UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

OR

☐ **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: 001-36284

Biocept, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**80-0943522**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5810 Nancy Ridge Drive, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 320-8200

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

Title of Each Class	**Name of Exchange on Which Registered**
Common Stock, par value $0.0001 per share	**The NASDAQ Stock Market LLC**

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 ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 ☒ NO ☐

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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. ☒

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 definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2014, was $14,155,783. Shares of common stock held beneficially by Claire K.T. Reiss and by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 2, 2015 was 15,966,052.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2015 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K. Except for the portions of the Proxy Statement specifically incorporated by reference in this Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Annual Report other than statements of historical fact, are forward-looking statements. You can identify these and other forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" in Part I, Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report and elsewhere in this Annual Report. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made except as required by law. Readers should, however, review the factors and risks we describe in the reports we file from time to time with the Securities and Exchange Commission, or the SEC.

PART I

Item 1. Business

Overview

We are a cancer diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, tests utilizing a standard blood sample, or "liquid biopsy." These tests provide information to oncologists and other physicians that enable them to select the most appropriate treatment for their patients based on better, timelier and more-detailed data on the characteristics of tumors. Our current OncoCEE-BR for breast cancer test, OncoCEE-LU for NSCLC test and OncoCEE-GA for gastric cancer test and our planned tests utilize our Cell Enrichment and Extraction, or CEE, technology for the enumeration and analysis of CTCs, and our CEE-Selector technology for the detection and analysis of ctDNA, each performed on a standard blood sample. The CEE technology is an internally developed, microfluidics-based CTC capture and analysis platform, with enabling features that change how CTC testing can be used by clinicians by providing real-time biomarker monitoring with a standard blood sample. The CEE-Selector technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood plasma for ctDNA. We believe CEE-Selector technology is an important part of certain of our pipeline CTC tests, and believe it could also be a stand-alone test for molecular analysis of biomarkers.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP, and manufacture our CEE microfluidic channels, related equipment and certain reagents to perform our current tests and our planned future tests at this facility. CLIA certification is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of health. The OncoCEE-BR, OncoCEE-LU, and OncoCEE-GA tests and the tests we plan to offer are classified as laboratory developed tests, or LDTs.

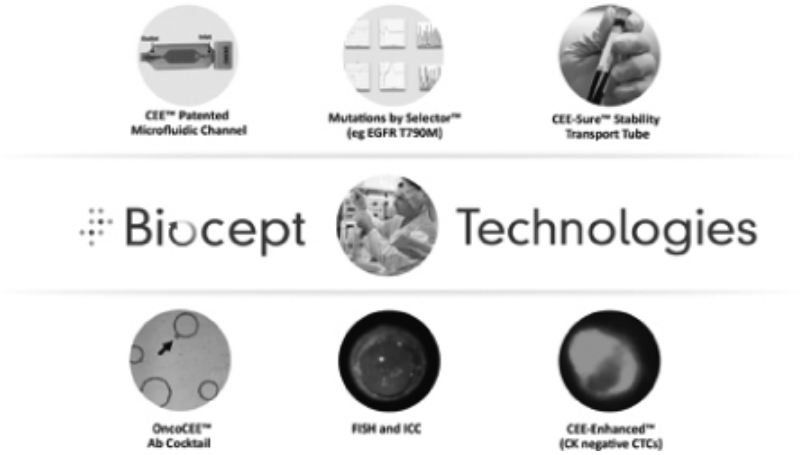
OncoCEE-BR is a breast cancer CTC test and OncoCEE-GA is a gastric cancer CTC test, each of which are performed on a standard blood sample. They detect CTCs, which are typically very rare compared to normal blood cells, and determine the patient's human epidermal growth factor receptor 2, or HER2, status by fluorescence *in situ* hybridization, or FISH. In addition, OncoCEE-BR is used to detect the presence of ER, which is the biomarker that indicates the likely responsiveness of a patient's tumor to hormonal therapies.

We believe that the OncoCEE-BR and OncoCEE-GA tests offers advantages over other available CTC tests, with improved sensitivity and enumeration results as well as diagnostic biomarker analyses. Competitive CTC tests rely on the expression of the epithelial cell adhesion molecule, or EpCAM, and cytokeratins for CTC capture, detection and enumeration. This approach may exclude CTCs that have undergone intrinsic modifications of their phenotype, such as the epithelial-to-mesenchymal transition, or EMT, thought to be critical for metastasis. EMT may represent a possible explanation for many patients who, despite an aggressive disease, are found to be negative for the presence of CTCs by current technologies. OncoCEE™ captures and detects EpCAM and cytokeratin negative CTCs, which are more mesenchymal-like. Additionally, the OncoCEE platform enables evaluation of treatment-associated biomarkers, like HER2 status, which qualifies patients as candidates for HER2-targeted therapeutics, and ER status, which qualifies patients as candidates for hormone therapies. We plan to include immunocytochemical analysis of progesterone receptor proteins, as well as mutation analysis as appropriate, into the OncoCEE-BR test within the next year.

We launched OncoCEE-LU, a test performed on a standard blood sample for non-small cell lung cancer, or NSCLC, in November of 2014. The biomarkers to be analyzed in the OncoCEE-LU test include ALK and ROS1 gene fusions by FISH, and the epidermal growth factor receptor, or EGFR, gene. We expect to add FISH testing for RET and MET genes, as well as mutation analysis for the EGFR gene, the K-ras gene and the B-raf gene during 2015.

Our OncoCEE-LU test is run against a standard blood sample.

We plan to add other biomarker analyses to our OncoCEE tests as their relevance is demonstrated in clinical trials, for example, RET proto-oncogene gene fusions in NSCLC, which may indicate a particular course of therapy. In addition, we are developing a series of other CTC and ctDNA tests for different solid tumor types, including colorectal cancer, prostate cancer, gastric cancer and melanoma, each incorporating treatment-associated biomarker analyses specific to that cancer, planned to be launched over the next two years.



Biomarkers are molecular or cellular features of a cancer cell that indicate an abnormality. This abnormality, typically a genetic mutation or aberration, detected at either the gene, protein or metabolite level, may in fact be responsible for the transformation of the cell from a normal cell to a cancer cell. We have focused our efforts on biomarkers associated with specific targeted cancer therapeutics, or resistance to those therapeutics. Examples include an amplified HER2 gene, which is associated with HER2-targeted therapeutics like Herceptin®, Perjeta®, Kadcyla® and Tykerb® for the treatment of breast cancer, or a mutated B-raf gene, which is associated with the drugs Zelboraf® (Daiichi-Sankyo/Genentech/Roche) and Tafinlar® (GlaxoSmithKline) for the treatment of melanoma. This is important because the presence or level of these biomarkers indicates to a physician that the associated therapy is appropriate for the patient, or instead that the patient has, or has developed, resistance to that therapy.

Biomarkers have traditionally been detected in tumor tissue after biopsy or re-section, with the analysis performed by a pathologist. We are able to perform these same analyses on CTCs or ctDNA on a standard blood sample using our CEE and CEE-Selector technology in our CLIA laboratory, meaning that the biomarkers detected in a patient's tumor can now be monitored on a real-time basis without the need for a tissue biopsy. Because of the difficulty or inability to obtain periodic tissue biopsies, especially at the time of recurrence, this offers the physician a new source and level of information than was previously available.

We also have a research and development program focused on technology enhancements and novel platform development and are evaluating clinical applications for cancer diagnostic tests in different cancer types and clinical settings. We offer our current and planned unique cancer diagnostic tests through our CLIA laboratory to physicians for patient care applications as well as to pharmaceutical and biopharmaceutical companies and academic centers using CTC or ctDNA testing, with biomarker analysis including genetic analysis, in their clinical trials and research efforts. CTC tests, particularly those that offer analysis of CTCs for treatment-associated biomarkers, are becoming powerful tools in the practice of personalized medicine. They enable physicians to utilize a standard blood sample as a "liquid biopsy" to assess the status of their patient's cancer at a cellular and molecular level on an ongoing basis, and to select therapies that have the highest likelihood of benefiting their patients.

Since launch, our average price received per OncoCEE-BR test performed for commercial customers has been approximately $787. This was heavily influenced by the fact that historically a high percentage of our sales were through our marketing partner, Clarient. We amended our arrangement with Clarient as of May 2013, and we do not expect a significant percentage of our future sales to come through Clarient. Our OncoCEE-LU and OncoCEE-GA tests were launched in late 2014 and we have not yet recognized significant revenues from these tests. Our future average price for commercial customers could increase from our historical figure, based on recognition of the medical value of our products, publication of clinical utility study results, possible improvement of the product, introduction of additional tests, increased demand generated by our future sales and marketing efforts, and similar commercial factors. Factors that could cause pricing for commercial customers to decrease include any perceived lack of clinical utility for CTC or ctDNA testing, or increased competition from other reference labs or IVD manufacturers. Third-party governmental and private payors have reimbursement policies and fee schedules which determine the amounts, if any, we would receive for performing tests for their covered patients. Such governmental and private third-party payors frequently make determinations about how much (if anything) they are willing to pay for tests such as ours, or for components of such tests; these determinations are important to our business and can have adverse or positive effects on the price we receive for our testing. For example, private payors often look to Medicare policies and rates when setting their reimbursement rates.

In addition, our reimbursement rates can vary based on whether we are considered by private third-party payors to be an "in-network" provider, a participating provider, a covered provider or an "out-of-network" provider. These definitions can vary from insurance company to insurance company, but we are generally considered an "out-of-network" or non-participating provider by the vast majority of private third-party payors. It is not unusual for a company that offers highly specialized or unique testing to be an "out-of-network" provider. An "in-network" provider usually has a contracted arrangement with the insurance company or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an "in-network" rate for our testing rather than pay the typical "out-of-network" rate. An "in-network" provider usually has rates that are lower per test than those that are "out-of-network", and that rate can vary from a single digit percentage deduction discount to upwards of 25% to 30% lower than an "out-of-network" provider. The discount rate varies based on the insurance company, the testing type and often times the specifics of the patient's insurance plan. In some plans, there is no benefit paid for out-of-network claims and our ability to collect from the patient may be hindered by the financial resources of the patient or by state laws that prohibit billing of patients for denied out-of-network claims.

We cannot predict whether, or under what circumstances, payors will reimburse for all components of our tests. Payment amounts can also vary across individual policies. Full or partial denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

To date, we have engaged in only limited sales and marketing activities. Such activities have primarily related to our OncoCEE-BR test. We have a sales and marketing team to market and sell OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA and our planned future cancer diagnostic tests directly to oncologists and other physicians. We have an initial group of 8 sales representatives, and, based on success and test volume, plan to grow this number to 15-20 within two years.

We collaborate with physicians and researchers at The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, Yale University and Columbia University and plan to expand our collaborative relationships to include other key thought leaders at other institutions for the cancer types we target with OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA and our planned future CTC and ctDNA tests. Such relationships help us develop and validate the effectiveness and utility of OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA and our planned future tests in specific clinical settings and provide us access to patient samples and data. We completed a study, recently published in *Cancer Medicine*, utilizing our OncoCEE-BR test, and a version of this test adapted for use with bone marrow samples, with a group at The University of Texas MD Anderson Cancer Center comprised of breast cancer surgeons, pathologists and basic researchers. In this study, we demonstrated the ability to identify HER2 positive CTCs and disseminated tumor cells, or DTCs, seen in bone marrow in patients that had been previously classified as HER2 negative by analysis of their tumor tissue. A HER2 positive result in a patient with breast cancer provides an indication to the physician that there is likely to be a survival benefit from treatment with Herceptin®, which has been demonstrated in a number of large clinical studies.

We are currently involved in a clinical study following up on this finding in CTCs, employing OncoCEE-BR tests for patient selection and monitoring. This study, led by investigators at the Dana-Farber Cancer Institute, has completed enrolling patients. In the screening phase of this study, we tested in our CLIA-certified, CAP accredited, and state-licensed laboratory blood samples from HER2 negative patients based on standard tumor tissue analysis, to identify those patients that have HER2 positive CTCs. These patients were then assigned to chemotherapy plus Herceptin®, and followed for a period of time, with additional CTC tests, including biomarker analysis for HER2 using FISH, performed at subsequent time points. In December 2014 we announced preliminary findings that were presented at the San Antonio Breast Conference that 22 percent of 311 patients tested, who were previously HER2 negative according to a solid tumor biopsy, were found, upon disease progression, to be HER2 positive by CTC analysis, making them potential candidates for anti-HER2 therapy as the cancer evolves. Moreover, our multi-antibody CTC capture method identified a substantial subset of patients who would not likely be detected with commonly used CTC capture technologies. This added 10 percent (included in the 22 percent) to the number of women who were candidates for this highly specific targeted therapy.

With our cooperation, researchers at Columbia published a study in the journal, Clinical and Translational Oncology in February 2015. The study demonstrated the high correlation (79%) of circulating tumor cells, primary tumor tissue biopsy and metastatic tumor tissue biopsy for determination of hormone receptor status (ER/PR) in breast cancer patients. The investigators also found that this high correlation was strongest when comparing metastatic tissue biopsy to CTCs (83%). The conclusion of the study was that determining ER/PR status in CTCs using the OncoCEE platform is feasible, with high concordance in ER/PR between tumor tissue (as determined with immunohistochemistry, or IHC) and CTCs (as determined with immunocytochemistry, or ICC). The authors suggest a larger trial to determine the prognostic significance of these findings.

We plan to grow our business by directly offering oncologists and other physicians our liquid biopsy CTC and ctDNA tests. Based on our product development data, as well as discussions with our collaborators, we believe that our planned tests should provide important information and clinical value to physicians. In particular, CTC and ctDNA tests should deliver important, actionable information not provided by other tests. For example, the market leading clinical CTC test is the United States Food and Drug Administration, or FDA, approved CellSearch® test (Janssen Diagnostics), which provides CTC enumeration, but is not FDA approved to perform biomarker analysis. We believe our ability to rapidly translate research insights about the utility of cytogenetic, immunocytochemical and molecular biomarkers to provide information to oncologists and other physicians for treatment decisions in the clinical setting will improve patient treatment and management, and that these tests will become a key component in the standard of care for personalized cancer treatment.

According to the National Cancer Institute, there will be approximately 230,000 new cases of breast cancer and approximately 220,000 new cases of lung cancer diagnosed in the United States in 2014, with over 3 million patients who have had a diagnosis of these cancers and either are living with these diseases and are undergoing treatment or are being monitored. For example, in breast cancer, many women have been deemed cancer-free, but continue to undergo periodic monitoring to assure there has been no disease recurrence. Our OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA tests and our other planned tests only require a readily accessible standard blood sample and thus may be used to help manage these patients, including supporting the selection of appropriate treatment, at multiple time points during the course of their disease. Because our tests require only a standard blood sample, they can be particularly useful when no, old or inadequate amounts of, biopsy or surgical material is available, as is often the case in lung cancer, even at the time of initial evaluation. For example, up to 25% of patients with lung cancer are not surgically treated for various reasons, including patient status (consensus statement from the American College of Chest Physicians and the Society of Thoracic Surgeons; *Chest*, Dec. 2012). This is also the case with breast and lung cancers once surgical resection of the tumor has taken place and treatment has been initiated. Patients with breast and lung cancer must often undergo surgical resection of their primary tumor as part of their treatment. Therefore, at the time of progression or recurrence there may be no ability to obtain a tissue biopsy. Additionally, many studies have shown that most tumors mutate during treatment and as the disease progresses, so information from the initial tumor tissue may not be relevant. Again, a significant benefit of our technology is that it allows physicians to assess the current status of the tumors on a real-time basis utilizing a standard blood sample or liquid biopsy.

We currently offer and conduct our breast and lung cancer diagnostic tests and offer our clinical trial services at our CLIA-certified, CAP-accredited and state- licensed laboratory. Our current tests and our planned near-term cancer diagnostic tests and clinical trial services include:

- *CTC and ctDNA Testing*. Our current tests and our other planned cancer diagnostic tests are based on our CEE and CEE-Selector technologies and are currently intended to be performed only in our clinical laboratory. After completing testing, we or our partner provide our customers with an easy to understand report that describes the results of the analyses performed, designed to help oncologists and other physicians make better decisions about the treatment of their patients.
- *Clinical Trial Services.* We plan to utilize our clinical laboratory and translational research capabilities to provide clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations to improve the efficiency and economic viability of their clinical trials. Our clinical trials and translational research services could leverage our knowledge of CTCs and ctDNA and our ability to develop and implement new cytogenetic, immunocytochemical and molecular diagnostic tests. Our current tests can, and our other planned cancer diagnostic tests and biomarker tests are anticipated to be able to, help optimize clinical trial patient selection, and as a result potentially improve the likelihood of success of the clinical trial. With positive results in a clinical trial, our tests would more easily then move into standard clinical practice, helping physicians select the most appropriate therapy for their patients.

We intend to commercialize cancer diagnostic tests in the United States as LDTs performed in our CLIA-certified, CAP-accredited, and state-licensed laboratory. We plan to evaluate potential opportunities for the commercialization of our products in other countries. We are currently exploring the possibility of introducing OncoCEE technology outside the United States as part of CE-marked IVD test kits and/or testing systems utilizing our CEE and/or CEE-Selector technologies.

Our sales strategy is to engage oncologists and other physicians in the United States at private and group practices, hospitals and cancer centers. In addition, we market our clinical trial and research services to pharmaceutical and biopharmaceutical companies and clinical research organizations.

Market Overview

Cancer Market Overview

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. According to the World Cancer Report 2014, cancers figure among the leading causes of morbidity and mortality worldwide, with approximately 14 million new cases and 8.2 million cancer related deaths in 2012. It is also expected that the number of new cases will rise by approximately 70% over the next two decades. The incidence of, and deaths caused by, the major cancers are staggering. The following data published by the National Cancer Institute shows estimated new cases and deaths for 2014, and prevalence in 2010, in the United States for the major solid cancers types:

Cancer Type	Est. Incidence (New Cases/Year-2014)	Est. Mortality (Deaths/Year-2014)	Est. Prevalence (Diagnosed and Alive as of 2010)**
Bladder	74,690	15,580	563,640
Breast*	232,670	40,000	2,843,629
Cervical	12,340	4,030	249,496
Colorectal*	136,830	50,310	1,154,481
Endometrial	52,630	8,590	600,346
Gastric*	22,220	10,990	72,269
Kidney	63,920	13,860	341,505
Lung*	224,210	159,260	399,431
Melanoma*	76,100	9,710	921,780
Ovarian	22,240	14,030	186,138
Pancreatic	46,420	39,590	41,609
Prostate*	233,000	29,480	2,617,682
Thyroid	62,980	1,890	534,973

* Areas where we currently have tests or active development programs.

** Includes active disease and disease-free.

In addition to the human toll, the financial cost of cancer is overwhelming. An independent study published in 2010 and conducted jointly by the American Cancer Society and LIVESTRONG ranked cancer as the most economically devastating cause of death in the world - estimated to be as high as $895 billion globally. According to an article in the Journal of the National Cancer Institute, the direct cost of cancer deaths in the United States in 2000 was over $115 billion, and if lost wages and caregiver costs were added, the total costs increased to over $230 billion.

Cancer is a Heterogeneous Disease

Cancer constitutes a heterogeneous class of diseases, characterized by uncontrolled cell growth that results from a combination of both environmental and hereditary risk factors. Many different tissue types can become malignant, such as breast, lung, liver, and skin, and even within a particular tumor there is heterogeneity, with certain cancer cells in a patient bearing specific cellular or genetic biomarkers which others lack. It has only been in recent years that technology has progressed far enough to enable researchers to understand many cancers at a cellular and molecular level, attribute specific cancers to associated genetic changes and determine the extent to which these changes are seen in a patient’s tumor.

Cancer cells contain genetic alterations compared to normal human cells. Common genetic abnormalities correlated to cancer include gains or losses of genetic material on specific chromosomal regions, or loci, or changes in specific genes, or mutations, which ultimately result in detrimental cellular changes followed by cancerous or pre-cancerous conditions. For example, multiple gains or losses of or on various chromosomes, and the rearrangement of genetic material among chromosomes, or chromosomal translocations, have been observed in different cancer types, such as HER2 in breast cancer and ALK rearrangements in NSCLC. In addition, mutations within gene sequences, or single nucleotide variations, can give rise to aberrant proteins that do not perform their functions correctly, leading to uncontrolled cell growth. Such genetic alterations can be a result of multiple factors, including genetic predisposition, environmental or lifestyle factors or viral infections. Importantly, these genetic changes can be used as biomarkers to help guide appropriate treatment. Detecting these biomarkers, particularly those representing drug targets, or those indicative of responsiveness or resistance of a tumor’s cells to specific therapies, helps clinicians to select drugs, design treatment regimens and optimize patient care and management. Tests that provide such predictive information have the potential to dramatically improve treatment outcomes for patients suffering from cancer.

