these are prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. The undersigned acknowledges that no borrowings may be requested at any time or date of determination that Borrower is not in compliance with any of the terms of the Agreement, and that compliance is determined not just at the date this certificate is delivered. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	**Required**	**Complies**
Quarterly financial statements with Compliance Certificate	Quarterly within 30 days	Yes No
Annual financial statement (CPA Audited) + CC	FYE within 180 days	Yes No
10-Q, 10-K and 8-K	Within 5 days after filing with SEC	Yes No
Annual financial projections, budget	Annually (within 60 days of FYE), and when revised	Yes No

Other Matters

Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No

The following are the exceptions with respect to the certification above: (If no exceptions exist, state “No exceptions to note.”)

BANK USE ONLY

Received by: _____
authorized signer
Date: _____

Verified: _____
authorized signer
Date: _____

Compliance Status:Yes No

TROVAGENE, INC.

By:
Name:
Title:

EXHIBIT D - LOAN PAYMENT/ADVANCE REQUEST FORM

Deadline for same day processing is Noon Pacific Time Unless otherwise provided for an Advance bearing interest at LIBOR.

Fax To: Date: _____

Loan Payment:

TROVAGENE, INC.

From Account #_____ To Account #_____
(Deposit Account #) (Loan Account #)
Principal $_____ and/or Interest $_____

Authorized Signature: Phone Number:
Print Name/Title:

Loan Advance:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #_____ To Account #_____
(Loan Account #) (Deposit Account #)

Amount of Advance $_____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature: Phone Number:
Print Name/Title:

Outgoing Wire Request:
Complete only if all or a portion of funds from the loan advance above is to be wired.
Deadline for same day processing is noon, Pacific Time

Beneficiary Name: _____ Amount of Wire: $
Beneficiary Bank: _____ Account Number:
City and State:

Beneficiary Bank Transit (ABA) #: Beneficiary Bank Code (Swift, Sort, Chip, etc.):
(For International Wire Only)

Intermediary Bank: Transit (ABA) #:
For Further Credit to:

Special Instruction:

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____
Print Name/Title: _____ Print Name/Title: _____
Telephone #: Telephone #:

SCHEDULE 1 - FORM OF LOAN AGREEMENT SUPPLEMENT

LOAN AGREEMENT SUPPLEMENT No. [ ]

LOAN AGREEMENT SUPPLEMENT No. [ ], dated _____, 20____ ("**Loan Supplement**"), to the Loan and Security Agreement dated as of November 17, 2015 (as amended, restated, or otherwise modified from time to time, the "**Loan Agreement**) by and between the undersigned TROVAGENE, INC. ("**Borrower**") and Silicon Valley Bank ("**Bank**"). Capitalized terms used herein but not otherwise defined herein are used with the respective meanings given to such terms in the Loan Agreement.

To secure the prompt payment by Borrower of all amounts from time to time outstanding under the Loan Agreement, and the performance by Borrower of all the terms contained in the Loan Agreement, Borrower grants Bank, a first priority security interest in each item of equipment and other property described in Annex A hereto, which equipment and other property shall be deemed to be additional Financed Equipment and Collateral. The Loan Agreement is hereby incorporated by reference herein and is hereby ratified, approved and confirmed. Annex A (Equipment Schedule) is attached hereto. The proceeds of the Equipment Advance should be transferred to Borrower's account with Bank set forth below:

Bank Name: Silicon Valley Bank

Account No.: [...***...]

Borrower hereby certifies that (a) the foregoing information is true and correct and authorizes Bank to endorse in its respective books and records, the interest rate applicable to the Funding Date of the Equipment Advance contemplated in connection with this Supplement and the principal amount set forth below; (b) the representations and warranties made by Borrower in the Loan Agreement are true and correct on the date hereof and shall be true and correct on such Funding Date. No Event of Default has occurred and is continuing under the Loan Agreement. This Supplement may be executed by Borrower and Bank in separate counterparts, each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute but one and the same instrument.

Equipment Advance Funding Date: _____, 20____

Equipment Advance Amount: $_____

Interest Rate: _____%

This Supplement is delivered as of this day and year first above written.

SILICON VALLEY BANK By: _____ Name: Title:	TROVAGENE, INC. By: _____ Name: Title:

Annex A - Description of Financed Equipment

Exhibit 21

List of Subsidiaries

Name of Subsidiary	Percentage of Ownership	Jurisdiction of Incorporation
Trovagene Srl	100%	Italy

Exhibit 21

Consent of Independent Registered Public Accounting Firm

Trovagene, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-208010) and Form S-8 (Nos. 333-205424 and 333-190415) of Trovagene, Inc. of our reports dated March 10, 2016, relating to the consolidated financial statements, and the effectiveness of Trovagene, Inc.'s internal control over financial reporting, which appear in this Form 10-K.

/s/ BDO USA, LLP

San Diego, California
March 10, 2016

Exhibit 31.1

CERTIFICATION

I, Antonius Schuh, certify that:

1. I have reviewed this annual report on Form 10-K of Trovagene, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2016

/s/ANTONIUS SCHUH

Antonius Schuh
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Stephen Zaniboni, certify that:

1. I have reviewed this annual report on Form 10-K of Trovagene, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 10, 2016

/s/ Stephen Zaniboni

Stephen Zaniboni
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trovagene, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Antonius Schuh, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1)

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 10, 2016

/s/ Antonius Schuh

Antonius Schuh
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Trovagene, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen Zaniboni, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1)

The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2)

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 10, 2016

/s/ Stephen Zaniboni

Stephen Zaniboni
Chief Financial Officer