Limitations of Traditional Cancer Diagnostic and Profiling Approaches

Cancer is difficult to diagnose and manage due to its heterogeneity at morphologic, genetic and clinical levels. Traditional methods of diagnosis for solid tumors, routinely used as the initial step in cancer detection, involve a tissue biopsy followed by a pathologist examining a thin slice of potentially cancerous tissue under a microscope. A recently obtained tissue sample is used in combination with chemical staining techniques to enable analysis of the biopsy. After staining, the pathologist determines through visual inspection whether the biopsy contains normal or cancerous cells, with those that are deemed cancerous being graded on a level of aggressiveness. Often an analysis of biomarkers relevant to that tumor type is also performed on the tissue, ranging from immunohistochemistry to FISH, to mutation analysis by various means such as microarrays and sequencing. After the diagnosis, a clinical workup is performed according to established guidelines for the specific cancer type. From there, the physician determines the stage of progression of the cancer based on a series of clinical measures, such as size, grade, metastasis rates, symptoms and patient history, and decides on a treatment plan that may include surgery, watchful waiting, radiation, chemotherapy, or stem cell transplant.

This type of analysis is dependent on the availability of a recently obtained tissue biopsy for the pathologist to analyze. Such a biopsy is often not available. A tumor may not be readily accessible for biopsy, a patient's condition may be such that a biopsy is not advised, and for routine periodic patient monitoring to evaluate potential progression or recurrence, a biopsy is a fairly invasive procedure and not typically performed. As the length of time between when the original biopsy, diagnosis or surgery is conducted to the current evaluation of the patient increases, the likelihood that an original biopsy specimen is truly representative of the current disease condition declines, as does the usefulness of the original biopsy for making treatment decisions. This risk intensifies in situations where a drug therapy is being administered, because the drug can put selective pressure on the tumor cells to adapt and change.

Similarly, the heterogeneity referred to above means that different parts or areas of the same tumor can have different molecular features or properties. In evaluating a biopsy specimen, the pathologist will take a few thin slices of the tumor for microscopic review rather than exhaustively analyzing the whole tumor mass. The pathologist can only report on the tumor sections analyzed and if other parts of the tumor have different features, such as biomarkers corresponding to specific treatments, they can be missed. A more representative analysis of the entire tumor, as well as any metastases if they are present, is very helpful.

CTCs, ctDNA and Cancer

CTCs are cancer cells that have detached from the tumor matrix and invaded the patient's blood or other bodily fluids. These cells are representative of the tumor and its metastases, and can function as their surrogates. Testing CTCs can complement pathologic information drawn from a biopsy or resected tissue sample, helping to insure that the analysis is comprehensive and not biased by tumor heterogeneity and sampling issues. They can also provide critical data when a biopsy is not possible. Clinical studies have demonstrated that the presence and number of CTCs provides information on the likely course of certain types of disease for the cancer patient, or in other words they are considered "prognostic." Since CTCs are representative of the tumor, they can also be used for biomarker analysis, such as helping to guide therapy selection. Such analyses are "predictive" in that they offer insight into the likely responsiveness or resistance to particular therapies. After surgery and during any subsequent therapy or monitoring period, blood samples can periodically be drawn in a standard manner and analyzed to evaluate a therapy's continuing effectiveness, as well as to detect other biomarkers such as new genetic mutations that may arise as a result of selection pressure by a particular therapy or by chance. Physicians can use this information to determine which therapy is most likely to benefit their patients at particular times through the course of their disease. Treatment decisions based on patient-specific information are the foundation of personalized medicine, and tests, or assays, that guide a physician in the selection of individualized therapy for a patient are termed "predictive assays."

ctDNA is nucleic acid that is released into blood by dying tumor cells. Cell death occurs in all tissues, especially those that are rapidly dividing, and in cancer, where cell growth is not only rapid but also uncontrolled. Parts of tumors often outgrow their blood supply, resulting in cell death. Tumor cells dying as a result of therapy also release nucleic acid into blood. As a consequence, ctDNA is common in cancer patients and scientists believe that like CTCs, it may be more representative of a patient's tumor than a few thin sections from a tissue biopsy, thus reducing the heterogeneity problem. ctDNA is found in the plasma component of blood and is readily accessible in a standard blood sample. Analyzing ctDNA for mutations that are used as biomarkers for therapy selection shows great promise. One of the strengths of this approach, in addition to not requiring a tissue biopsy, is that it is not dependent on capturing rare tumor cells from blood to provide a sample for testing. The difficulty with this approach is that the cellular context is lost since the ctDNA is mixed with a much larger amount of circulating DNA from normal cells that are continuously dying and being replaced in the body, thus making analysis challenging. This requires a mutation detection methodology with enhanced sensitivity and specificity, to distinguish mutations in particular gene regions in cancer cells from the normal gene sequence present in those same genes in normal cells which co-exist in blood as normal cells die and are replaced in the body. Our CEE-Selector technology provides this necessary sensitivity and specificity and creates an opportunity for ctDNA analysis to complement CTC analysis, or potentially to serve as the platform for stand-alone tests.

Given the incidence of cancer in the United States, with an estimated 925,000 new cases in 2014 for the major solid tumors targeted by our planned test products, the markets for our current and planned cancer diagnostic tests are very large. Furthermore, these market opportunities are even greater due to the benefits of CTC and ctDNA testing, including not only the ability to offer physicians a simple way to augment an initial tumor biopsy analysis but also to provide a means for relatively frequent monitoring of the tumor's molecular status, utilizing a standard blood sample as a "liquid biopsy." The latter application enables the physician to determine if or how a tumor is changing over time or is responding to therapy and what the next treatment should be. For example, in the United States, the incidence of new cases of breast cancer alone is estimated to be over 230,000 in 2014, and the prevalence of this disease is over 2.8 million (the number of women with a history of breast cancer in the United States, including women being treated and women who have finished treatment), with an estimated 330,000 lumpectomies performed annually in the United States. Of these lumpectomies, 20% need to be repeated because on pathological examination it is shown the procedure did not result in "clean margins," thus suggesting not all the tumor was removed, according to a Johns Hopkins report. If a CTC test were performed at the time of initial diagnosis, at the time of surgery, or in lieu of, or as an adjunct to, a PET/CT scan (as a CTC test has the potential to identify a single tumor cell in a blood sample, while a scan requires a tumor mass of millions of cells to be detectable), to monitor disease progression or test for recurrence, thousands of tests, in breast cancer alone, could be performed per year with still relatively low market penetration.

Use of CTC- and ctDNA-Derived Biomarker Data in Cancer Treatment

CTCs and ctDNA are derived from, and are understood to be representative of, a solid tumor and its metastases and can be analyzed as adjuncts to or in place of the tumor, especially when a recent tumor biopsy is not available. This is also referred to as a liquid biopsy. In theory, almost any analysis that can be performed on tumor tissue can also be performed on CTCs, while ctDNA, because it is only nucleic acid, is more limited. We have focused our analysis of CTCs and ctDNA on known biomarkers associated with specific therapies to support treatment decisions and therapy selection made by physicians. The biomarkers we analyze and internal to analyze consist of proteins or protein modifications that can be identified by immunocytochemical means, cytogenetic or chromosomal aberrations, which are detected by FISH, and gene mutations which are detected in CTCs or ctDNA by molecular diagnostic tests, including CEE-Selector techniques and gene sequencing. Specific examples include (i) for immunocytochemistry, the detection of the estrogen receptor protein in breast cancer, indicative of the likely responsiveness to hormonal therapies like tamoxifen, often sold under the trade name Nolvadex®, (ii) for FISH, the presence of an amplified HER2 gene in breast cancer, indicative of the likely responsiveness to HER2-targeted agents like trastuzumab, often sold under the trade name Herceptin®, and (iii) for mutation detection, the presence of an EGFR activating mutation in NSCLC like L858R, indicative of the likely responsiveness to EGFR-targeted agents like Tarceva®. All of these biomarkers are currently tested on tumor tissue and can be tested on CTCs, and in the latter case on ctDNA. The resulting information could then be used to guide patient care, and specifically treatment selection.

To date these types of molecular and genetic detection methods have been successfully utilized to provide predictive information for several cancers, including breast, colon, NSCLC, melanoma and others in the form of companion diagnostics, typically performed on tumor tissue. CTC and ctDNA tests, which analyze the same biomarkers but in a more convenient standard blood sample test that also permits periodic monitoring, may be used in the same way.

Our Business Strategy

We plan to provide oncologists and other physicians with a straightforward means to profile and characterize their patients' tumors on a real-time basis by analyzing CTCs and ctDNA found in standard blood draws. Biomarkers are currently detected and analyzed primarily in tissue biopsy specimens. We believe that our technology, which not only provides information on CTC enumeration but also the assessment of treatment-associated biomarkers identified within the CTCs or in ctDNA, will provide information to physicians that improves patient treatment and management and will become a key component in the standard of care for personalized cancer treatment.

Our approach is to develop and commercialize CTC and ctDNA tests and services to enable us to offer to oncologists standard blood sample based, real-time, testing solutions for a range of solid tumor types, starting with breast cancer and progressing to future launches of tests for NSCLC, gastric cancer, colorectal cancer, prostate cancer, melanoma and others, to improve patient treatment with better prognostic and predictive tools. To achieve this, we intend to:

- Develop and commercialize a portfolio of proprietary CTC and ctDNA tests and services, to enable physicians to develop personalized treatment plans. We intend to continue the development of additional prognostic and predictive tests and services to provide information that is essential to personalized cancer treatment. By including predictive information on biomarkers linked to specific therapies in our analysis in addition to CTC enumeration, our tests are designed to provide a more complete profile of a patient's disease than existing CTC tests. The biomarker information will assist physicians in selecting appropriate therapies for individual patients. Our ctDNA tests are expected to offer enhanced sensitivity and specificity based on the CEE-Selector technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions. We have launched our CTC tests, OncoCEE-BR for breast cancer, OncoCEE-GA for gastric cancer and OncoCEE-LU for NSCLC, performed in our CLIA-accredited testing facility. We are also developing a number of other CTC and ctDNA tests, including OncoCEE-CR for colorectal cancer, OncoCEE-PR™ for prostate cancer and OncoCEE-ME™ for melanoma. We plan to perform the necessary validation studies to allow us to commercialize these tests through our clinical laboratory.
- Scale our internal sales and marketing capabilities. We are actively seeking additional partners to increase our market reach. Our specialized sales force with experience in cancer diagnostic testing focuses on key identified territories in order to provide geographic coverage throughout the United States. We have 8 sales representatives, and depending on test volume, expect to increase this group to 15-20 within two years and potentially 40-50 within five years. This team will educate physicians directly on the benefits of our tests and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners.
- Develop and expand our collaborations with leading university hospitals and research centers. We collaborate with key thought leaders, physicians and clinical researchers, including those at The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, Yale University and Columbia University. Our collaborations enable us to test new technologies, validate the effectiveness and utility of our planned tests in a clinical setting and provide us access to clinically well-characterized and highly annotated patient data. These samples and data accelerate our validation process and facilitate the testing and refinement of our planned new tests.
- Enhance our efforts in reaching and educating oncologists and other physicians about CTC and ctDNA tests. According to the State of Cancer Care in America 2014 Report, published in the Journal of Clinical Oncology in March of 2014 there were approximately 13,000 medical oncologists in the United States or 15,500 if gynecologic and pediatric oncologists are included. With the support of our key thought leader collaborators, we intend to focus on oncologists and other physicians who treat cancer patients by targeting our sales and marketing efforts on this important customer segment. We believe this will expand and optimize the oncology testing services and personalization of cancer treatment provided by oncologists and other physicians so that they can better serve their cancer patients.
- Increase our efforts to provide biopharmaceutical companies and clinical research organizations with our current and planned CTC and ctDNA tests and services. Oncology drugs have the potential to be among the most personalized of therapeutics, yet oncology drugs have one of the worst approval rates, at 11% for leading indications and 2% for secondary indications of cancer drug compounds from first administration in humans to approval (2004-2011, Biotechnology Industry Organization). In an effort to improve the outcome of clinical trials for oncology drugs, and more rapidly advance targeted therapeutics, pharmaceutical and biopharmaceutical companies are increasingly looking to companies that have cancer diagnostic tests that specifically address their needs, including the ability to characterize and monitor a patient's tumor over time using CTC and ctDNA tests to analyze biomarkers of interest. There are over 5,000 active trials in the United States in breast, lung, colorectal, prostate and gastric cancers and melanoma according to clinicaltrials.gov. We expect to increase our sales and marketing focus in this business as well as seek additional collaborations and partnerships with pharmaceutical and biopharmaceutical companies.
- Conduct additional clinical studies of breast cancer, NSCLC and other CTC and ctDNA tests we plan to introduce. Clinical utility and validation studies for our planned ctDNA tests may rely on archived plasma or blood samples from clinical trials in which patient outcomes are already available, in a retrospective-prospective design that significantly shortens the length of such studies.

- Continue to enhance our current and planned CTC and ctDNA tests and reduce the costs associated with providing them through internal research and development and partnering with leading technology developers and reagent suppliers. We intend to work closely with select key technology developers and suppliers to further automate the optical interpretation of our current tests and our planned additional CTC tests, including enumeration, immunocytochemical biomarker staining and FISH. We also intend to reduce the costs associated with key material components of these tests, including FISH probes. We have identified a technology group that, based on initial studies, can provide an automation system that will significantly reduce the hands-on time of our cytotechnicians for microfluidic channel analysis while increasing the uniformity, and potentially the sensitivity and quality, of the data we generate. This system is also expected to provide the ability to evaluate multiple fluorescent signals of different wavelengths simultaneously for multiplexed analysis, again enhancing efficiency. Similarly, we have identified suppliers that can provide FISH probes at reduced cost and with a broader choice of available fluors, enabling more extensive multiplexing of tests.

Our Competitive Advantages

We believe that the competitive advantages of our tests, including our tests which are still under development, would include the following. In general, because OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA and our planned tests share our CEE platform, their competitive advantages would be the same.

OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA each enable, and we anticipate our planned CTC and ctDNA tests will each enable, detailed analysis of a patient's cancer utilizing a standard blood sample, facilitating testing at any time, including when a biopsy is not available or inconclusive, offering real-time monitoring of the cancer and the response of the cancer to therapy, and allowing oncologists and other physicians to select timely modifications to treatment regimens. Because CTCs and ctDNA are derived from the primary tumor or its metastases, they function as surrogates for the tumor, with the advantage of being readily accessible in a standard blood sample. This is especially important in situations where a biopsy is not available or advised. The simplicity of obtaining a standard blood sample permits repeat testing in a monitoring mode to detect recurrence or progression and to offer information on treatment modifications based on a current assessment of the cancer's properties.

OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA each provide, and we anticipate our planned tests will each provide, more information than competitors' existing tests, including predictive information on biomarkers linked to specific therapies. We anticipate that such additional biomarker information will enable a physician to develop a personalized treatment plan. By including biomarker information in our analysis, in addition to CTC enumeration, our current tests and our planned tests are designed to provide a more complete profile of a patient's disease than existing CTC tests. We intend for our tests to contain actionable information to assist physicians in selecting appropriate therapies for individual patients. Our ctDNA tests are expected to offer enhanced sensitivity and specificity based on the CEE-Selector technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions.

OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA and our planned CTC tests are designed to capture and detect a broader range of CTCs than existing tests and to be applicable to, or quickly modifiable for, a wide range of cancer types. Our CEE-Cap antibody capture cocktail includes antibodies targeting not only EpCAM, the traditional epithelial CTC capture antigen utilized in the CellSearch® system and in other platforms, but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis. Our detection methods include cytokeratin staining with a broader range of cytokeratin isotypes than existing CTC tests, and we plan to introduce our CEE-Enhanced staining which would enable detection of cells specifically captured with our antibody cocktail, including EMT cells lacking cytokeratin. We believe that through our planned CEE-Enhanced staining, more CTCs and different types of CTCs will be able to be identified and potentially at earlier stages of disease, resulting in fewer non-informative cases and more information for physicians.

OncoCEE-BR, Onco-CEE-LU, OncoCEE-GA are, and we anticipate our planned CTC and ctDNA tests will be, flexible and readily configurable to accommodate new biomarkers with clinical relevance as they are identified. In theory, our CEE platform permits essentially any analysis that is currently performed on tumor tissue to be performed on CTCs, including immunocytochemical staining, FISH and molecular analysis. As new therapies are approved, and to the extent that they are targeted therapies for which knowledge of a particular gene amplification event, mutation or presence, absence or modification, such as phosphorylation, of a protein are indicative of likely response or resistance to that therapy, we will be able to include them in our tests with minimal changes. This is attractive to pharmaceutical and biotechnology companies that are developing such therapies, or seeking ways to make their clinical trials more efficient, as this flexibility would enable them to focus on patients more likely to respond to a particular therapy and demonstrate a benefit from that therapy.

Collaborative relationships with physicians at The University of Texas MD Anderson Cancer Center. We have worked closely with a number of physicians at The University of Texas MD Anderson Cancer Center on various collaborative projects in different cancer types including breast, NSCLC, prostate, colorectal, ovarian, bladder, renal and endometrial. These projects provide us access to leading researchers, clinicians and key thought leaders, access to valuable patient samples and insight into clinical applications for our tests. Some of these projects have resulted in publications in leading journals, such as *Cancer Discovery* and *Cancer Medicine*, which enhances our standing in the oncology community and supports our marketing efforts.

Our planned CEE-Selector mutation tests would not be platform dependent. These tests are being designed to be able to be performed on almost any molecular instrument, which will provide flexibility in laboratory operations. To the extent we elect to develop these tests as IVDs, including pursuing CE marks for them to be marketed outside the United States, the ability to rapidly deploy them on different approved instrument platforms already in many laboratories should greatly simplify their distribution and commercialization.

Our Tests and Services

We have launched OncoCEE-BR for breast cancer, OncoCEE-GA for gastric cancer and OncoCEE-LU for NSCLC and plan to continue to launch a series of tests for CTCs in different tumor types, including colorectal and prostate cancers and melanoma, incorporating analyses for different biomarkers, over the next two years. OncoCEE-BR, OncoCEE-GA and OncoCEE-LU are and the planned tests will be based on the CEE technology platform. The CEE system isolates CTCs from blood samples of cancer patients for enumeration (or count) and genetic analysis. A sample is shipped to us in our specialized blood collection tube, called the CEE-Sure tube, for recovery and analysis of CTCs. When performing the CTC assay, the sample is processed in our laboratory. The specimen of blood is separated into its parts (red blood cells, buffy coat and plasma). The buffy coat is incubated with the antibody solution and passed through a proprietary microfluidic channel containing 9,000 microscopic posts coated with reagents to capture antibody-labeled tumor cells. The captured cells are suitable for further testing of whole cells directly in the microfluidic channel or by releasing the cells from the microfluidic channel and performing CEE-Selector or similar techniques.

Clinicians acknowledge limitations of currently available CTC test systems such as CellSearch® that rely on capture solely by anti-EpCAM antibodies and detection by anti-cytokeratin antibodies. Capture and detection based only on these two antigens is unlikely to identify all CTCs, and clinically this may result in no CTCs being detected in cases in which they are present. For example, some tumor cells that have been released into the circulatory system have undergone an EMT. These mesenchymal cells are less differentiated than epithelial cells and more similar to stem cells. OncoCEE-BR, Onco-CEE-LU and OncoCEE-GA enable, and we believe our planned assays will enable, the capture of significantly more CTCs than is accomplished through the use of traditional anti-EpCAM immuno-capture alone.

In addition to enhanced capture, our technology also improves the detection of CTCs. As with EpCAM, tumor cells that have undergone EMT can down-regulate the synthesis of cytokeratin, leading to an underestimate or even an apparent absence of CTCs since their positive identification has traditionally relied on anti-cytokeratin staining. We have developed alternative methods of fluorescent cell staining that are uniquely possible within the CEE system to enhance or enable detection of CTCs with low or no cytokeratin signal. This technology is called CEE-Enhanced. We believe that the combination of specific cocktails of tumor-associated capture antibodies and more sensitive fluorescent detection of CTCs through CEE-Enhanced methodology will lead to major advances in the capture, enumeration and analysis of CTCs. CEE-Enhanced methodology is expected to be included in our commercially available tests in 2015.

Analysis of CTCs performed by us incorporates both standard and proprietary methods. Immunocytochemistry which looks at proteins, analogous to the immunohistochemistry performed on tissues, can be readily applied and performed in the microfluidic channel, dependent only on suitable biomarkers. Similarly, FISH, used to evaluate cytogenetic abnormalities in cells, may be performed in our microfluidic channel using validated assays available from a number of vendors. For genetic mutation analysis, standard technologies can be applied. We have also developed proprietary CEE-Selector technology for mutation analysis in CTCs and ctDNA, with enhanced sensitivity and specificity.

CTCs are generally very rare and outnumbered many-fold by white blood cells. This complexity has been a challenge for standard technologies. We believe our CEE-Selector technology will offer enhanced specificity and sensitivity (greater than 1-in-10,000 of mutated sequence to normal sequence in a complex genetic background) compared to other approaches, and that it will potentially have broader application than just CTC analysis, including analysis of ctDNA in plasma, both in a CLIA-certified laboratory setting and as an IVD.

OncoCEE-BR, OncoCEE-GA and OncoCEE-LU are, and our planned tests would be, Laboratory Developed Tests. FDA clearance or approval is not currently required to offer these types of tests in our laboratory once they have been clinically and analytically validated. We seek licenses and approvals for our laboratory facility and for LDTs from the appropriate regulatory authorities, such as the Centers for Medicare & Medicaid Services, which oversees CLIA, and various state regulatory bodies. Certain states, such as New York, require us to obtain state licensure in order for us to perform testing on specimens taken from patients or received from ordering physicians from those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as laboratory developed tests, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our tests. We are currently in the process of addressing the requirements for licensure in New York, and we expect to have soon re-obtained all required licenses and approvals from all other states requiring licensure of out-of-state laboratories. (We were required to re-license in these other states as a result of our July 2013 reincorporation to Delaware.)

The following outline indicates our current and planned tests and indicates the stage the product is in and the targeted date of commercialization. As discussed in "Test Development Process" below, prospective assays initially begin in research (stage 1) and progress through to development (stage 2), validation (stage 3) and finally availability for commercialization (stage 4). The OncoCEE-BR, OncoCEE-LU, OncoCEE-GA tests have completed all stages as to CTC and certain FISH test capabilities. Our remaining identified proposed tests have completed the research stage and are at the stages shown in the table below with their respective estimated timetables for completing stage 4. As with all scientific endeavors, such timetables are only estimates; unanticipated problems might result in delays. We consider these timetables to be fairly aggressive, given the likelihood of our experiencing such unanticipated problems and associated delays.

In the development stage, there is still work to be done to finalize sensitivity and specificity of the assay. This work will vary as the assay is tested and fine-tuned in order to prepare it for validation and eventual commercial offering. In the validation stage, the assay has been fully developed and we are now able to run (or are in the process of running) a specific number of samples, both positive and negative, in order to validate that the assay results are reproducible. A validated assay is considered to have completed the availability for commercialization stage when the necessary training has been given and any necessary governmental licenses and approvals have been obtained so that we can start selling the assay through our commercial sales channel and provide patient results.

Our proposed tests have certain commonalities. For example, in each proposed test, biomarkers will be examined by one or both of FISH or CEE-Selector. Given the development, validation and commercialization of our first CTC/FISH test (OncoCEE-BR), all subsequent FISH- and Immunofluorescence-based assays have effectively been developed for the planned biomarker. Progression of these planned assays through stage 3 is largely dependent on the timing of our obtaining suitable validation specimens, although various scientific and other factors can also affect the pace of a particular proposed test's progress through the validation stage. CTC-based OncoCEE-CR and OncoCEE-PR tests are targeted to be commercial in 2015 given our estimate of the timing to acquire appropriate positive and negative validation samples.

For ctDNA based assays, CEE-Selector will be used to detect each relevant mutation. CEE-Selector development was completed in 2014. Biomarker mutations (such as B-raf and K-ras) are often commonly seen in different tumor types, thus, once a particular mutation assay is developed for CEE-Selector, it can be applied to any tumor type. The OncoCEE-LU ctDNA test was our first CEE-Selector test to undergo validation. Given the nature of a molecular based test such as CEE-Selector, specimens can be batched and tested simultaneously, thereby reducing the validation time. All remaining currently proposed ctDNA tests will follow and are currently targeted to be commercial in 2015.

We currently intend to fund further research and development and related activities. This includes all of the expenditures which we believe are needed to complete all four stages of development for the planned tests described below. Primarily these expenditures will be for existing and additional scientific personnel in the time periods reflected in the table below, and secondarily for obtaining a sufficient number of suitable validation specimens.

Test Name/ Solid Tumor Type	Biomarkers	Status of Test or Project	Targeted Quarter of Availability for Commercialization
OncoCEE-BR™ / Breast Cancer	Enumeration, HER2 by FISH, ER	Currently available	N/A
	PR	Validation	2015 Q3
OncoCEE-LU™ / Lung Cancer	Enumeration, ALK and ROS1 by FISH	Currently available	N/A
	EGFR T790M, L858R and Del19 mutations by CEE-Selector™	Currently available	N/A
	MET by FISH	Validation	2015 Q2
	K-ras, B-raf, and ALK mutations by CEE-Selector™	Development and Validation	2015 Q2, Q3
OncoCEE-GA™ / Gastric Cancer	Enumeration, HER2 by FISH	Currently available	N/A
OncoCEE-CR™ / Colorectal Cancer	Enumeration, EGFR by FISH	Validation	2015 Q3
	K-ras and B-raf by CEE-Selector™	Development	2015 Q2
OncoCEE-PR™ / Prostate Cancer	Enumeration, PTEN deletion by FISH and AR by ICC	Validation	2015 Q4
OncoCEE-ME™ / Melanoma	Enumeration, B-raf and N-ras mutations by CEE-Selector™	Development	2015 Q3
	PDL-1 by ICC	Development	2015 Q3
CEE-Selector™/ Sequencing application for multiple cancer types	K-ras, B-raf, EGFR and other mutations detected in plasma.	Development	2015 Q4

Our Marketed OncoCEE CTC Tests

Our OncoCEE-BR breast cancer test was the first CTC test we developed and we are currently offering it to physicians through our CLIA laboratory. It is based on a standard blood sample and can be used at the time of diagnosis and for monitoring, including at the time of progression or recurrence. This allows the physician to characterize the tumor to help define treatment options, either augmenting tissue analysis or replacing it when a tumor biopsy is not available. The test currently includes CTC enumeration and determination of HER2 status by FISH and immunocytochemistry analysis of CTCs for estrogen receptor (ER) on the captured CTCs. HER2 status is used by physicians to determine suitability of a patient for treatment with HER2-targeted therapeutics. ER status provides information on suitability of breast cancer patients for endocrine or hormonal therapies. We plan to add immunocytochemistry analysis of CTCs for progesterone receptor to our OncoCEE-BR test, which will also provide information on suitability of breast cancer patients for endocrine or hormonal therapies.

OncoCEE-LU

Up to 25% of lung cancer patients, especially those diagnosed at Stage IIIB or Stage IV, do not have sufficient tissue for molecular profiling for various reasons, including tumor accessibility and status of the patient. In these cases, CTC and ctDNA tests are alternatives for obtaining more detailed information about the molecular status of the tumor that helps the physician select appropriate therapy. The OncoCEE-LU test's biomarker analysis currently includes FISH testing for anaplastic lymphoma kinase, or ALK, c-ros oncogene 1, receptor tyrosine kinase, or ROS1, gene rearrangements and molecular analysis of the T790M mutation of the epidermal growth factor receptor or EGFR gene using our CEE-Selector™ platform. We plan to add FISH testing for RET and MET genes, as well as mutation analysis for deletions 19 and l858R mutation in the ECFR gene, the K-ras gene and the B-raf gene in the future.

The L858R mutation of the EGFR gene and Exon 19 deletions are activators of EGFR kinase activity. The codon 12 and 13 mutations of the K-ras gene are linked to non-responsiveness to the EGFR kinase inhibitors, and the codon 600 mutations of the B-raf gene are linked to melanoma therapies in clinical trials for lung cancer. Our OncoCEE-LU test would be performed on a standard blood sample.

OncoCEE-GA

Our OncoCEE-GA test for gastric cancer is based on the identification of HER2 as a biomarker for this disease. We employ our CTC HER2 FISH test, which we previously developed for breast cancer, for the analysis of gastric cancer CTCs. Current clinical practice relies on a biopsy for tumor tissue analysis to detect elevated HER2, in the same manner as is done for breast cancer. Our tests circumvent this need for tissue, as well as providing straightforward monitoring of HER2 status from a standard blood sample, on a real-time basis during treatment.

Other OncoCEE CTC Tests in Development

We are now following a similar development path for additional OncoCEE CTC tests for other cancer types with a focus on large population solid tumor types, or cancers for which there are approved therapies that rely on biomarker tests we have previously developed. Examples of these tests include, OncoCEE-CR™ for colorectal cancer, OncoCEE-PR for prostate cancer, and OncoCEE-ME for melanoma, each described below.

OncoCEE-CR

Our current plan for our OncoCEE-CR test for colorectal cancer is to offer mutation testing analogous to that performed in lung cancer, namely detection of key mutations in the K-ras and B-raf genes, along with CTC enumeration. Testing on the K-ras gene would focus on codons 12 and 13 mutations. Testing on the B-raf gene would focus on V600 mutations. Our OncoCEE-CR test would be run on a standard blood sample.

This testing is important because certain targeted therapies for colorectal cancer, including the monoclonal antibodies targeting EGFR are ineffective in patients who have a K-ras mutation, which is found in up to 40% of cases according to the National Comprehensive Cancer Network. While for each of codons 12 and 13 in K-ras, up to 15-20 mutations have been reported, there are reports in the scientific literature that patients with one particular mutation, G13D, do respond well and that there may be variability in response to different chemotherapies based on the specific K-ras mutation, suggesting that detailed information on mutation status is clinically relevant.

OncoCEE-PR

Our OncoCEE-PR test for prostate cancer would be based on the analysis of CTCs found in a standard blood sample for key biomarkers: the androgen receptor, and phosphatase and tensin homolog (PTEN). The test would also include CTC enumeration, and our CEE-Cap antibody capture cocktail would be modified from that used for breast and lung cancer to include prostate specific membrane antigen.

The androgen receptor normally binds the hormones testosterone and dihydrotestosterone, and is the target for several drug molecules, including those acting directly as antagonists for the receptor and those acting indirectly through inhibition of androgen synthesis.

Phosphatase and tensin homolog, an enzyme that functions as a tumor suppressor, if mutated, deleted or otherwise functionally disrupted, removes a brake from cell replication and allows uncontrolled growth, which is seen in many cancers. If phosphatase and tensin homolog is mutated, deleted or disrupted, chemotherapy or polytherapy is usually recommended.

OncoCEE-ME

Our OncoCEE-ME melanoma test, performed on a standard blood sample, would provide information on the presence or absence and specific nature of the V600 mutation in the B-raf gene, which indicates whether the B-raf inhibitors are candidate therapies for the patient. CTC enumeration would also be a component of our test.

Disseminated Tumor Cell (DTC) Assays Performed on Bone Marrow

We have shown that our CEE-Sure blood collection tubes and CEE microfluidic channels work well with bone marrow samples, and we have further demonstrated the ability to perform FISH on disseminated tumor cells, or DTCs, from bone marrow that are isolated in this way. While bone marrow biopsies are not performed routinely in the United States, they are utilized in Europe, especially in prostate cancer. In addition, we were involved in a study at The University of Texas MD Anderson Cancer Center in which bone marrow was isolated from early stage operable breast cancer patients at the time of surgery. In this later study, published in *Cancer Medicine* (2013, 2(2) 226-233), we found a significant percentage of patients classified as HER2 negative by their primary tumor had HER2 positive DTCs, and hence could be considered for Herceptin® therapy. DTCs provide an interesting adjunct to CTC analysis that is well suited for our technology platform, and we plan to work with collaborators and key thought leaders to determine how best to introduce a series of tests based on a bone marrow sample type.

ctDNA Tests

We plan to introduce ctDNA tests for mutation analysis performed on blood plasma isolated from a standard blood sample using the CEE-Selector technology, based on increasing interest from physicians in this type of analysis. We plan to launch the first tests, for K-ras, B-raf and EGFR mutations, in conjunction with, or as a complement to, our OncoCEE-LU test. Tests for other mutations will be added as they are developed. These tests would be similar to those performed on CTCs but would instead focus on ctDNA in plasma. These tests would lack the cellular context provided by CTCs but would not require CTC isolation and would be simpler to perform. In addition, one of the benefits of this technology is its ability to detect and identify mutations in blood plasma. This indicates the importance of the enhanced sensitivity of the CEE-Selector technology and the ability of ctDNA tests to complement CTC tests.

Laboratory Testing

From our CLIA-certified laboratory in San Diego, California, we plan to provide test results from our current and planned CTC and ctDNA tests to oncologists and other physicians in community hospitals, cancer centers, group practices and offices. At the federal level, clinical laboratories, such as ours, must be certified under CLIA in order for us to perform testing on human specimens. Our laboratory is also accredited by CAP, which is one of six accreditation organizations approved by CMS under CLIA. Our clinical laboratory is located in California and we hold the requisite license from the California Department of Public Health to operate our laboratory. In addition, we hold licenses issued by the states of Florida, Maryland, Pennsylvania and Rhode Island to test specimens from patients in those states or received from ordering physicians from those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as laboratory developed tests, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our tests. We are currently in the process of addressing the requirements for licensure in New York, and we expect to have soon re-obtained all required licenses and approvals in all other states requiring licensure of out-of-state laboratories. (We were required to re-license in these other states as a result of our July 2013 reincorporation to Delaware.)

Clinical Trial Services

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a study by Princess Margaret Hospital in Toronto estimated that over a five-year study period 85% of the new therapies for solid tumors which were tested in early clinical trials in the United States, Europe and Japan failed, and that of those that survive through to Phase III trials only half will actually be approved. Given such a high failure rate of oncology drugs in clinical development, combined with constrained budgets for pharmaceutical and biopharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to help decrease these failure rates. For specific molecular-targeted therapeutics, the identification of appropriate biomarkers may help to optimize clinical trial patient selection and success rates by helping clinicians identify patients that are most likely to benefit from a therapy based on their individual genetic profile.

In addition to testing for physicians and their patients, we plan to offer clinical trials testing services to help increase the efficiency and economic viability of clinical trials for pharmaceutical and biopharmaceutical companies and clinical research organizations. Our clinical trial services will be aimed at developing customizable tests and techniques utilizing CTC and ctDNA technologies to provide sensitive, real-time characterization of individual patient's tumors using a standard blood sample. These tests may be useful as, and ultimately developed into, companion diagnostics associated with a specific therapeutic. Additionally, through our services we may gain further insights into biomarkers for disease progression and drug resistance, as well as those associated with current drug development efforts, which we can incorporate into tests.

Test Development Process

Our OncoCEE-BR, OncoCEE-GA and OncoCEE-LU tests were, and our planned additional CTC and ctDNA tests are being, developed and validated in conjunction with leading academic and clinical research centers to ensure that the needs of the clinical community are being met with the latest research on key biomarkers that affect patient care. We utilize a research and validation process to help ensure that we are providing diagnostic, prognostic and predictive information that is clinically relevant and accurate. The time-frame for this process from design through development and market launch is dependent upon, among other things, the biomarkers in question having been discovered and validated before we incorporate them in a test, the specific clinical claims we plan to pursue, and the availability of high quality samples for validation. Our development protocol calls for us to monitor and review the process in four stages as detailed below:

- **Stage 1, Research**. We review known, validated biomarkers, preferably linked to a specific therapeutic or other high value treatment decision, and discuss with clinical collaborators and key thought leaders to characterize the opportunity, the specific clinical setting and the product profile of the candidate test.
- **Stage 2, Test Development**. We design the test, which typically has two parts: efficient capture of CTCs and/or ctDNA from the targeted cancer type and development of the biomarker assays that will be included. For example, the first part may involve modification of the antibody capture cocktail and the second could include development of specific CEE-Selector mutation tests or testing of FISH probes. The test will be used on normal control specimens and clinical samples to assure performance and the process includes defining the performance characteristics of the test as well as developing standard protocols for our CLIA-certified, CAP accredited, and state-licensed laboratory, where the test will ultimately be performed. This assessment includes such features as reproducibility, accuracy, sensitivity, and specificity.
- **Stage 3, Clinical Validation**. When the assay is performing as desired it is validated on clinical samples, typically in comparison to the existing gold standard for that biomarker, which is usually tumor tissue analysis. Depending on the tumor type and specimen requirement, samples are collected from patients through collaborators, or in the case of ctDNA tests, from sample banks, where clinical information on the patients, including outcomes, is already available.
- **Stage 4, Availability for Commercialization**. As clinical validation is completed and before launch, we take several steps to prepare a test for marketing as a LDT. We create standard operating procedures and quality assurance and quality control measures to ensure repeatability and high standards of quality. We train both our commercial and laboratory staff on the interpretation and use of the data. Licenses and approvals for our laboratory to perform or use LDTs have been obtained from the appropriate regulatory authorities, such as CMS, which oversees CLIA, and different state regulatory bodies.

Our CTC/FISH-based OncoCEE-BR, OncoCEE-GA and OncoCEE-LU tests, which have already launched, are considered to have completed this test development process. All other planned tests which are mentioned in this Annual Report are all considered to currently be in Stage 2 or Stage 3 of this test development process.

We will be required to seek FDA clearance or approval to expand the commercial use of tests to other laboratories and testing sites in the United States. We will also need to complete additional activities to submit each of these tests for regulatory clearance or approval before commercialization in each of the international markets where we would plan to introduce them.

If the FDA finalizes its current draft guidance on a risk-based framework for regulation of LDTs, our process would also need to allow for obtaining FDA review, clearance or approval, as applicable, which would add delay, expense and risk to our current test development process.

Research and Development

We incurred research and development expenses of $3.1 million, which represents 2,299% of our net revenue, for the year ended December 31, 2013 and $4.5 million, which represents 3,371% of our net revenue, for the year ended December 31, 2014. Research and development expenses represented 54% and 38% of our total operating expenses for the years ended December 31, 2013 and 2014, respectively. Major components of the research and development expenses were direct personnel costs, laboratory equipment and consumables and overhead expenses.

Technology Development

In addition to developing new CTC and ctDNA tests for different cancers to be offered through our CLIA testing laboratory, and adapting additional predictive biomarkers to these tests as their importance is demonstrated by the scientific and clinical research communities, we continue to focus on improving the base technologies underlying our tests and processes. We are exploring various ways to improve CTC capture efficiency and detection, as well as approaches to sub-categorize CTCs into different populations that may have clinical relevance. For example, by determining which antigens individual CTCs expressed that enabled their capture, we could differentiate, and enumerate, various CTC phenotypes, for example, epithelial versus mesenchymal. We are also working to simplify the test process, and in general to provide a broader range of useful data on a patient's cancer to assist the physician in determining an appropriate treatment. Some of these projects and initiatives include:

- **Improve Ability to Capture CTCs**
  - Continued modification and optimization of our CEE microfluidic channel as a way to further enhance CTC capture efficiency. Capture efficiency directly impacts sensitivity, informative rate, and the ability to perform accurate and reliable biomarker analyses on the CTCs, all of which increase the value of our offering. We are utilizing some of our early research experience to improve CTC capture rates and reduce background contamination from normal white blood cells.
- **Automation of Our Test Process**
  - Development of automation throughout the test process, but particularly at the visual evaluation steps, which include enumeration, any immunocytochemistry for biomarkers beyond those used to identify CTCs, for example protein biomarkers, and FISH analysis, is a way to drive efficiencies, reduce costs, speed up turnaround time, and generate more reliable, uniform, and in some cases more sensitive data. We have identified an automation solution for the visual analysis, which is being validated in our CLIA laboratory. We have also adapted a semi-automated system for the separation, processing and washing steps before running a sample on the microfluidic channel, which is now being used in the research laboratory and similarly needs to be transferred and validated in the CLIA laboratory. These measures will reduce costs and time as well as allow for higher-throughput as sample volumes increase.
- **Development of Second Generation Platform for CTC Testing**
  - Evaluating and developing techniques for CTC capture that take advantage of our CEE-Cap antibody capture cocktail and CEE-Enhanced staining technology to modify our current CTC process to a simpler, essentially IVD, format. In addition to reducing internal costs, such an advance would offer the opportunity for us to offer a product format that enable us to access the worldwide CTC testing market. The distribution of such kits could create a new business opportunity for us.
- **Utilization of CEE-Selector Technology for Highly Multiplexed Mutation Testing**
  - The CEE-Selector technology should enable us to multiplex mutation testing such that larger panels of genes can be analyzed in a single step and interfaced with genetic sequencing. This should position us for the analysis at the molecular level of whole signaling pathways or enzyme cascades. We plan to take advantage of the sensitivity and specificity of the CEE-Selector technology and leverage interest in the clinical research community for detecting any actionable biomarker in a particular tumor, as opposed to only those that are known to occur at relatively higher frequencies in that type of tumor. Such multiplexed mutation tests, relying on our CEE-Selector technology, could provide a more global evaluation of a tumor through analysis of either CTCs or ctDNA. This would offer a broader range of potential treatment options as well as enable the monitoring of the effectiveness of those treatments over time.

- **Development of Single Cell CTC Isolation Techniques for Molecular Analysis**
  - Tumor heterogeneity is a well-recognized problem for tissue analysis and is in part addressed by focusing on CTCs, which may provide a more universal sampling of a tumor. One result of this can be a diverse population of CTCs in a sample, with different phenotypes and genotypes represented. We are working with a collaborator on techniques for subsequent sorting of our highly enriched CTC samples released from our CEE microfluidic channels into pools of CTCs with similar phenotypes, and ultimately to single CTCs, for molecular analysis.

Translational/Clinical Research

In the course of our research and validation studies, we have processed several hundred cancer patient samples and normal control samples for CTC enumeration and analysis. Our initial focus has been on breast cancer, where validation studies for the OncoCEE-BR test, including enumeration of CTCs compared to the CellSearch® system, and HER2 FISH performed on CTCs and compared with HER2 analysis performed on tumor tissue from the same patients, involved over 120 patient samples. The results of our validation studies, and the demonstration of a reliable and reproducible method for CTC capture and analysis using the OncoCEE platform were published in a paper entitled "Novel Platform for the Detection of Cytokeratin Positive (CK+) and Cytokeratin Negative (CK+) CTCs" appearing in the December 2011 issue of *Cancer Discovery* and a paper entitled "Efficient capture of circulating tumor cells with a novel immunocytochemical microfluidic device" appearing in the September 2011 issue of *BioMicrofluidics*.

Additional studies were conducted in breast and other tumor types, including lung, prostate and colorectal cancers, utilizing patient samples for comparison to the CellSearch® system. In head-to-head studies, the CEE system detected cytokeratin positive CTCs in comparable numbers of breast cancer patients, and in considerably more patients in the other cancer types (*Cancer Discovery*, December 2011). Moreover, the results clearly demonstrated that our use of the CEE-Cap capture antibody cocktail enabled recovery of more CTCs as compared to using only anti-EpCAM antibodies. This data served as a clinical validation study for CTC enumeration. When CEE-Enhanced staining is applied to detect cytokeratin-negative CTCs, we expect to see far more CTCs based on preliminary studies reported in a paper entitled "Detection of EpCAM-Negative and Cytokeratin-Negative CTCs in Peripheral Blood" appearing in the 2011 issue of the *Journal of Oncology*.

The CEE system has the added advantage of post-capture immunocytochemical, cytogenetic and molecular genomic analyses of the CTCs. The CEE system captured cells can be analyzed directly within the microfluidic channel, thereby removing the need to re-deposit cells on a slide, which could result in cell loss or damage. Furthermore, given the transparency of the microfluidic channel, it can be immediately analyzed on a microscope. Together these two important features allow for a very efficient process that is well suited for a LDT performed in a CLIA laboratory. The post-capture analyses, which focus on the evaluation of biomarkers, are particularly important and valuable to physicians and patients, as they focus on actionable information related to therapy selection. We have performed a number of clinical research studies in collaboration with The University of Texas MD Anderson Cancer Center investigators involving various tumor types, including breast, ovarian, endometrial, lung, colorectal, bladder and prostate cancers.

In a collaboration with physicians and researchers at The University of Texas MD Anderson Cancer Center, we evaluated matched samples of tumor tissue, blood for CTCs and bone marrow for DTCs in recently diagnosed breast cancer patients for evidence of HER2 amplification, which would indicate eligibility for HER2-targeted therapies like Herceptin®, a potentially life-saving treatment. These results were also presented at both the 2011 and 2012 annual meetings of the American Society of Clinical Oncology. In a study published in *Cancer Medicine* (2013, 2(2) 226-233) and involving 96 patients, HER2 positive CTCs and/or DTCs were identified in 18.8% of cases in which the primary tumor was HER2 negative. In the same cohort of patients, only 12.5% were HER2 positive in their primary tumor. In other words, beyond the 12 (of the 96) which traditional tumor tissue analysis had indicated could benefit from Herceptin-based therapy, the OncoCEE-BR test detected 18 (of the 96) patients who (despite the fact they were identified as being HER2 negative by primary-tumor testing) could benefit from Herceptin-based therapy. Patients classified as HER2 negative based on tumor tissue and found to have HER2 positive CTCs and/or DTCs will continue to be followed by our collaborators at The University of Texas MD Anderson Cancer Center to assess their overall and progression-free survival. Tumor heterogeneity is one likely cause of the discordance for HER2 status between tumor tissue and our test performed on blood and bone marrow samples. Tumor heterogeneity indicates an important clinical application for the OncoCEE-BR test, confirmation and crosschecking of the tissue analysis performed by the pathologist at the time of biopsy or surgery, especially if HER2 negative, with a CTC analysis derived from a standard blood sample.

Clinical utility studies, which demonstrate the specific clinical setting in which a particular CTC or ctDNA test is used, and how to use the information generated for medical, specifically treatment-related, decision making is a key part of our strategy and research and development plan. Data resulting from such studies is critical not only in the sales and marketing process, but also for reimbursement, as many payors now ask for peer-reviewed publications describing such studies and results before agreeing to coverage of a specific test. The study with Dana-Farber Cancer Institute is the first example of a clinical utility study for one of our tests and we plan to conduct additional studies in breast cancer and similar studies in NSCLC and other cancers for which we develop tests, including sponsoring such studies ourselves.

Sales and Marketing

Our sales organization currently consists of an initial group of 8 sales representatives placed in strategic locations around the country that have high concentrations of cancer patients, and we may, depending on test volume, potentially grow this number to 15-20 sales representatives within two years, and to 40-50 within five years. We have defined the initial sales territories and have hired sales professionals with an average of 10 years of successful experience in clinical oncology sales or oncology diagnostic testing sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We plan on growing this specialized, oncology-focused sales force and supporting it with clinical specialists who bring significant technical knowledge in the use of CTC and ctDNA tests. We have also invested in sales headcount focusing on biopharma clinical trial opportunities.

Finally, we have invested in a managed care sales and marketing expert in order to pursue favorable payment and coverage for our testing. The key value proposition for these customers will be focused on cost savings by offering our tests as alternatives to expensive surgeries when tumor biopsy tissue is not available.

Our sales and marketing efforts are and will be based on a five-part marketing strategy:

- Work with oncologists, other physicians and group practices at community hospitals and cancer centers to educate them on the advantages and opportunities that CTC and ctDNA tests provide for better information, allowing them to select the most appropriate therapy for their patients, and how and when these tests are most effectively used;
- Build relationships with key thought leaders in oncology, specifically in the cancers for which we are offering or plan to offer tests, to educate and support community oncologists;
- Collaborate with leading research universities and institutions that enable the validation of our new tests, as well as the generation of clinical utility data;
- Partner with pharmaceutical companies for clinical trial work focusing on CTC and ctDNA testing and analysis; and
- Add value for the payor community by avoiding costly surgeries by providing the option of a simple blood test.

We also take advantage of customary marketing channels commonly used by the diagnostic and pharmaceutical industries, such as medical meetings, broad-based publication of our scientific and clinical data, and the Internet. In addition, we provide easy-to-access information to our customers through our website and a data portal for physicians who wish to access test results electronically. Our customers value easily accessible information in order to quickly review their patients' information and begin developing a treatment protocol.

Outside the United States

Outside the United States, where a central laboratory business model is less developed, we will evaluate opportunities with our existing and other partners for the conversion and/or development of our current and planned CTC and ctDNA tests to test systems or IVDs, and related strategies to develop and serve such regional oncology markets. We also plan to sell our clinical trial services to biopharmaceutical companies and research organizations outside the United States.

We plan to cooperate with partners on accessing markets internationally. We plan for this to be accomplished either through partnerships with local groups and distributors or the development of IVDs and/or test systems, including instrumentation.

Competition

As a cancer diagnostics company focused on current and planned tests for CTCs and ctDNA from standard blood samples, we rely extensively on our ability to combine novel technology and biomarker information with high-quality, state-of-the art clinical laboratory testing. We believe that we compete principally on the basis of:

- our ability to utilize standard blood samples, enabling testing of patients frequently through the course of their disease without a biopsy, thereby reducing cost and trauma, saving time, and providing real-time information on the current status of the tumor;
- our ability to include biomarker information in our analysis, in addition to CTC enumeration, thereby providing a more complete profile of a patient's disease than existing CTC tests can. This is actionable information that can assist physicians in selecting more personalized treatment plans for individual patients;

- our current and planned CTC tests' ability to capture and detect a broader range of CTC phenotypes than existing tests, and potentially at earlier stages of disease, resulting in fewer non-informative cases and more information for physicians. For example, our antibody capture cocktail targets not only EpCAM but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis;
- our ability to rapidly integrate new biomarkers, either validated in academic laboratories or of interest to pharmaceutical and biopharmaceutical companies in the context of their new therapies, into our current and planned tests, facilitating the expansion of actionable information for oncologists and other physicians;
- our research and clinical collaborations with key academic and clinical study groups, which enhance our research and development resources and, by enhancing our standing in the oncology community, support our marketing efforts; and
- our planned ctDNA tests based on the CEE-Selector technology are expected to offer enhanced sensitivity and specificity in detecting mutation targets or resistance markers, again supporting treatment decisions.

We believe that we compete favorably with respect to these factors, although we cannot assure you that we will be able to continue to do so in the future or that new products or tests that perform better than our current and planned tests and services will not be introduced. We believe that our continued success depends on our ability to:

- expand and enhance our current and planned OncoCEE tests to provide clinically meaningful information in additional cancers;
- work with clinicians to design and implement clinical studies that demonstrate the clinical utility of our products;
- continue to innovate and maintain scientifically advanced technology;
- successfully market and sell tests;
- continue to comply with regulatory guidelines and obtain appropriate regulatory approvals in the United States and abroad as applicable;
- continue to validate our pipeline of tests;
- conduct or collaborate with clinical utility studies to demonstrate the application and medical value of our tests;
- seek to obtain positive coverage and reimbursement decisions from Medicare and private third-party payors;
- continue to enter into sales and marketing partnerships;
- maintain existing and enter into new research and clinical collaborations with key academic and clinical study groups;
- continue to attract and retain skilled scientific and clinical personnel;
- continue to participate in and gain clinical trial work through biopharma partnerships;
- receive payment for the testing we provide for patients;
- obtain patents or other protection for our technologies, tests and services; and
- obtain and maintain our clinical reference laboratory accreditations and licenses.

Our principal competition comes from mainstream diagnostic methods, used by pathologists and oncologists and other physicians for many years, which focus on tumor tissue analysis. It may be difficult to change the methods or behavior of oncologists and other physicians to incorporate our CTC and ctDNA testing, including molecular diagnostic testing, into their practices in conjunction with or instead of tissue biopsies and analysis. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption. We plan to focus our marketing and sales efforts on medical oncologists rather than on pathologists.

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA testing in various cancers. In particular, Janssen Diagnostics, LLC markets its CellSearch® test and Atossa Genetics markets its ArgusCYTE® test, which are competitive to our OncoCEE-BR test for CTC enumeration, and HER2 analysis, respectively. However, the ArgusCYTE® test measures HER2 mRNA, which is not typically used for HER2 analysis, while we employ FISH for this analysis. FISH is generally considered to be the gold standard. CTC and ctDNA testing is a new area of science and we cannot predict what tests others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the tests we develop. In addition to Janssen Diagnostics and Atossa Genetics, our competitors include public companies such as Alere (Adnagen) and Illumina as well as many private companies, including Apocell, EPIC Sciences, Clearbridge Biomedics, Cynvenio Biosystems, Fluxion Biosciences, RareCells, ScreenCell and Silicon Biosystems. Many of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents.

We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized cancer diagnostic sector as the potential and prevalence increases of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics. For example, the FDA has recently approved three such agents—Xalkori® from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc., Zelboraf® from Daiichi-Sankyo/Genentech/Roche along with its companion B-raf kinase V600 mutation test from Roche Molecular Systems, Inc. and Tafinlar® from GlaxoSmithKline along with its companion B-raf kinase V600 mutation test from bioMerieux. These recent FDA approvals are only the second, third and fourth instances of simultaneous approvals of a drug and companion diagnostic. The first approval was the 2010 approval of Genentech's Herceptin® for HER2 positive breast cancer along with the HercepTest from partner Dako A/S. Our competitors may invent and commercialize technology platforms or tests that compete with ours.

There are a number of companies which are focused on the oncology diagnostic market, such as Biodesix, Caris, Clarient, Foundation Medicine, Response Genetics, Neogenomics, Agendia, Genomic Health, and Genoptix, and which, while not currently offering CTC or ctDNA tests which are truly competitive with ours, are selling to the medical oncologists and pathologists. Large laboratory services companies, such as Sonic USA, Quest and LabCorp, provide more generalized cancer diagnostic testing.

Additionally, projects related to cancer diagnostics and genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current and planned tests in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Third-Party Suppliers and Manufacturers

Some of the components used in our current or planned products are currently sole-source, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers (particularly K.R. Anderson, Inc., which supplies a custom-packaged silicone compound used in our manufacturing) may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

Patents and Technology

The proprietary nature of, and protection for, our products, services, processes, and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our products, services, technology, and know-how, to operate without infringing on the proprietary rights of others, and to prevent others from infringing our proprietary rights. We seek patent protection in the United States and internationally for our products, services and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business.

We also rely on trade secrets, know-how, and continuing innovation to develop and maintain our competitive position. We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology.

Our success depends on an intellectual property portfolio that supports our future revenue streams and erects barriers to our competitors. We are maintaining and building our patent portfolio through filing new patent applications, prosecuting existing applications, and licensing and acquiring new patents and patent applications.

Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Intellectual Property Risks Related to Our Business" in Part I, Item 1A of this Annual Report.

As of December 31, 2014, we owned 8 issued U.S. patents, 5 pending U.S. patent applications and corresponding patents and patent applications internationally. In addition, as of December 31, 2014, we co-owned 2 pending U.S. patent applications as well as corresponding foreign patents and applications. The patent portfolios for our leading programs as of December 31, 2014 are summarized below.

CEE Microfluidic Channels. We have 2 issued U.S. patents that are related to our current business, and a number of additional U.S. and foreign patent applications, which cover our microfluidic channel technology.

CEE-Sure Blood Collection Tubes. We have a U.S. patent application in prosecution for our CEE-Sure blood collection tubes, which contain reagents designed to prevent clumping of blood cells and CTCs that could clog the microfluidic channels and disrupt our assays.

CEE-Cap Antibody Capture Cocktail. We have 2 pending U.S. patent applications as well as their corresponding foreign patent applications directed to our antibody capture cocktail technology, which includes using antibodies to a number of tumor-associated antigens from cancer cells of both epithelial and mesenchymal phenotype, as well as cancer stem cells.

CEE-Enhanced Staining. We have 1 U.S. pending application as well as its corresponding foreign patent applications directed to this technology.

CEE-Selector Mutation Detection Technology. We co-own 2 pending U.S. patent applications with Aegea Biotechnologies, Inc., or Aegea. Under our agreement with Aegea, we have certain exclusive rights for oncology clinical testing and diagnostics as well as limited exclusive rights for oncology basic and clinical research. Aegea is responsible for the prosecution of 1 U.S. application and their corresponding foreign applications while we are responsible for the prosecution of the rest of U.S. applications and their corresponding foreign applications. Lyle J. Arnold, Ph.D., our Senior Vice-President of Research & Development and Chief Scientific Officer, is the controlling person of Aegea.

In addition to patents, we hold various U.S. registered trademarks, including a federal registration for the "CEE" mark, as well as several foreign registered trademarks and U.S. trademark applications for certain of our current and planned tests.

Operations and Production Facilities

Our research and development laboratories, our CLIA-certified, CAP accredited, and state-licensed diagnostic testing laboratory and our manufacturing facility are located in our San Diego, California headquarters. The laboratories employ commercial state-of-the-art equipment as well as custom-made components specific to our CTC process that are generated in a small in-house engineering shop. The manufacturing facility used for the production of our CEE microfluidic channels is a Class 10,000 suite in which polydimethylsiloxane is formed into the base of our proprietary microfluidic channels in a molding process. A glass cover slip suitable for optical analysis is added to seal the channels and make them watertight by making them reactive using plasma techniques. The inside of the microfluidic channels is subsequently chemically derivatized to enable the attachment of binding elements that strongly bind to antibody-tagged or coated CTCs. Because the microfluidic channels have micrometer dimensions, and we are seeking individual cells in a blood sample to interact with the surface of the microfluidic channel, dust particles and other microscopic debris that could clog the channel needs to be avoided.

The process of performing our tests is straightforward. When a health care professional takes a standard blood sample from a patient for CTC or ctDNA testing, he or she will place the blood sample in our CEE-Sure blood collection tubes, complete a requisition form, and package the specimen in our shipping kit for direct shipment to us. Once we receive the specimen at our laboratory and we enter all pertinent information about the specimen into our clinical laboratory information system, our laboratory technologists prepare the specimen for processing and analysis. Laboratory technologists, including clinical laboratory technologists and clinical laboratory scientists then conduct the analysis, including enumeration of CTCs and biomarker analysis such as FISH. The data, including images and the processed cells, are sent to our in-house or contracted pathologists or a commercialization partner's pathologists who are experienced in the analysis and evaluation requested by the referring oncologist or pathologist.

After analysis, our in-house or contracted pathologists or a commercialization partner's pathologists use laboratory information systems to prepare a comprehensive report, which may include selected relevant images associated with the specimen. Our Internet reporting portal allows a referring oncologist or pathologist to access his or her patient's test results in real time in a secure manner that we believe to be compliant with HIPAA and other applicable standards. The reports are generated in industry standard .pdf formats which allows for high definition color images to be reproduced clearly. We send the results to the ordering physician and bill the payor through an arrangement we have with Xifin, Inc.

Quality Management Program

We are committed to providing reliable and accurate diagnostic testing to our customers. Accurate specimen identification, timely communication of test results, and prompt correction of errors, is critical. We monitor and improve our performance through a variety of methods, including performance improvement indicators, internal proficiency testing and external quality audits conducted by CAP. All quality concerns and incidents are subject to review and analysis, and our procedures are designed to ensure that we are providing the best services possible to our patients and customers. Protection of patient results from misuse and improper access is imperative and electronic and paper results are guarded via password-protection and identification cards.

We have established a Quality Management Program for our laboratory designed to help ensure accurate and timely test results, a consistent high quality of our testing services. The Quality Management Program documents the quality assurance and performance improvement plans and policies, the laboratory quality assurance and quality control procedures that are necessary to ensure that we offer the highest quality of diagnostic testing services. This program is designed to satisfy all the requirements necessary for local and state licensures and accreditation for clinical diagnostic laboratories by CAP. We follow the policies and procedures for patient and employee safety, hazardous waste disposal and fire codes stated in the general laboratory procedure manual. We believe that all pertinent regulations of CLIA, the Occupational Safety and Health Administration, the Environmental Protection Agency and the FDA are satisfied by following the established guidelines and procedures of our Quality Management Program.

In addition to the compulsory proficiency programs and external inspections required by CMS and other regulatory agencies, we have developed a variety of internal systems and procedures to emphasize, monitor and continuously improve the quality of our operations. We maintain internal quality controls by routinely processing specimens with known diagnoses in parallel with patient specimens. We also have an internally administered proficiency program for specimen testing.

The CAP accreditation program involves unannounced on-site inspections of our laboratories. CAP is an independent, non-governmental organization of board-certified pathologists that accredits laboratories nationwide on a voluntary basis and that has been recognized by CMS as an accreditation organization to inspect laboratories to determine adherence to the CLIA standards.

Third-Party Payor Reimbursement

Revenues from our clinical laboratory testing are derived from several different sources. Depending on the billing arrangement, the instruction of the ordering physician and applicable law, parties that reimburse us for our services include:

- third-party payors that provide coverage to the patient, such as an insurance company, a managed care organization or a governmental payor program;
- physicians or other authorized parties, such as hospitals or independent laboratories, that order the testing service or otherwise refer the services to us;
- patients in cases where the patient has no insurance, has insurance that partially covers the testing, or owes a co-payment, co-insurance or deductible amount;
- collaboration partners ; or
- biopharmaceutical companies, universities or researchers for clinical trial work.

We are reimbursed for two categories of testing, anatomic pathology, which includes cell staining and the enumeration component of CTC tests, FISH, immunocytochemistry and immunofluorescence, and molecular pathology, which includes mutation analysis. Reimbursement under the Medicare program for the diagnostic services that we offer is based on either the Medicare Physician Fee Schedule or the Medicare Clinical Laboratory Fee Schedule, each of which is subject to geographic adjustments and is updated annually. Medical services provided to Medicare beneficiaries that require a degree of physician supervision, judgment or other physician involvement, such as pathology services, are generally reimbursed under the Medicare Physician Fee Schedule, whereas clinical diagnostic laboratory tests are generally reimbursed under the Medicare Clinical Laboratory Fee Schedule. Some of the services that we provide are genetic and molecular testing, which are reimbursed as clinical diagnostic laboratory tests.

Regardless of the applicable fee schedule, Medicare payment amounts are established for each CPT code. In addition, under the Clinical Laboratory Fee Schedule, Medicare also sets a cap on the amount that it will pay for any individual test. This cap, usually referred to as the National Limitation Amount, is set at a percentage of the median of all the contractor fee schedule amounts for each billing code.

Medicare also has policies that may limit when we can bill directly for our services and when we must instead bill another provider, such as a hospital. When the testing that we perform is done on a specimen that was collected while the patient was in the hospital, as either an inpatient or outpatient, we may be required to bill the hospital for clinical laboratory services and for the technical component of pathology services. Which party is to be billed depends primarily on whether the service was ordered at least 14 days after the patient's discharge from the hospital. Complying with these requirements is complex and time-consuming and may affect our ability to collect for our services. In addition, hospitals may refuse to pay our invoices or may demand pricing that negatively affects our profit margin.

Medicare requires a beneficiary to pay a 20% co-insurance amount for services billed under the Physician Fee Schedule. Medicare covers the remaining 80%. There is currently no patient co-payment or co-insurance amount applicable to testing billed under the Clinical Laboratory Fee Schedule. Patients often have supplemental insurance policies that cover the co-insurance amount for physician services.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC capture/enumeration portion of our testing. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto GBA, LLC, adopted a negative coverage policy for CTC capture/enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore the capture/enumeration portion of our OncoCEE testing is not currently covered and we will receive no payment from Medicare for this service unless and until the coverage policy is changed. On November 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of the capture/enumeration testing in order to seek to persuade the MACs to allow coverage for this portion of our testing. Palmetto GBA responded on November 27, 2013, denying our request for Medicare coverage for the CTC capture/enumeration portion of our OncoCEE testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

Reimbursement rates paid by private third-party payors can vary based on whether we are considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. These definitions can vary among payors, but we are generally considered an "out-of-network" or non-participating provider by the vast majority of private third-party payors. An in-network provider usually has a contract with the payor or benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances an insurance company may negotiate an in-network rate for our testing. An in-network provider may have rates that are lower per test than those that are out-of-network, and that rate can vary widely. The rate varies based on the payor, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients.

Billing and Billing Codes for Third-Party Payor Reimbursement

CPT codes are the main data code set used by physicians, hospitals, laboratories and other health care professionals to report separately-payable clinical laboratory and pathology services for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association. We believe there are existing codes that describe nearly all of the other steps in our testing process. We currently use a combination of different codes to bill for our testing and analysis. Many of the CPT codes used to bill for molecular pathology tests such as those used for our OncoCEE-LU test were significantly revised by the CPT Code Editorial Panel effective January 1, 2013. These new codes replace the more general "stacking" codes that were previously used to bill for these services with more test-specific codes. In the Physician Fee Schedule Rule issued in November 2012, CMS stated that it had determined it would pay for the new codes as clinical laboratory tests under the Medicare Clinical Laboratory Fee Schedule. CMS has also started a process to "gapfill" the new codes. In other words, it will ask each of the MACs to determine a reasonable price for each of the new codes.

Changes in coding and reimbursement methods could have an adverse impact on our revenues going forward. However, we are currently working with our billing consultants to determine what will be required by the new coding changes. The elimination of the "stacking" codes will require us to either use the new more specific codes where applicable effective January 2013, or to use other "Not Otherwise Classified" codes when billing. The implementation of these new codes will vary from payor to payor, and it is too early to assess the impact, if any, that the migration to the new codes may have on our results of operations. The introduction of the new codes by CMS, in combination with the other actions it is considering with regard to pricing, could result in a reduction in the payments that we receive for our current tests and our planned future tests and make it more difficult to obtain coverage from Medicare or other payors. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

We are moving forward with plans to obtain reimbursement coverage for the capture/enumeration components of OncoCEE-BR, OncoCEE-GA, OncoCEE-GA and our planned CTC tests. For other components and types of testing provided or anticipated to be provided by us, specific CPT codes were provided by the American Medical Association in January 2013 or we are able to utilize existing CPT codes from the Medicare Physician Fee Schedule. For these established CPT codes (for example, the codes for FISH and immunocytochemistry, or ICC), positive coverage determinations have been adopted as part of national Medicare policy or under applicable Local Coverage Determinations. Specific codes for our tests, however, do not assure an adequate coverage policy or reimbursement rate. Please see the section entitled "Legislative and Regulatory Changes Impacting Clinical Laboratory Tests" for further discussion of certain legislative and regulatory changes to these billing codes and the anticipated impact on our business.

Coverage and Reimbursement for our Current Tests and our Planned Future Tests

Because of our previous relationship with Clarient, under which Clarient had responsibility for billing and reimbursement until mid-2013, we do not have established coverage and reimbursement policies set with all third-party payors. Our Medicare Administrative Contractor has issued a negative coverage determination for the capture/enumeration component of all CTC tests. We have received reimbursement for the capture/enumeration component of our tests from some private payors, including major private third-party payors, based on submission of standard CPT codes. FISH, ICC and Molecular Testing CPT codes are the subject of positive coverage national or local Medicare determinations. We believe these codes can be used to bill for the analysis components of our current and anticipated CTC tests.

We expect these analysis components to have a significantly greater reimbursement value than the capture/enumeration components of our current and anticipated CTC tests, based on a comparison of what we believe CellSearch® capture/enumeration reimbursement rates currently are, versus existing reimbursement rates for analysis components such as FISH and ICC analysis and molecular testing.

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clarient was responsible for all billing associated with our tests. We do not have data for Clarient's billing and collection experience with respect to our tests, because Clarient paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month, and from July to December 2014, we performed an average of 65 physician-ordered tests per month (in addition to the tests which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute, with an average of 15-30 tests per month performed during the trial's enrollment period through May 2014). Billing for these physician-ordered tests is now handled for us by a non-Clarient billing service provider. Between May 2013 and December 2014, we invoiced, through this service provider, for 239 physician-ordered tests. Of these, 37 tests were billed to Medicare and the remainder were billed to other payors. As of December 31, 2014, we have been paid by private payors for 67 of these tests. As of December 31, 2014, all of our revenue recognized has come from private payors, and processing of the Medicare claims above was delayed due to a new application process relating to a change in our tax identification number. We cannot assure you that, even if OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests are otherwise successful, reimbursement for the currently Medicare-covered portions of OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests would, without Medicare reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Where there is a private or governmental third-party payor coverage policy in place, we bill the payor and the patient in accordance with the established policy. Where there is no coverage policy in place, we pursue reimbursement on a case-by-case basis. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all. We are working to decrease risks of nonpayment by implementing a revenue cycle management system.

We cannot predict whether, or under what circumstances, payors will reimburse for all components of our tests. Payment amounts can also vary across individual policies. Full or partial denial of coverage by payors, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

Legislative and Regulatory Changes Impacting Clinical Laboratory Tests

From time to time, Congress has revised the Medicare statute and the formulas it establishes for both the Medicare Clinical Laboratory Fee Schedule and the Medicare Physician Fee Schedule. The payment amounts under the Medicare fee schedules are important because they not only determine our reimbursement under Medicare, but those payment amounts are also often used as a basis for payment amounts set by other governmental and private third - party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

Under the statutory formula for Medicare Clinical Laboratory Fee Schedule amounts, increases are made annually based on the Consumer Price Index for All Urban Consumers as of June 30 for the previous twelve-month period. From 2004-2008, Congress eliminated the Consumer Price Index for All Urban Consumers update in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008 mandated an approximately 0.5% cut to the Consumer Price Index for All Urban Consumers update. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. The ACA has, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. The ACA replaced the 0.5% cut enacted by the Medicare Improvements for Patients and

Providers Act with a "productivity adjustment" that will reduce the Consumer Price Index update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, the ACA includes a separate 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The MCTRJCA, enacted in 2012, mandated an additional change in reimbursement for clinical laboratory service programs. This legislation requires CMS to reduce the Medicare Clinical Laboratory Fee Schedule by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. CMS has projected that because of the changes required by ACA and MCTRJCA, payment for clinical laboratory services will go down by approximately 3% by 2013.

With respect to our diagnostic services for which we expect to be reimbursed under the Medicare Physician Fee Schedule, because of the statutory formula the rates would have decreased for the past several years if Congress failed to intervene. In the past, when the application of the statutory formula results in lower payment, Congress has passed interim legislation to prevent the reductions. In November 2013, CMS issued its 2014 Physician Fee Schedule Final Rule, or the 2014 Final Rule. In the 2014 Final Rule, CMS called for a reduction of approximately 23.7% in the 2014 conversion factor that is used to calculate physician reimbursement. If in future years Congress does not adopt interim legislation to block or offset, and/or CMS does not moderate, any substantial CMS-proposed reimbursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations. In addition, for 2012, CMS requested that the American Medical Association's Relative Value Scale Update Committee reexamine the relative values of certain codes, including FISH codes. The Relative Value Scale Update Committee is an expert panel that provides relative value recommendations to CMS for use in annual updates to the Medicare Physician Fee Schedule. These relative values are used by CMS to determine payments, and CMS seeks to assess whether such codes are misvalued and an adjustment is necessary. In July 2013 CMS published the proposed Physician Fee Schedule for 2014. As part of that proposed rule, CMS sought to decrease payment for approximately 200 CPT codes, including those for certain anatomic and molecular pathology services, to make payments to independent laboratories and hospital outpatient departments consistent. The proposed rates were generally lower than the current rates paid to independent laboratories and physicians for the same services. For example, CMS proposed to decrease the reimbursement rate for the technical component of FISH analysis by 47%. In fact, the 2014 Final Rule as adopted left FISH reimbursement rates for independent laboratories and physicians essentially unchanged from 2013 reimbursement levels.

In addition, the 2014 Final Rule included both increases and decreases in certain relative value units and geographic adjustment factors used to determine reimbursement for a number of codes used in our current tests and our planned future tests. These codes describe services that we must perform in connection with our tests and we bill for these codes in connection with the services that we provide.

Under the Protecting Access to Medicare Act of 2014, or PAMA, which was signed to law in April 2014, there will be major changes to the payment formula under the Medicare Clinical Laboratory Fee Schedule, or CLFS. Beginning January 1, 2016, clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. It is too early to predict the impact of this federal legislation on reimbursement for our products.

Further, with respect to the Medicare program, Congress has proposed on several occasions to impose a 20% coinsurance charge on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

Some of our Medicare claims may be subject to policies issued by Palmetto GBA and Noridian Healthcare Solutions, our former and current Medicare Administrative Contractor for California, respectively. Palmetto GBA, acting on behalf of many MACs, recently issued a Local Coverage Decision that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, Palmetto GBA will not cover any molecular diagnostic tests, such as the capture/enumeration component of our current tests and our planned future tests, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto GBA. Currently, laboratories may submit coverage determination requests to Palmetto GBA for consideration and apply for a unique billing code for each test (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. In addition, effective January 1, 2013, Palmetto GBA implemented its new Molecular Diagnostic Services Program, under which, among other things, laboratories must use the newly-assigned billing codes specific to the test (as implemented by the American Medical Association), in order to receive the indicated reimbursement amounts. Reimbursement amounts under these new single molecular diagnostics billing codes were in some cases lower, and in some cases

higher, than amounts allowed by Medicare before January 1, 2013, but most were significantly lower. Palmetto GBA currently has a negative coverage determination for the capture/enumeration component of CTC tests such as our current and anticipated CTC tests, but there is no such negative coverage determination for the analysis component of such CTC tests. Denial (or continuation of denial) of coverage for the capture/enumeration component of our current and anticipated CTC tests by Palmetto GBA or its successor MAC, Noridian Healthcare Solutions, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our current tests and our planned future tests. Noridian Healthcare Solutions intends to follow, for CTC tests, the positive or negative coverage determinations which from time to time Palmetto GBA makes. On November 27, 2013, Palmetto GBA denied our request for coverage for the enumeration/detection portion of our OncoCEE testing. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

Additionally, the Centers for Disease Control and Prevention, or CDC, CMS and the Office of Civil Rights, or OCR, issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA privacy rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Similarly, the final rule amended CLIA to state that CLIA laboratories and CLIA-exempt laboratories may provide copies of the patient's completed rest reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Governmental Regulations

Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a provider of laboratory testing on human specimens for the purpose of diagnosis, prevention, or treatment, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. In 1988, Congress enacted CLIA, which established quality standards for all laboratories providing testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. Our laboratory holds a CLIA certificate of accreditation. As to state laws, we are required to meet certain laboratory licensing and other requirements. Our laboratory holds the required licenses from the applicable state agencies in which we operate. For more information on state licensing requirements, see the sections entitled see the section entitled "Governmental Regulations—California State Laboratory Licensing" and "Governmental Regulations—Other States' Laboratory Licensing."

Under CLIA, a laboratory is defined as any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. CLIA also requires that we hold a certificate applicable to the complexity of the categories of testing we perform and that we comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they comply with various operational, personnel, facilities administration, quality and proficiency testing requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. CLIA certification is also a prerequisite to be eligible to be reimbursed for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as "high complexity" under CLIA may obtain analyte specific reagents, which are used to develop LDTs.

In addition to CLIA requirements, we must comply with the standards set by CAP, which accredits our laboratory. Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA. Therefore, because we are accredited by CAP, we are deemed to also comply with CLIA. CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and certain states have implemented their own more stringent laboratory regulatory schemes.

Federal, State and Foreign Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. For further discussion of the impact of federal and state health care fraud and abuse laws and regulations on our business, see the section entitled "Risk Factors—Regulatory Risks Relating to Our Business." We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

In addition, HIPAA also created new federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, and some of these state laws apply where a claim is submitted to any third-party payor. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from $5,500 to $11,000 for each false claim.

Additionally, the civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, many states have laws similar to those listed above that may be broader in scope and may apply regardless of payor.

Additionally, in Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a "financial relationship"—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against us and/or the professional through licensure proceedings, and we could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Direct Billing Laws and Other State Law Restrictions on Billing for Laboratory Services

Laws and regulations in certain states prohibit laboratories from billing physicians or other purchasers for testing that they order. Some of those laws and regulations apply only to anatomic pathology services while others extend to other types of testing. Some states may allow laboratories to bill physicians directly but may prohibit the physician (and, in some cases, other purchasers) from charging more than the purchase price for the services (or may allow only for the recovery of acquisition costs) or may require disclosure of certain information on the invoice. In some cases, and if not prohibited by law or regulation, we may bill physicians, hospitals and other laboratories directly for the services that they order. An increase in the number of states that impose similar restrictions could adversely affect us by encouraging physicians to perform laboratory services in-house or by causing physicians to refer services to other laboratories that are not subject to the same restrictions.

Physician Licensing

A number of the states where specimens originate require that the physician interpreting those specimens be licensed by that particular state. Physicians who fail to comply with these licensure requirements could face fines or other penalties for practicing medicine without a license and we could be required to pay those fines on behalf of our pathologists or subject to liability under the federal False Claims Act and similar state laws if we bill for services furnished by unlicensed pathologists. We do not believe that the services our pathologist performs constitute the practice of medicine in any state that requires out-of-state physician licensure. We believe that our pathologist thus is not required to obtain licensure in any state where he does not reside.

In addition, many states also prohibit the splitting or sharing of fees between physicians and non-physician entities. We do not believe that our contractual arrangements with physicians, physicians group practices or hospitals will subject us to claims under such regulations. However, changes in the laws may necessitate modifications in our relationships with our clients.

California State Laboratory Licensing

Our laboratory is licensed and in good standing under the State of California Department of Public Health standards. Our current licenses permit us to receive specimens obtained in California.

California state laws and regulations also establish standards for the day-to-day operations of clinical laboratories, including physical facility requirements and equipment, quality control and proficiency testing requirements. If we are found to be out of compliance with California statutory or regulatory standards, we may be subject to suspension, restriction or revocation of our laboratory license or assessed civil money penalties. The operator of a noncompliant laboratory may also be found guilty of a misdemeanor under California law. A finding of noncompliance, therefore, may result in harm to our business.

Other States' Laboratory Licensing

Several states require the licensure of out-of-state laboratories that accept specimens from those states. We hold licenses from the states of Florida, Maryland, Pennsylvania and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. We are currently in the process of addressing the requirements for licensure in New York.

From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from such states. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

U.S. Food and Drug Administration

We provide our tests as laboratory-developed tests, or LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of production, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Segment and Geographical Information

We operate in one reportable business segment and historically have derived revenues only from the United States.

Employees

As of December 31, 2014, we had a total of 42 full-time employees and one part time employee, four of whom hold doctorate degrees and six of whom are engaged in full-time research and development activities. We plan to expand production, sales and marketing and our research and development programs, and we plan to hire additional staff as these initiatives are implemented. None of our employees is represented by a labor union.

Available Information

Our website address is www.biocept.com. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Company Information

We maintain our principal executive offices at 5810 Nancy Ridge Drive, San Diego, California 92121. Our telephone number is (858) 320-8200 and our website address is www.biocept.com. The information contained in, or that can be accessed through, our website is not incorporated into and is not part of this Annual Report. We were incorporated in California on May 12, 1997 and reincorporated as a Delaware corporation on July 30, 2013.

Item 1A. Risk Factors

An investment in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results and prospects. Certain statements below are forward-looking statements. For additional information, see the information included under the heading "Special Note Regarding Forward-Looking Statements."

Risks Relating to Our Financial Condition and Capital Requirements

We are an early stage company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.

We have historically incurred substantial net losses, including net losses of $9.2 million and $15.9 million for the years ended December 31, 2013 and 2014, respectively, and we have never been profitable. At December 31, 2014, our accumulated deficit was approximately $138.3 million. Before 2008, we were pursuing a business plan relating to fetal genetic disorders and other fields, all of which were unrelated to cancer diagnostics. The portion of our accumulated deficit that relates to the period from inception through December 31, 2007 is approximately $66.5 million.

We expect our losses to continue as a result of costs relating to our lab operations as well as increased sales and marketing costs and ongoing research and development expenses. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows. Our chief executive officer Michael W. Nall, who joined us in August 2013, has not previously been the chief executive officer of a public or private company, and therefore his lack of experience may result in some of his time being spent acclimating to his new position and responsibilities. A lack of significant experience in being the chief executive officer of a public company could have an adverse effect on his ability to quickly respond to problems or effectively manage issues surrounding the operation of a public company.

We may need to raise additional capital.

We may need to raise additional capital to expand our business to meet our long-term business objectives. Additional financing may be from the sale of equity or convertible or other debt securities in a public or private offering, from a new credit facility or strategic partnership coupled with an investment in us or a combination of both. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Failure to raise additional capital in sufficient amounts would significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

Risks Relating to Our Business and Strategy

If we are unable to increase sales of our OncoCEE diagnostic tests or successfully develop and commercialize other tests, our revenues will be insufficient for us to achieve profitability.

We currently derive substantially all of our revenues from sales of cancer diagnostic tests. We recently began offering our OncoCEE cancer tests through our CLIA-certified, CAP accredited, and state-licensed laboratory. We are in varying stages of research and development for other cancer diagnostic tests that we may offer. If we are unable to increase sales of our OncoCEE-BR for breast cancer, OncoCEE-LU for NSCLC and OncoCEE-GA for gastric cancer diagnostic test or successfully develop and commercialize other cancer diagnostic tests, we will not produce sufficient revenues to become profitable.

If we are unable to execute our sales and marketing strategy for cancer diagnostic tests and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

We are an early-stage company and have engaged in only limited sales and marketing activities for the OncoCEE-BR for breast cancer, OncoCEE-LU for NSCLC and OncoCEE-GA for gastric cancer diagnostic tests we offer through our CLIA-certified, CAP accredited, and state-licensed laboratory. To date, we have received very limited revenue.

Although we believe that our current tests and our planned diagnostic tests represent a promising commercial opportunity, our tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our cancer diagnostic tests and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publication in leading peer-reviewed journals of results from studies using our current tests and/or our planned cancer tests. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current tests and our planned tests.

Our ability to successfully market the cancer diagnostic tests that we may develop will depend on numerous factors, including:

- conducting clinical utility studies of such tests in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our current or future partners, vigorously support our offerings;
- the success of our sales force;
- whether healthcare providers believe such diagnostic tests provide clinical utility;
- whether the medical community accepts that such diagnostic tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
- whether private health insurers, government health programs and other third-party payors will cover such cancer diagnostic tests and, if so, whether they will adequately reimburse us.

Failure to achieve widespread market acceptance of our current tests and our planned cancer diagnostic tests would materially harm our business, financial condition and results of operations.

If we cannot develop tests to keep pace with rapid advances in technology, medicine and science, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer drugs have been approved, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new cancer diagnostic tests and enhance any existing tests to keep pace with evolving standards of care. Our current tests and our planned tests could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with cancer. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to develop cancer diagnostic tests based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the applicability of our current tests and our planned tests to new treatments, by incorporating important biomarker analysis, sales of our tests could decline, which would have a material adverse effect on our business, financial condition and results of operations.

If our current tests and our planned tests do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic results. We believe that our customers are likely to be particularly sensitive to test defects and errors. As a result, the failure of our current or planned tests to perform as expected would significantly impair our reputation and the public image of our cancer tests, and we may be subject to legal claims arising from any defects or errors.

If our sole laboratory facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell and provide cancer diagnostic tests and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our OncoCEE-BR for breast cancer, OncoCEE-LU for NSCLC and OncoCEE-GA for gastric cancer diagnostic tests conducted in our CLIA-certified, CAP accredited, and state-licensed laboratory. We do not have any clinical reference laboratory facilities other than our facility in San Diego, California. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages, which may render it difficult or impossible for us to perform our diagnostic tests for some period of time. The inability to perform our current tests and our planned tests or the backlog of tests that could develop if our facility is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

The San Diego area has recently experienced serious fires and power outages, and is considered to lie in an area with earthquake risk.

Additionally, a key component of our research and development process involves using biological samples as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facility where we store these biological samples were damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our CLIA-certified, CAP accredited, and state-licensed laboratory became inoperable we may not be able to license or transfer our technology to another facility with the necessary qualifications, including state licensure and CLIA certification, under the scope of which our current tests and our planned cancer diagnostic tests could be performed. Even if we find a facility with such qualifications to perform our tests, it may not be available to us on commercially reasonable terms.

If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principal competition comes from mainstream diagnostic methods, used by pathologists and oncologists and other physicians for many years, which focus on tumor tissue analysis. It may be difficult to change the methods or behavior of oncologists and other physicians to incorporate our CTC and ctDNA testing, including molecular diagnostic testing, in their practices in conjunction with or instead of tissue biopsies and analysis. In addition, companies offering capital equipment and kits or reagents to local pathology laboratories represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption. We plan to focus our marketing and sales efforts on medical oncologists rather than pathologists.

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA testing in various cancers. In particular, Janssen Diagnostics, LLC markets its CellSearch® test and Atossa Genetics markets its ArgusCYTE® test, which are competitive to our tests for CTC enumeration and HER2 analysis. CTC and ctDNA testing is a new area of science and we cannot predict what tests others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the tests we develop. In addition to Janssen Diagnostics and Atossa Genetics, our competitors also include public companies such as Alere (Adnagen) and Illumina as well as many private companies, including Apocell, EPIC Sciences, Clearbridge Biomedics, Cynvenio Biosystems, Fluxion Biosciences, Guardant Health, RareCells and Silicon Biosystems. Many of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents. Our sales and distribution agreements are non-exclusive and our partners could enter into agreements with competitors.

We expect that pharmaceutical and biopharmaceutical companies will increasingly focus attention and resources on the personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. For example, the FDA has recently approved two such agents—Xalkori® from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc., Zelboraf® from Daiichi-Sankyo/Genentech/Roche along with its companion B-raf kinase V600 mutation test from Roche Molecular Systems, Inc. and Tafinlar® from GlaxoSmithKline along with its companion B-raf kinase V600 mutation test from bioMerieux. These recent FDA approvals are only the second, third and fourth instances of simultaneous approvals of a drug and companion diagnostic, the first being the 2010 approval of Genentech's Herceptin® for HER2 positive breast cancer along with the HercepTest from partner Dako A/S. Our competitors may invent and commercialize technology platforms or tests that compete with ours.

There are a number of companies which are focused on the oncology diagnostic market, such as Biodesix, Caris, Clarient, Foundation Medicine, Neogenomics, Response Genetics, Agendia, Genomic Health, and Genoptix, who while not currently offering CTC or ctDNA tests are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA tests. Large laboratory services companies, such as Sonic USA, Quest and LabCorp, provide more generalized cancer diagnostic testing.

Additionally, projects related to cancer diagnostics and particularly genomics have received increased government funding, both in the United States and internationally. As more information regarding cancer genomics becomes available to the public, we anticipate that more products aimed at identifying targeted treatment options will be developed and that these products may compete with ours. In addition, competitors may develop their own versions of our current or planned tests in countries where we did not apply for patents or where our patents have not issued and compete with us in those countries, including encouraging the use of their test by physicians or patients in other countries.

Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that payors, pathologists and oncologists and other physicians could view as functionally equivalent to our current or planned tests, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more sensitive or specific than ours may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect to continue to incur significant expenses to develop and market cancer diagnostic tests, which could make it difficult for us to achieve and sustain profitability.

In recent years, we have incurred significant costs in connection with the development of cancer diagnostic tests. For the year ended December 31, 2013, our research and development expenses were $3.1 million and our sales and marketing expenses were $0.1 million. For the year ended December 31, 2014, our research and development expenses were $4.5 million and our sales and marketing expenses were $2.1 million. We expect our expenses to continue to increase for the foreseeable future as we conduct studies of our current tests and our planned cancer diagnostic tests, establish a sales and marketing organization, drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we need to generate significant revenues in order to achieve sustained profitability.

If oncologists and other physicians decide not to order our OncoCEE cancer diagnostic tests or our future cancer diagnostic tests, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current tests and our planned cancer diagnostic tests, we will need to educate oncologists, pathologists, and other health care professionals on the clinical utility, benefits and value of the tests we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we need to assure oncologists and other physicians of our ability to obtain and maintain coverage and adequate from third-party payors. We need to hire additional commercial, scientific, technical and other personnel to support this process. Unless an adequate number of medical practitioners order our current tests and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

Clinical utility studies are important in demonstrating to both customers and payors a test's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that a test provides clinically meaningful information and value, commercial adoption of such test may be slow, which would negatively impact our business.

Clinical utility studies show when and how to use a clinical test, and describe the particular clinical situations or settings in which it can be applied and the expected results. Clinical utility studies also show the impact of the test results on patient care and management. Clinical utility studies are typically performed with collaborating oncologists or other physicians at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a clinical test, as well as why they should use it. These publications are also used with payors to obtain coverage for a test, helping to assure there is appropriate reimbursement.

Our OncoCEE-BR test is currently part of a clinical utility study led by investigators at the Dana-Farber Cancer Institute. We will need to conduct additional studies for this test, as well as other CTC and ctDNA tests we plan to introduce, to increase test adoption in the marketplace and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for oncologists and other physicians, adoption of our tests could be impaired and we may not be able to obtain coverage and adequate reimbursement for them.

We are undergoing a management transition.

Until August 26, 2013, David F. Hale, our Chairman, served as our principal executive officer. On that date, Michael W. Nall began his employment with us as our Chief Executive Officer and President, with David F. Hale remaining employed as our Executive Chairman until February 10, 2014. Mr. Hale currently serves as non-Executive Chairman of our Board of Directors. We intend to recruit and hire other senior executives. Such a management transition subjects us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge. In addition, Mr. Nall has not previously been the chief executive officer of a public or private company, and therefore his lack of experience may result in some of his time being spent acclimating to his new position and responsibilities. A lack of significant experience in being the chief executive officer of a public company could have an adverse effect on his ability to quickly respond to problems or effectively manage issues surrounding the operation of a public company.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Michael W. Nall, our Chief Executive Officer and President, Lyle J. Arnold, Ph.D., our Senior Vice-President of Research & Development and Chief Scientific Officer, and Veena M. Singh, M.D., our Senior Vice President and Senior Medical Director, William G. Kachioff, our Senior Vice-President of Finance and Chief Financial Officer and Raaj Trivedi, Vice President, Commercial Operations. The collective efforts of each of these persons and others working with them as a team are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our Chief Executive Officer and President, Chief Financial Officer, Chief Scientific Officer, Vice President, Commercial Operations and Senior Medical Director have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain "key person" life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

Our failure to continue to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for our cancer diagnostic test, to expand geographically and to successfully commercialize any other tests or products we may develop.

To succeed in selling our diagnostic tests and any other tests or products that we are able to develop, we must expand our sales force in the United States and/or internationally by recruiting additional sales representatives with extensive experience in oncology and established relationships with medical oncologists, surgeons, oncology nurses, pathologists and other hospital personnel. To achieve our marketing and sales goals, we will need to continue to build our sales and commercial infrastructure, with which to date we have had limited experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

Our dependence on commercialization partners for sales of tests could limit our success in realizing revenue growth.

We intend to grow our business through the use of commercialization partners for the sales, marketing and commercialization of our current tests and our planned future tests, and to do so we must enter into agreements with these partners to sell, market or commercialize our tests. These agreements may contain exclusivity provisions and generally cannot be terminated without cause during the term of the agreement. We may need to attract additional partners to expand the markets in which we sell tests. These partners may not commit the necessary resources to market and sell our cancer diagnostics tests to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such partners or if such partners terminate their agreement with us.

Any relationships we form with commercialization partners are subject to change over time. For example, over 75% of our revenue in 2012 was generated through our arrangement with Clarient, but Clarient is no longer marketing the OncoCEE-BR test as actively as before. In May 2013, we amended our commercialization agreement with Clarient such that Clarient is no longer the exclusive marketer of the OncoCEE-BR test. In 2013 and 2014, only 10% and 6%, respectively, of our revenues were generated through our arrangement with Clarient, and we expect that in the future the percentage of our revenue which is generated through our arrangement with Clarient will diminish further. If we cannot replace any diminution in revenues we receive through Clarient, our results will be weakened.

If current or future commercialization partners do not perform adequately, or we are unable to locate commercialization partners, we may not realize revenue growth.

We depend on third parties for the supply of blood samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase or our third party suppliers terminate their relationship with us, our business may be materially harmed.

We have relationships with suppliers and institutions that provide us with blood samples and other biological materials that we use in developing and validating our current tests and our planned future tests. If one or more suppliers terminate their relationship with us or are unable to meet our requirements for samples, we will need to identify other third parties to provide us with blood samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, our research and academic institution collaborators may seek additional financial contributions from us, which may negatively affect our results of operations.

We currently rely on third-party suppliers for critical materials needed to perform our current tests and our planned future tests and any problems experienced by them could result in a delay or interruption of their supply to us.

We currently purchase raw materials for our microfluidic channels and testing reagents under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our materials or reagents, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing the microfluidic channels or performing tests while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have a significant negative impact on our ability to perform cancer diagnostic tests in a timely manner.

Some of the components used in our current or planned products are currently sole-source, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our current tests and our planned future diagnostic tests could lead to the filing of product liability claims against us if someone alleges that our tests failed to perform as designed. We may also be subject to liability for errors in the test results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Although we believe that our existing product and professional liability insurance is adequate, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, result in the recall of tests, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

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 have a material adverse effect on our financial condition, results of operations and cash flows. 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.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

If we cannot support demand for our current tests and our planned future diagnostic tests, including successfully managing the evolution of our technology and manufacturing platforms, our business could suffer.

As our test volume grows, we will need to increase our testing capacity, implement automation, increase our scale and related processing, customer service, billing, collection and systems process improvements and expand our internal quality assurance program and technology to support testing on a larger scale. We will also need additional clinical laboratory scientists and other scientific and technical personnel to process these additional tests. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional tests are commercialized, we may need to bring new equipment on line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform tests on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our test results or that we will respond successfully to the growing complexity of our testing operations. If we encounter difficulty meeting market demand or quality standards for our current tests and our planned future tests, our reputation could be harmed and our future prospects and business could suffer, which may have a material adverse effect on our financial condition, results of operations and cash flows.

We may encounter manufacturing problems or delays that could result in lost revenue.

We currently manufacture our proprietary microfluidic channels at our San Diego facility and intend to continue to do so. We believe we currently have adequate manufacturing capacity for our microfluidic channels. If demand for our current tests and our planned future tests increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. If we or third party manufacturers engaged by us fail to manufacture and deliver our microfluidic channels or certain reagents in a timely manner, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing or quality control problems will not arise as we attempt to increase the production of our microfluidic channels or reagents or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot manufacture our microfluidic channels consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform tests and generate revenues.

International expansion of our business would expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy contemplates possible international expansion, including partnering with academic and commercial testing laboratories, and introducing OncoCEE technology outside the United States as part of CE-marked IVD test kits and/or testing systems utilizing our CEE and/or CEE-Selector technologies. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current tests and our planned future tests in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current tests and our planned future diagnostic tests cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities; and
- Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

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

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate does not improve, or it deteriorates, our business, including our access to patient samples and the addressable market for diagnostic tests that we may successfully develop, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

Intrusions into our computer systems could result in compromise of confidential information.

Despite the implementation of security measures, our technology or systems that we interface with, including the Internet and related systems, may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act of 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as 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, collectively referred to as business associates. 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, or Final Omnibus Rule,

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, or HHS. 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 United States 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.

We depend on our information technology and telecommunications systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant aspects of our operations. In addition, our third-party billing and collections provider depends upon telecommunications and data systems provided by outside vendors and information we provide on a regular basis. These information technology and telecommunications systems support a variety of functions, including test processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing tests, providing test results to oncologists, pathologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

Regulatory Risks Relating to Our Business

Healthcare policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, makes a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the ACA:

- Mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, annual Consumer Price Index update of 1.75% for the years 2011 through 2015. In addition, a multifactor productivity adjustment is made to the fee schedule payment amount, which could further reduce payment rates. These changes in payments may apply to some or all of the tests we furnish to Medicare beneficiaries.
- Establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020.
- Requires each medical device manufacturer to pay an excise tax equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. We believe that at this time this tax does not apply to our current cancer diagnostic test or to our products that are in development; nevertheless, this could change in the future if either the FDA or the Internal Revenue Service, which regulates the payment of this excise tax, changes its position.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extends coverage to over 30 million previously uninsured people, which may result in an increase in the demand for our current tests and our planned future cancer diagnostic tests. The mandatory purchase of insurance has been strenuously opposed by a number of state governors, resulting in lawsuits challenging the constitutionality of certain provisions of the ACA. In 2012, the Supreme Court upheld the constitutionality of the ACA, with the exception of certain provisions dealing with the expansion of Medicaid coverage under the law.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly alters the current payment methodology under the CLFS. Under the new law, starting January 1, 2016 and every three years thereafter (or annually in the case of advanced diagnostic lab tests), clinical laboratories must report laboratory test payment data for each Medicare-covered clinical diagnostic lab test that it furnishes during a time period to be defined by future regulations. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2017, the Medicare payment rate for each clinical diagnostic lab test will be equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. Although the PAMA changes are generally viewed by industry as a favorable alternative to other proposals to update the CLFS payment methodology, it is too early to predict the impact on reimbursement for our products. Also under PAMA, the Centers for Medicare & Medicaid Services, or CMS, is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS must publicly report payment for the tests no later than January 1, 2016. Also under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. We cannot determine at this time the full impact of PAMA on our business, financial condition and results of operations.

Additionally, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, starting in 2013, and will remain in effect through 2024 unless additional congressional action is taken. The full impact on our business of the ACA and the sequester law is uncertain. In addition, the Middle Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, mandated an additional change in Medicare reimbursement for clinical laboratory tests.

Some of our laboratory test business is subject to the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. A recent legislative intervention was passed with PAMA, which provided for a 0.5% update from 2013 Medicare Physician Fee Schedule payment rates through 2014 and a 0% update from January 1 until April 1, 2015. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue and results of operations. If in future years Congress does not adopt interim legislation to block or offset, and/or CMS does not moderate, any substantial CMS-proposed reimbursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations.

In November 2014, CMS issued the Physician Fee Schedule Final Rule to take effect January 1, 2015 the overall reduction was 2% but pricing for some codes including FISH pricing were reduced by approximately 53%.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government's role in the U.S. health care industry as a result of the ACA's implementation, and changes to the reimbursement amounts paid by Medicare and other payors for our current tests and our planned future cancer diagnostic tests, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require us to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for our tests could often exceed the amount actually received from the patient.

Our commercial success could be compromised if hospitals or other clients do not pay our invoices or if third-party payors, including managed care organizations and Medicare, do not provide coverage and reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our current tests and our planned future tests.

Oncologists and other physicians may not order our current tests and our planned future cancer diagnostic tests unless third-party payors, such as managed care organizations and government payors (e.g., Medicare and Medicaid), pay a substantial portion of the test price. Coverage and reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that tests using our technologies are:

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

Uncertainty surrounds third-party payor coverage and adequate reimbursement of any test incorporating new technology, including tests developed using our technologies. Technology assessments of new medical tests conducted by research centers and other entities may be disseminated to interested parties for informational purposes. Third-party payors and health care providers may use such technology assessments as grounds to deny coverage for a test or procedure. Technology assessments can include evaluation of clinical utility studies, which define how a test is used in a particular clinical setting or situation.

Because each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our cancer diagnostic tests, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current tests and our planned future tests will be provided in the future by additional third-party payors or that existing agreements, policy decisions or reimbursement levels will remain in place or be fulfilled under existing terms and provisions. If we cannot obtain coverage and adequate reimbursement from private and governmental payors such as Medicare and Medicaid for our current tests, or new tests or test enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we may experience delays and interruptions in the receipt of payments from third-party payors due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, to the extent that our testing is ordered for Medicare inpatients and outpatients, only the hospital may receive payment from the Medicare program for the technical component of pathology services and any clinical laboratory services that we perform, unless the testing is ordered at least 14 days after discharge and certain other requirements are met. We therefore must look to the hospital for payment for these services under these circumstances. If hospitals refuse to pay for the services or fail to pay in a timely manner, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow.

We expect to depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our current tests and our planned future tests, our revenues could decline.

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clarient was responsible for all billing associated with our tests. We do not have data for Clarient's billing and collection experience with respect to our tests, because Clarient paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month, and from July to December 2014, we performed an average of 65 physician-ordered tests per month (in addition to the tests which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute, with an average of 15-30 tests per month performed during the trial's enrollment period through May 2014). Billing for these physician-ordered tests is now handled for us by a non-Clarient billing service provider. Between May 2013 and December 2014, we invoiced, through this service provider, for 239 physician-ordered tests. Of these, 37 tests were billed to Medicare and the remainder were billed to other payors. As of December 31, 2014, we have been paid by private payors for 67 of these tests. As of December 31, 2014, all of our revenue recognized has come from private payors, and processing of the Medicare claims above was delayed due to a new application process relating to a change in our tax identification number. We cannot assure you that, even if OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests are otherwise

successful, reimbursement for the currently Medicare-covered portions of OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests would, without Medicare reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

Medicare and other third-party payors may change their coverage policies or cancel future contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues. Payors have increased their efforts to control the cost, utilization and delivery of health care services. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory testing generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our current tests and our planned future cancer diagnostic tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we are currently considered a "non-contracted provider" by the majority of third-party payors because we have not entered into a specific contract to provide cancer diagnostic tests to their insured patients at specified rates of reimbursement. If we were to become a contracted provider with additional payors in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients. Medicare reimbursement revenues are an important component of our business model, and private payors sometimes look to Medicare determinations when making their own payment determinations; therefore, incomplete or inadequate reimbursement from Medicare would negatively affect our business.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC capture/enumeration portion of our testing. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto GBA, LLC, adopted a negative coverage policy for CTC capture/enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore the capture/enumeration portion of our OncoCEE testing is not currently covered and we will receive no payment from Medicare for this service unless and until the coverage policy is changed. On November 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of the capture/enumeration testing in order to seek to persuade the MACs to allow coverage for this portion of our testing. Palmetto GBA responded on November 27, 2013, denying our request for Medicare coverage for the CTC capture/enumeration portion of our OncoCEE testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

We cannot assure you that, even if OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests are otherwise successful, reimbursement for the currently Medicare-covered portions of OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests would, without Medicare reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

The processing of Medicare claims is subject to change at CMS' discretion at any time. Cost containment initiatives may be a threat to Medicare reimbursement levels (including for the covered components of OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests, including FISH analysis and molecular testing) for the foreseeable future.

Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we must satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We must also comply with numerous other laws applicable to billing and payment for healthcare services, including, for example, privacy laws. Failure to comply with these requirements may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. In addition, failure by third-party payors to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate of accreditation under CLIA to perform high complexity testing, and our laboratory is accredited by the College of American Pathologists, or CAP, one of six CLIA-approved accreditation organizations. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process. The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition, our laboratory is located in California and is required by state law to have a California state license; as we expand our geographic focus, we may need to obtain laboratory licenses from additional states. California laws establish standards for operation of our clinical laboratory, including the training and skills required of personnel and quality control. In addition, we hold licenses from the states of Pennsylvania, Florida, Maryland and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as laboratory developed tests, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our tests. We currently do not have the necessary New York license, but we are in the process of addressing the requirements for licensure in New York. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our tests outside the United States.

If we were to lose our CLIA certification or California laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenues and harm our business. If we were to lose, or fail to obtain, a license in any other state where we are required to hold a license, we would not be able to test specimens from those states.

If the FDA were to begin requiring approval or clearance of our current tests and our planned future tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our tests.

Historically, the U.S. Food and Drug Administration, or FDA, has exercised enforcement discretion with respect to most LDTs and has not required laboratories that furnish LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of general enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. It is unclear at this time when, or if, the draft guidance documents will be finalized, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance (in as little as 12 months after the draft guidance is finalized for certain high-priority LDTs such as LDTs with the same intended use as a cleared or approved companion diagnostic). Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

The container we provide for collection and transport of blood samples from a health care provider to our clinical laboratory may be a medical device subject to the FDA regulation but is currently exempt from pre-market review by the FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that the FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition.

In addition, HHS requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report's recommendations for increased oversight of genetic testing were to result in further regulatory burdens, they could negatively affect our business and delay the commercialization of tests in development.

The requirement of pre-market review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling our cancer diagnostic tests pending pre-market clearance or approval. If the FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from physicians or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a pre-market approval application with the FDA. If the FDA requires pre-market review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Additionally, should future regulatory actions affect any of the reagents we obtain from suppliers and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform our testing.

If we were required to conduct additional clinical studies or trials before continuing to offer tests that we have developed or may develop as LDTs, those studies or trials could lead to delays or failure to obtain necessary regulatory approval, which could cause significant delays in commercializing any future products and harm our ability to achieve sustained profitability.

If the FDA decides to require that we obtain clearance or approvals to commercialize our current tests or our planned future cancer diagnostic tests, we may be required to conduct additional pre-market clinical testing before submitting a regulatory notification or application for commercial sales. In addition, as part of our long-term strategy we may plan to seek FDA clearance or approval so we can sell our tests outside our CLIA laboratory; however, we would need to conduct additional clinical validation activities on our tests before we can submit an application for FDA approval or clearance. Clinical trials must be conducted in compliance with FDA regulations or the FDA may take enforcement action or reject the data. The data collected from these clinical trials may ultimately be used to support market clearance or approval for our tests. We believe it would likely take two years or more to conduct the clinical studies and trials necessary to obtain approval from the FDA to commercially launch our current tests and our planned future tests outside of our clinical laboratory. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our test claims or that the FDA or foreign authorities will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing 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 trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. Moreover, the clinical trial process may fail to demonstrate that our current tests and our planned future tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals 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 current tests and our planned future tests. 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 tests or to achieve sustained profitability.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established federal crimes for, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal false claims and civil monetary penalties laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government;
- The federal Physician Payment Sunshine Act requirements under the ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and certain physician ownership and investment interests in such manufacturers; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal health care fraud statutes. Where the intent requirement has been lowered, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may now assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, administrative, civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal—the California Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We may be required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information used or disclosed by health care providers and other covered entities.

The privacy regulations regulate the use and disclosure of Protected Health Information by covered entities engaging in certain electronic transactions or "standard transactions." They also set forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a covered entity, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. The HIPAA security regulations establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of Protected Health Information in electronic form. These standards apply to covered entities and also to "business associates" or third parties providing services to covered entities involving the use or disclosure of Protected Health Information. The HIPAA privacy and

security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing Protected Health Information. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws.

Moreover, the Health Information Technology for Economic and Clinical Health Act, or HITECH, enacted as part of ARRA, among other things, established certain health information security breach notification requirements, which were later further modified by the Final Omnibus Rule. In the event of a breach of unsecured Protected Health Information, a covered entity must notify each individual whose Protected Health Information is breached, federal regulators and in some cases, must publicize the breach in local or national media. Breaches affecting 500 individuals or more may be publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected.

These laws contain significant fines and other penalties for wrongful use or disclosure of Protected Health Information. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. Adding to the complexity is that our operations are evolving and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

Clinical research is heavily regulated and failure to comply with human subject protection regulations may disrupt our research program leading to significant expense, regulatory enforcement, private lawsuits and reputational damage.

Clinical research is subject to federal, state and, for studies conducted outside of the United States, international regulation. At the federal level, the FDA imposes regulations for the protection of human subjects and requirements such as initial and ongoing institutional review board review; informed consent requirements, adverse event reporting and other protections to minimize the risk and maximize the benefit to research participants. Many states impose human subject protection laws that mirror or in some cases exceed federal requirements. HIPAA also regulates the use and disclosure of Protected Health Information in connection with research activities. Research conducted overseas is subject to a variety of national protections such as mandatory ethics committee review, as well as laws regulating the use, disclosure and cross-border transfer of personal data. The costs of compliance with these laws may be significant and compliance with regulatory requirements may result in delay. Noncompliance may disrupt our research and result in data that is unacceptable to regulatory authorities, data lock or other sanctions that may significantly disrupt our operations.

Violation of a state's prohibition on the corporate practice of medicine could result in a material adverse effect on our business.

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against us and/or the professional through licensure proceedings, and we could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Intellectual Property Risks Related to Our Business

If we are unable to obtain and maintain effective patent rights for our products or services, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies, products and services. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or services in the United States or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products and services, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products and services, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our products and services. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any products and services that we may offer. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product or service under patent protection could be reduced.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our products or services, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third-party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may infringe.

In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our products or services, the holders of any such patents may be able to block our ability to commercialize such products or services unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to our products or services through acquisitions and in-licenses.

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our products and services. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our products or services. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

We sometimes collaborate with U.S. and foreign institutions to accelerate our research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Although we are not currently involved in any litigation, we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. Although we are not currently involved in any litigation, if we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or services, the defendant could counterclaim that the patent covering our product or service is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise sufficient capital to continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help commercialize our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ certain individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our products or services. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on products and services in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Our collaborators may assert ownership or commercial rights to inventions we develop from our use of the biological materials which they provide to us, or otherwise arising from the collaboration.

We collaborate with several institutions, physicians and researchers in scientific matters. We do not have written agreements with certain of such collaborators, or the written agreements we have do not cover intellectual property rights. Also, we rely on numerous third parties to provide us with blood samples and biological materials that we use to develop tests. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

Risks Relating to Our Common Stock

The price of our common stock may be volatile.

Before our recently completed initial public offering, there was no public market for our common stock. Market prices for securities of early-stage life sciences companies have historically been particularly volatile. The factors that may cause the market price of our common stock to fluctuate include, but are not limited to:

- progress, or lack of progress, in developing and commercializing our current tests and our planned future cancer diagnostic tests;
- favorable or unfavorable decisions about our tests from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled "Risk Factors"; and
- general market and economic conditions.

In addition, the equity markets have experienced significant price and volume fluctuations that have affected the market prices for the securities of newly public companies for a number of reasons, including reasons that may be unrelated to our business or operating performance. These broad market fluctuations may result in a material decline in the market price of our common stock and you may not be able to sell your shares at prices you deem acceptable. In the past, following periods of volatility in the equity markets, securities class action lawsuits have been instituted against public companies. Such litigation, if instituted against us, could result in substantial cost and the diversion of management attention.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock.

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the NASDAQ minimum bid price requirement or prevent future non-compliance with NASDAQ's listing requirements.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The NASDAQ Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- the rate of adoption and/or continued use of our current tests and our planned future tests by healthcare practitioners;
- variations in the level of expenses related to our development programs;
- addition or reduction of resources for sales and marketing;
- addition or termination of clinical utility studies;
- any intellectual property infringement lawsuit in which we may become involved;
- third party payor determinations affecting our tests; and
- regulatory developments affecting our tests.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We had outstanding 15,966,052 shares of common stock as of March 2, 2015, 2,549,603 of which are restricted securities that may be sold

only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended. In addition, as of March 2, 2015, we had outstanding options to purchase 906,194 shares of our common stock, 251,618 shares of common stock were issuable upon the settlement of outstanding restricted stock units and we had outstanding warrants to purchase 5,094,325 shares of our common stock. Shares issued upon the exercise of stock options or upon the settlement of outstanding restricted stock units generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

Our largest stockholder continues to have substantial influence over us and could delay or prevent a change in corporate control.

Claire K. T. Reiss beneficially owned approximately 12% of our common stock at March 2, 2015. Mrs. Reiss has significant influence over 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. Accordingly, this concentration of ownership might harm the market price of our common stock by:

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

If we are unable to favorably assess the effectiveness of our internal control over financial reporting, investors may lose confidence in our financial reporting and our stock price could be materially adversely affected.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an "emerging growth company," may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until December 31, 2019, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the

Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted in 2010, that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period. We intend to continue taking advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. 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 the manner in which we operate our business in ways we cannot currently anticipate.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. (For example, Delaware law provides that if a corporation has a classified board of directors, stockholders cannot remove any director during his or her term without cause.) These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- classify our Board of Directors into three classes of equal (or roughly equal) size, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are "staggered";
- allow the authorized number of directors to be changed only by resolution of our Board of Directors;

- authorize our Board of Directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the Board of Directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our Board of Directors does not approve;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholders meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credits may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an "ownership change," as defined by Section 382 of the Code, occurs. If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with this or future offerings, as well as other changes that may be outside of our control), may trigger an "ownership change" and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. As of December 31, 2014, we had federal and state net operating loss carryforwards of approximately $124.6 million and $84.8 million, respectively, and federal and California research and development credits of $3.2 million and $3.1 million, respectively, which could be limited if we have experienced or do experience any "ownership changes." We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple "ownership changes" since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because early-stage life sciences companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We have a lease for approximately 48,000 square feet of space in San Diego, California for use as a clinical reference laboratory and corporate headquarters, including manufacturing and research laboratories. The average rent for the remaining lease period is approximately $106,500 per month. This lease expires in 2020.

In September 2013, we entered into an amendment of the lease, extending the term for 21 months so that it now ends on July 31, 2020 and providing for five months of free base rent (August 2013—December 2013). In return, we agreed, among other things, to forfeit our security deposit and to issue common stock warrants to the landlord exercisable for 50,260 shares, at a price of $10.00 per share. The warrants will expire on February 4, 2019.

Immediately following the execution of such amendment, we paid all amounts due under our lease. As of December 31, 2013 and December 31, 2014, we owed no rent in arrears.

In September 2012, in connection with an amendment of the lease, which included a rent deferral through November 30, 2012, we issued to our landlord warrants which, in connection with the closing of our initial public offering, became exercisable for 1,587 shares of our common stock at an exercise price of $25.20 per share.

Item 3. Legal Proceedings.

In the normal course of business, we may be involved in legal proceedings or threatened legal proceedings. We are not party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on our financial condition, results of operations or liquidity.

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

Market Information

Our common stock began trading on The NASDAQ Capital Market on February 5, 2014 under the symbol "BIOC." Before such time, there was no public market for our common stock.

The last sale price for our common stock as reported by The NASDAQ Capital Market on March 2, 2015 was $3.63 per share.

Holders of Record

As of March 2, 2015, there were 204 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board of Directors. Additionally, any payment of a dividend would require the prior approval of our lender.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Repurchases of Equity Securities

In July, 2013, we repurchased 711 shares of common stock in connection with the settlement of a shareholder lawsuit.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-191323), which was declared effective by the Securities and Exchange Commission on February 4, 2014. On February 4, 2014, additional shares of our common stock were registered through a Registration Statement on Form S-1 (File No. 333-193760) filed pursuant to Rule 462(b) under the Securities Act. On February 10, 2014, a total of 1,900,000 shares of common stock were sold on our behalf at an initial public offering price of $10.00 per share, for aggregate gross offering proceeds of $19 million, managed by Aegis Capital Corp. We paid to the underwriters underwriting discounts totaling approximately $1.3 million in connection with the offering. In addition, we incurred additional costs of approximately $1.2 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total costs of approximately $2.5 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $16.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our initial public offering were invested in cash equivalents. As of December 31, 2014, we estimate that we had used approximately $11.7 million for the funding of commercialization of our OncoCEE-BR, OncoCEE-LU, and OncoCEE-GA tests, research and development and other operating activities, $3.0 million for repayments of indebtedness and purchases of fixed assets, and $2.3 million for payments of deferred salaries, interest, and taxes thereon as well as initial public offering costs. We intend to use the remainder of the net proceeds from the initial public offering and other resources to fund commercialization of our current and future tests, further research and development, to acquire equipment, and to fund other general corporate purposes and the continued expansion of our business. The actual amounts and timing of our actual expenditures depend on numerous factors, including the success of our efforts to market OncoCEE-BR, OncoCEE-LU, and OncoCEE-GA, the timing and progress of our research and development activities for the tests in our pipeline, the success of our efforts to increase sales of our laboratory services, changes in regulatory requirements for LDTs, and other unforeseen regulatory or compliance costs. The costs and timing of test development activities, particularly conducting clinical validation studies and obtaining regulatory clearance or

approval, if required, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities and other unforeseen events, our plans and priorities may change and we may apply the net proceeds from our initial public offering in different proportions than we currently anticipate.

A second public offering of common stock and warrants to purchase common stock was effected through a Registration Statement on Form S-1 (File No. 333-201437), which was declared effective by the Securities and Exchange Commission on February 9, 2015. On February 9, 2015, additional shares of our common stock were registered through a Registration Statement on Form S-1 (File No. 333-201999) filed pursuant to Rule 462(b) under the Securities Act. On February 13, 2015, a total of 8,000,000 shares of common stock and warrants to purchase up to 8,000,000 shares of common stock were sold on our behalf at a combined price of $1.25, for aggregate gross offering proceeds of $10 million, managed by Aegis Capital Corp. We paid to the underwriters underwriting discounts totaling approximately $0.7 million in connection with the offering. In addition, we incurred additional costs of approximately $0.4 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total costs of approximately $1.1 million. As of March 5, 2015, additional cash proceeds of approximately $6.7 million have been received from the exercise of warrants sold in such offering. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, have been approximately $15.6 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

There has been no material change in the expected use of the net proceeds from our second public offering as described in our Registration Statement on Form S-1 for such offering.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in the Annual Report. This discussion contains forward-looking statements based upon our current plans, estimates, beliefs and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the sections entitled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and elsewhere in this Annual Report.

We are an early-stage cancer diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, tests utilizing a standard blood sample, or "liquid biopsy." Our current CTC breast, lung and gastric cancer tests provide, and our planned future tests would provide, information to oncologists and other physicians that enable them to select appropriate personalized treatment for their patients based on better, timelier and more-detailed data on the characteristics of their patients' tumors.

Our current breast, lung and gastric cancer tests and our planned future tests utilize our CEE technology for the enumeration and analysis of CTCs, and our CEE-Selector technology for the detection and analysis of ctDNA from plasma, each performed on a standard blood sample. The CEE technology is an internally developed, microfluidics-based CTC capture and analysis platform, with enabling features that change how CTC testing can be used by clinicians by providing real-time biomarker monitoring with only a standard blood sample. The CEE-Selector technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood plasma for ctDNA. We believe the CEE-Selector technology is an important part of our pipeline and will be a stand-alone test for molecular analysis of biomarkers.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We manufacture our CEE microfluidic channels, related equipment and certain reagents to perform our current tests and our planned future tests at this facility. CLIA certification is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of health. The tests we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations.

We are in the process of commercializing our first test, OncoCEE-BR, for breast cancer, and recently launched our OncoCEE-LU test for non-small cell lung cancer, or NSCLC, and our OncoCEE-GA test for gastric cancer in late 2014. These tests utilize our CEE technology platform and provide CTC enumeration as well as biomarker analysis from a standard blood sample. In the case of the OncoCEE-BR and OncoCEE-GA tests, biomarker analysis involves fluorescence in situ hybridization, or FISH, for the detection and quantitation of the human epidermal growth factor receptor 2, or HER2, gene copy number as well as immunocytochemical analysis of estrogen receptor (ER) protein, which is currently commercially available. We plan to include immunocytochemical analysis of progesterone receptor proteins in the OncoCEE-BR test during 2015. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. Estrogen receptor and progesterone receptor (PR) status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

The OncoCEE-LU test's biomarker analysis currently includes FISH testing for ALK and ROS1 gene rearrangements and molecular analysis of the T790M mutation of the epidermal growth factor receptor or EGFR gene using our CEE-Selector™ platform. We plan to add FISH testing for RET and MET genes, as well as mutation analysis for deletions 19 and l858R mutation in the ECFR gene, the K-ras gene and the B-raf gene in the future. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are linked to the drugs Tarceva®, Gilotrif® and Iressa®. The codon 12 and 13 mutations of the K-ras gene are found in patients whose tumors are unlikely to respond to the EGFR kinase inhibitors such as Erbitux® and Vectibix®, and the codon 600 mutations of the B-raf gene are linked to Zelboraf® and Tafinlar®, which are both approved for melanoma and are in clinical trials for lung cancer. Our OncoCEE-LU test is performed on a standard blood sample.

We plan to add other biomarker analyses on blood samples to our current tests and our planned future OncoCEE tests as their relevance is demonstrated in clinical trials, for example, RET proto-oncogene gene fusions in NSCLC, which may indicate a particular course of therapy, and NRAS genes for melanoma, which may predict therapy resistance. In addition, we are developing a series of other CTC and ctDNA tests for different solid tumor types, including colorectal cancer, prostate cancer, gastric cancer and melanoma, each incorporating treatment-associated biomarker analyses specific to that cancer, planned to be launched as noted in the table below.

Test Name/ Solid Tumor Type	Biomarkers	Status of Test or Project	Targeted Quarter of Availability for Commercialization
OncoCEE-BR™ / Breast Cancer	Enumeration, HER2 by FISH, ER	Currently available	N/A
	PR	Validation	2015 Q3
OncoCEE-LU™ / Lung Cancer	Enumeration, ALK and ROS1 by FISH	Currently available	N/A
	EGFR T790M, EGFR L858R and Del19 mutations by CEE-Selector™	Currently available	N/A
	MET by FISH	Validation	2015 Q2
	K-ras, B-raf, and ALK mutations by CEE-Selector™	Development and Validation	2015 Q2, Q3
OncoCEE-GA™ / Gastric Cancer	Enumeration, HER2 by FISH	Currently available	N/A
OncoCEE-CR™ / Colorectal Cancer	Enumeration, EGFR by FISH	Validation	2015 Q3
	K-ras and B-raf by CEE-Selector™	Development	2015 Q2
OncoCEE-PR™ / Prostate Cancer	Enumeration, PTEN deletion by FISH and AR by ICC	Validation	2015 Q4
OncoCEE-ME™ / Melanoma	Enumeration, B-raf and N-ras mutations by CEE-Selector™	Development	2015 Q3
	PDL-1 by ICC	Development	2015 Q3
CEE-Selector™/ Sequencing application for multiple cancer types	K-ras, B-raf, EGFR and other mutations detected in plasma.	Development	2015 Q4

Our revenue generating efforts are focused in three areas:

- providing clinical testing that physicians use in order to determine the best treatment plan for their patients;
- providing clinical trial, research and development services to biopharma companies developing cancer therapies; and
- licensing our proprietary testing and/or technologies to partners in the United States and abroad.

Key Factors Affecting our Results of Operations and Financial Condition

Our overall long-term growth plan depends on our ability to develop and commercialize tests through our CLIA laboratory. We have the OncoCEE-BR, OncoCEE-LU and OncoCEE-GA tests available as commercial products and we plan to enhance revenue for these products through the efforts of our sales and marketing organization, which we plan to expand. We plan to add additional biomarker analyses to OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned tests as their clinical relevance is demonstrated, for example, RET proto-oncogene gene fusions in NSCLC. In addition, we are developing a series of other CTC and ctDNA tests for different solid tumor types, including colorectal cancer, prostate cancer, gastric cancer and melanoma, each incorporating treatment-associated biomarker analyses specific to that cancer. We also have a research and development program focused on technology enhancements, novel platform development, and evaluating clinical applications for our cancer diagnostic tests in different cancer types and clinical settings. We anticipate launching four new OncoCEE™ cancer tests over the next two years.

To facilitate market adoption of our tests, we anticipate having to successfully complete additional clinical utility studies with clinical samples to generate clinical utility data and then publish our results in peer-reviewed scientific journals. Our ability to complete such clinical studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research, to conduct the appropriate clinical studies and to obtain favorable clinical data. We collaborate with physicians and researchers at The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, Yale University and Columbia University and plan to expand our current collaborative relationships to include other key thought leaders for the types of cancer we are targeting with OncoCEE-BR, OncoCEE-LU, OncoCEE-GA and our planned CTC and ctDNA tests. Such relationships are designed to help us develop and validate the effectiveness and utility of our current tests and our planned tests in specific clinical settings and provide us access to patient samples and data.

We believe that the factors discussed in the following paragraphs have had and are expected to continue to have a material impact on our results of operations and financial condition.

Revenues

We accessioned 402 commercial cases during the year ended December 31, 2014 as compared to 48 commercial cases for the same period in 2013, an increase of 354 cases, or 738%. The average reimbursement collected during the year ended December 31, 2014 was approximately $1,050 per commercial case. Revenues from commercial cases are recognized as collected, and the expected collection period for a commercial case often extends beyond the end of the quarter in which accessioned.

Almost all of our revenues in 2013 and 2014 were generated by our OncoCEE-BR test. Until May 2013, revenues were billed to our commercial partner, Clarient, who had responsibility for billing the third-party payors. Because Clarient paid us a contracted amount per test performed regardless of their billing and collections, we do not have data about the payor mix, reimbursement history and collectability experience for the tests performed under such arrangement. In the May 2013 revision of our arrangements with Clarient, we undertook responsibility for billing the payors and for reporting the results of the tests to the ordering physicians, and the exclusivity of Clarient's marketing partner rights for OncoCEE-BR ended. The May 2013 revision of our arrangements with Clarient will, in general, have the effect of delaying the timing of revenue recognition (see the "Revenue Recognition" paragraph of Note 4 of the notes to our audited financial statements) and adding uncertainty to the collectability of our accounts receivable.

Approximately 10% and 6% of annual revenues were generated through our arrangement with Clarient in 2013 and 2014, respectively. Approximately 77% and 32% of annual revenues were generated through our relationship with the Dana-Farber Cancer Institute in 2013 and 2014, respectively. The clinical laboratory industry is highly competitive, and our relationships and our partners' relationships with decision-makers at hospitals, cancer centers or physician offices is a critical component of securing their business. Consequently, our ability to establish and manage partnerships with groups that have sales and marketing capabilities in our target markets and attract and maintain productive sales personnel that have and can grow these relationships will largely determine our ability to grow our clinical services revenue.

We expect that in the future the percentage of our revenue which is generated through our arrangement with Clarient will diminish. Since May 2013, the number of tests performed under our agreement with Clarient has decreased significantly.

In 2013, approximately $104,000 was billed to our clinical partner, the Dana-Farber Cancer Institute, which represented the majority of our revenue for that year. From January through August 2014, approximately $43,000 was billed to the Dana-Farber Cancer Institute.

In November 2013, we first directly billed payors for physician-ordered testing; until May 2013, our commercialization partner Clarient was responsible for all billing associated with our tests. We do not have data for Clarient's billing and collection experience with respect to our test, because Clarient paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month, and from July to December 2014,

we performed an average of 65 physician-ordered tests per month (in addition to the tests which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute, with an average of 15-30 tests per month performed during the trial's enrollment period through May 2014). Billing for these physician-ordered tests is now handled for us by a non-Clarient billing service provider. Between May 2013 and December 2014, we invoiced, through this service provider, for 239 physician-ordered tests. Of these, 37 tests were billed to Medicare and the remainder were billed to other payors. As of December 31, 2014, we have been paid by private payors for 67 of these tests. As of December 31, 2014, all of our revenue recognized has come from private payors, and processing of the Medicare claims above was delayed due to a new application process relating to a change in our tax identification number.

The transition period to the new billing service provider was lengthened due to our focus on other priorities, as we knew the amounts for the small number of unbilled physician-ordered tests were immaterial. The transition of the billing function to our billing service provider was completed in December 2013. Our small backlog of unbilled tests has now been billed, and all future tests will be billed in a timely manner.

Cost of Revenues

Our cost of revenues consists principally of personnel costs, laboratory and manufacturing supplies and overhead. We are pursuing various strategies to reduce and control our cost of revenues, including automating aspects of our processes, developing more efficient technology and methods, attempting to negotiate improved terms with our suppliers and exploring relocating our operations to a lower-cost facility.

Operating Expenses

We classify our operating expenses into three categories: research and development, sales and marketing, and general and administrative. Our operating expenses principally consist of personnel costs, outside services, laboratory consumables and overhead, development costs, and legal and accounting fees.

Research and Development Expenses. We incur research and development expenses principally in connection with our efforts to develop and improve our tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables and overhead expenses. We anticipate that research and development expenses will increase in the near-term, principally as a result of hiring additional personnel to develop and validate tests in our pipeline and to perform work associated with clinical utility studies and development collaborations. In addition, we expect that our costs related to collaborations with research and academic institutions will increase. All research and development expenses are charged to operations in the periods in which they are incurred.

Sales and Marketing Expenses. Our sales and marketing expenses consist principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including sales collaterals and trade shows.

General and Administrative Expenses. General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, occupancy costs, and other general expenses. We expect that our general and administrative expenses will increase as we expand our business operations. We further expect that general and administrative expenses will increase significantly due to increased information technology, legal, insurance, accounting and financial reporting expenses associated with being a public company.

Seasonality

We expect our test volume to decrease during vacation and holiday seasons, when patients are less likely to visit their health care providers. We expect this trend in seasonality to continue for the foreseeable future.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our audited financial statements, which are included elsewhere in this Annual Report, contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

- revenue recognition;
- accounts receivable and bad debts;
- stock-based compensation;
- common stock valuation; and
- warrant liability.

Revenue Recognition

We recognize revenue in accordance with ASC 605, *Revenue Recognition*, and ASC 954-605, *Health Care Entities, Revenue Recognition* which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. For contract partners, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, we consider whether we have sufficient payment history to reliably estimate a payor's individual payment patterns. For new tests where there is limited evidence of payment history at the time the tests are completed, we recognize revenue equal to the amount of cash received until such time as reimbursement experience can be established.

Accounts Receivable and Bad Debts

We carry accounts receivable at original invoice amounts, less an estimate for doubtful receivables, based on a review of all outstanding amounts on a periodic basis. The estimate for doubtful receivables is determined from an analysis of the accounts receivable on a quarterly basis, and is recorded as bad debt expense. Since we only recognize revenue to the extent we expect to collect such amounts, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the statements of operations. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received.

Stock-Based Compensation Expense

We account for stock-based compensation under the provisions of ASC Topic 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model, or Black-Scholes valuation model. The fair value of restricted stock unit awards is determined by the price of the Company's common stock on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. We estimate forfeitures at the time of grant and revise our estimates in subsequent periods if actual forfeitures differ from those estimates.

We account for stock-based compensation awards to non-employees in accordance with ASC Topic 505-50, *Equity-Based Payments to Non-Employees*. Under ASC 505-50, we determine the fair value of the warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. All issuances of equity instruments issued to non-employees as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. These awards are recorded in expense and additional paid-in capital in stockholders' equity over the applicable service periods based on the fair value of the options at the end of each period.

Calculating the fair value of stock-based awards requires the input of highly subjective assumptions into the Black-Scholes valuation model. Stock-based compensation expense is calculated using our best estimate, which involves inherent uncertainties, and the application of our management's judgment. Significant estimates include the fair value of our common stock at the date of grant for awards granted prior to our initial public offering, the expected life of the stock option, stock price volatility, risk-free interest rate and forfeiture rate.

Common Stock Valuation

Prior to our initial public offering in February 2014, in the absence of a public trading market, our Board of Directors determined a reasonable estimate of the then-current fair value of our common stock for purposes of granting stock-based compensation based on input from management and valuation reports prepared by an independent third-party valuation specialist. We

determined the fair value of our common stock utilizing methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Practice Aid, "Valuation of Privately-Held-Company Equity Securities Issued as Compensation," which we refer to as the AICPA Practice Aid. In addition, we exercised judgment in evaluating and assessing the foregoing based on several factors including:

- the nature and history of our business;
- our historical operating and financial results;
- the market value of companies that are engaged in a similar business to ours;
- the lack of marketability of our common stock;
- the price at which shares of our equity instruments have been sold;
- the overall inherent risks associated with our business at the time stock option grants or warrants were approved; and
- the overall equity market conditions and general economic trends.

Warrant Liability

Warrants for shares that are contingently redeemable and for which the exercise price is not fixed are classified as liabilities on the accompanying balance sheets and carried at their estimated fair value, determined through use of a probability-weighted Black-Scholes valuation model. At the end of each reporting period, any changes in fair value are recorded as a component of total other income/(expense). As of the closing of the Company's initial public offering on February 10, 2014, the exercise price underlying the majority of the Company's warrants was fixed and the fair value of those warrants was reclassified to shareholders' deficit, while a preferred stock warrant to purchase an equivalent of 1,587 shares of common stock remained liability-classified at December 31, 2014.

Results of Operations

Years Ended December 31, 2013 and 2014

The following table sets forth certain information concerning our results of operations for the periods shown:

	For the year ended December 31,		Change	
	2013	2014	$	%
(dollars in thousands)				
Revenue	$ 134	$ 133	$ (1)	(1%)
Cost of revenues	2,330	2,170	(160)	(7%)
Research and development expenses	3,086	4,498	1,412	46%
General and administrative expenses	2,513	5,202	2,689	107%
Sales and marketing expenses	149	2,137	1,988	1,334%
Loss from operations	(7,944)	(13,874)	(5,930)	75%
Interest expense, net	(2,070)	(1,789)	281	(14%)
Change in fair value of warrant liability	782	(201)	(983)	(126%)
Loss before income taxes	(9,232)	(15,864)	(6,632)	72%
Income tax expense	(1)	(2)	(1)	100%
Net loss	$ (9,233)	$ (15,866)	$ (6,633)	72%

Revenue

Revenues were approximately $133,000 for the year ended December 31, 2014, compared with approximately $134,000 for the year ended December 31, 2013, a decrease of approximately $1,000, or 1%. The decrease was primarily related to lower Dana-Farber Cancer Institute sample volume as the trial's enrollment approached completion in May 2014, with 115 development services tests performed during the year ended December 31, 2014 as compared to 261 during the same period in 2013. This decrease was partially offset by an increase of approximately $68,000 in commercial test revenues. The average price collected per commercial test increased from $636 for the year ended December 31, 2013 to an average of $1,050 for the year ended December 31, 2014. The average price per development services test was $400 for the year ended December 31, 2013 and $391 for the year ended December 31, 2014.

Cost of Revenues

Cost of revenues was approximately $2,170,000 for the year ended December 31, 2014, compared with approximately $2,330,000 for the year ended December 31, 2013, a decrease of $160,000, or 7%. The decrease was primarily due to a $669,000

decrease associated with a reduction in the proportion of lab volume that related to revenue-generating activities relative to the total number of samples processed for the year ended December 31, 2014 as compared to the same period in 2013, partially offset by increases of approximately $509,000 in personnel, materials and allocated facilities costs.

Operating Expenses

Research and Development Expenses. Research and development expenses were $4.5 million for the year ended December 31, 2014, compared with $3.1 million for the year ended December 31, 2013, an increase of $1.4 million, or 46%. The increase was primarily due to an increase of $994,000 in validation samples and allocated costs related to the higher proportion of lab activities associated with product development, an increase of $279,000 in facilities, repairs and maintenance costs, and an increase of $269,000 in personnel costs for the year ended December 31, 2014 as compared to the same period in 2013, partially offset by a decrease of $159,000 in stock-based compensation expense.

General and Administrative Expenses. General and administrative expenses were $5.2 million for the year ended December 31, 2014, compared with $2.5 million for the year ended December 31, 2013, an increase of $2.7 million, or 107%. The increase was primarily due to an increase of $953,000 in stock-based compensation expense, an increase of $907,000 in insurance, legal, accounting, and consulting expenses as a result of becoming a publicly traded company in February 2014, an increase of $500,000 in personnel costs, an increase of $166,000 in facilities, repairs and maintenance expenses, and an increase of $161,000 in legal fees associated with patents for the year ended December 31, 2014 as compared to the same period in 2013.

Sales and Marketing Expenses. Sales and marketing expenses were $2.1 million for the year ended December 31, 2014, compared with $0.1 million for the year ended December 31, 2013, an increase of $2.0 million, or 1,334%. The increase was primarily due to personnel-related expenses resulting from the deployment of our sales and marketing function. For the year ended December 31, 2014, the sales and marketing function included an average of six employees, with 11 employees as of December 31, 2014. We had no significant sales and marketing function during the year ended December 31, 2013.

Interest Income and Expense

Interest expense was approximately $1.8 million during the year ended December 31, 2014, compared with approximately $2.1 million for the year ended December 31, 2013, a decrease of $0.3 million, or 14%. The decrease was primarily due to a decrease of approximately $1.1 million in non-cash interest expense related to the notes payable that were converted to preferred stock and common stock in June 2013 and in conjunction with our initial public offering in February 2014, respectively, partially offset by an increase of $575,000 in non-cash interest expense related to amortization of discounts to convertible notes payable and our revolving line of credit that were converted into common stock and repaid in February 2014, respectively, as well as an increase of $228,000 in cash interest expense primarily associated with the April 2014 Credit Facility.

Change in Fair Value of Warrant Liability

The non-cash loss resulting from the change in the fair value of warrant liability of approximately $201,000 for the year ended December 31, 2014 compared with the non-cash gain of approximately $782,000 for the year ended December 31, 2013 represents an increase in non-cash loss of $983,000, or 126%. The increase is due to a relative increase in the average price of the shares underlying warrants, as well as a greater number of average estimated warrants outstanding upon which the price of the shares underlying warrants is applied, during the year ended December 31, 2014 as compared to same period in 2013.

Income Taxes

Over the past several years we have generated operating losses in all jurisdictions in which we may be subject to income taxes. As a result, we have accumulated significant net operating losses and other deferred tax assets. Because of our history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized. We do not expect to report a provision for income taxes until we have a history of earnings, if ever, that would support the realization of our deferred tax assets.

We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future. We estimate that if such a change did occur, the federal and state net operating loss carryforwards and research and development credits that can be utilized in the future will be significantly limited.

Inflation

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods presented.

Liquidity and Capital Resources

We are actively working to improve our financial position and enable the growth of our business, by raising new capital and generating revenues.

Equity Financings

Pursuant to an underwriting agreement dated February 4, 2014 between us and Aegis Capital Corp., as representative of the several underwriters named therein, an initial public offering of 1,900,000 shares of common stock at $10.00 per share was effected on February 5, 2014. The closing of the sale of these shares to the underwriters occurred on February 10, 2014. We received, after deducting underwriting discounts and additional costs paid to the underwriters, approximately $17.4 million of net cash proceeds from the sale of these 1,900,000 shares. The total increase in capital as a result of the sale of these shares was approximately $16.5 million after deducting $0.9 million of additional non-underwriter costs incurred that are netted against these proceeds under applicable accounting guidance. In addition, designees of Aegis were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock at $12.50 per share with a term of five years.

Pursuant to an underwriting agreement dated February 9, 2015 between us, Aegis Capital Corp. and Feltl and Company, as underwriters named therein, a public offering of 8,000,000 shares of our common stock and warrants to purchase up to an aggregate of 8,000,000 shares of our common stock was effected at a combined offering price of $1.25. All of the members of our Board of Directors participated in this offering, purchasing an aggregate 142,000 shares of our common stock and warrants to purchase up to an aggregate of 142,000 shares of our common stock for total proceeds of $177,500. All warrants sold in this offering have a per share exercise price of $1.56, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the underwriters occurred on February 13, 2015, when we received, after deducting underwriting discounts and additional costs paid to the underwriters, approximately $9.1 million of net cash proceeds. The total increase in capital as a result of the sale of these shares and warrants is expected to be approximately $8.9 million after deducting an estimated $0.2 million of additional non-underwriter costs incurred. Additionally, the underwriters were granted a 45-day option to purchase up to 1,200,000 additional shares of common stock at a price of $1.25 per share and/or additional warrants to purchase up to 1,200,000 shares of common stock at a price of $0.0001 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any. As of March 5, 2015, additional cash proceeds of approximately $6.7 million have been received from the exercise of warrants sold in such offering.

Note and Warrant Financings

From February 2011 to November 2012, we sold secured convertible promissory notes with an aggregate principal amount of approximately $12.3 million, together with warrants that subsequently became exercisable for 108,786 shares of our common stock at an exercise price of $10.00 per share, to 11 accredited investors, for aggregate gross proceeds of approximately $12.3 million.

From January 2012 to December 2012, we sold promissory notes with an aggregate principal amount of approximately $6.0 million, together with warrants that subsequently became exercisable for 52,557 shares of our common stock to five accredited investors at an exercise price of $10.00 per share, for aggregate gross proceeds of approximately $6.0 million. These promissory notes were converted into shares of our common stock upon the closing of our initial public offering.

From December 2012 through January 2014, we sold promissory notes with an aggregate principal amount of approximately $5.2 million, together with warrants that subsequently became exercisable for 258,249 shares of our common stock at an exercise price of $10.00 per share, to 14 accredited investors, for aggregate gross proceeds of approximately $5.2 million.

Other Debt and Warrant Financings

In July 2013, we entered into a revolving line of credit with UBS Bank USA in the initial amount of $1.5 million. The maximum amount of this line of credit was subsequently increased to approximately $2.6 million. Interest accrued daily on the outstanding balance and was paid monthly at a variable rate, which was 2.75% over the 30 day LIBOR rate, or an effective annual interest rate of 2.92%. UBS Bank USA had the right to terminate the revolving line of credit at any time, and if it did, all amounts drawn under the revolving line of credit would be immediately payable. An affiliate of our director David F. Hale, and an affiliate of Claire K. T. Reiss, a 5% shareholder and at the time a director, an affiliate of our director Edward Neff, an affiliate of our director Bruce E. Gerhardt, and an affiliate of our director Ivor Royston guaranteed the loan and pledged financial assets to UBS Bank USA to secure their guaranties. In return, we issued common stock warrants to the guarantors. The number of shares underlying the associated common stock warrants were fixed so that such warrants became exercisable at $10.00 per share for an aggregate of 128,903 shares of common stock. We entered into an agreement with the guarantors that provided for us to reimburse them for any amounts paid by

them on such guaranties. This reimbursement obligation was secured by a security interest in our assets. In connection with the closing of our initial public offering on February 10, 2014, the current outstanding balance under the line of credit of $2,346,000 plus accrued interest of approximately $27,000 was paid in full, and exercise price of the warrants associated with the $2.6 million of collateral provided was fixed at $10.00 per share for an aggregate 128,903 shares of common stock, with associated derivative warrant liabilities of approximately $514,000 reclassified to additional paid-in capital.

On April 30, 2014, we received net cash proceeds of approximately $4.9 million pursuant to the execution of a term loan agreement with Oxford Finance LLC, or the April 2014 Credit Facility. A second term loan of up to a principal amount of $5 million will be funded at our request prior to December 31, 2015, subject to our achieving product and services revenues of at least $9 million for the trailing six months, with such six-month period ending no later than November 30, 2015. Upon the entry into the April 2014 Credit Facility, we were required to pay the lenders a facility fee of $50,000 in conjunction with the funding of the first term loan. Another $50,000 facility fee will be due and payable to the lenders on the funding date of the second term loan (if such date occurs). The April 2014 Credit Facility is secured by substantially all of our personal property other than our intellectual property. Each term loan under the April 2014 Credit Facility bears interest at an annual rate equal to the greater of (i) 7.95% or (ii) the sum of (a) the three-month U.S. LIBOR rate reported in the Wall Street Journal three business days prior to the funding date of the applicable term loan, plus (b) 7.71%, such rate to be fixed at the time of borrowing. The first term loan bears interest at an annual rate of 7.95%. We are required to make interest-only payments on the first term loan through February 1, 2016 if the funding date of the second term loan occurs before June 30, 2015, or through August 1, 2015 otherwise. If we request and the lenders fund the second term loan, we are required to make interest-only payments on the second term loan through February 1, 2016 if the funding date of the second term loan occurs before June 30, 2015, or through the seventh month following the funding date of the second term loan otherwise. All outstanding term loans under the April 2014 Credit Facility will begin amortizing at the end of the applicable interest-only period, with monthly payments of principal and interest being made by us to the lenders in consecutive monthly installments following such interest-only period. The first term loan under the April 2014 Credit Facility matures on July 1, 2018, and the second term loan matures on the first day of the 29th month following the end of the applicable interest-only period. Upon repayment of each term loan, we are also required to make a final payment to the lenders equal to 5.50% of the original principal amount of such term loan funded. At our option, we may prepay the outstanding principal balance of the term loans in whole but not in part, subject to a prepayment fee of 3% of any amount prepaid if the prepayment occurs on or prior to April 30, 2015, 2% of the amount prepaid if the prepayment occurs after April 30, 2015 but on or prior to April 30, 2016, and 1% of any amount prepaid after April 30, 2016. The April 2014 Credit Facility includes affirmative and negative covenants applicable to us and any subsidiaries we create in the future. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on our transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject to certain exceptions. The April 2014 Credit Facility also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against us and the collateral securing the term loans under the April 2014 Credit Facility, including foreclosure against our properties securing the April 2014 Credit Facility, including our cash. These events of default include, among other things, our failure to pay any amounts due under the April 2014 Credit Facility, a breach of covenants under the April 2014 Credit Facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, and a final judgment against us in an amount greater than $250,000. In connection with the April 2014 Credit Facility, we issued Oxford Finance LLC a warrant to purchase up to 52,966 shares of our common stock, at an exercise price of $4.72 per share with a term of ten years.

Inducement Warrants

In September 2012, we issued 66,666 Series A preferred stock warrants, at an exercise price of $0.60 per share, to our landlord in exchange for certain real estate lease accommodations. The Series A preferred stock warrants have become exercisable for 1,587 shares of our common stock at an exercise price of $25.20 per share.

In June 2013, we issued 23,809 common stock warrants, at an exercise price to be determined in accordance with a contract, to a lender (a 5% beneficial holder at the time) in connection with a note conversion. Upon the completion of our initial public offering in February 2014, the exercise price of these common stock warrants was fixed at $10.00 per share.

In September 2013, we issued an indeterminate number of common stock warrants, at an exercise price to be determined in accordance with a contract, to our landlord in connection with a lease amendment. Upon the completion of our initial public offering in February 2014, the exercise price of the common stock warrants issued to our landlord was fixed at $10.00 per share for an aggregate 50,260 shares of our common stock.

Conversions

In June 2013, the holders of promissory notes with an aggregate principal balance of approximately $20.2 million and accrued but unpaid interest of approximately $2.6 million voluntarily converted such principal and interest into 42,245,834 shares of our Series A preferred stock. Such shares of Series A preferred stock were subsequently converted into 1,652,851 shares of our common stock upon completion of our initial public offering in February 2014.

Also upon the completion of our initial public offering in February 2014:

- The $1.4 million principal amount and the approximate $234,000 of accrued interest on convertible notes issued in 2008 held by a trust affiliated with our majority stockholder, Claire K. T. Reiss, were converted at $10.00 per share into a total of 163,399 shares of common stock.
- The $5.2 million principal amount and the approximate $313,000 of accrued interest on convertible notes issued in 2013 held by various persons, including several affiliates, were converted at $10.00 per share into a total of 547,803 shares of common stock. The following persons received the following numbers of such shares:
  - Affiliates of Claire K. T. Reiss, majority stockholder—270,484
  - Affiliate of David F. Hale, Chairman—47,181
  - Affiliate of Edward Neff, Director—108,140
  - Marsha Chandler, Director—5,078
  - M. Faye Wilson, Director—2,650
  - Bruce E. Gerhardt, Director—1,055

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows:

	For the year ended December 31,	
	2013	2014
(dollars in thousands)		
Cash provided by (used in):		
Operating activities	$ (6,202)	$ (14,605)
Investing activities	(1)	(395)
Financing activities	6,087	20,295
Net increase (decrease) in cash and cash equivalents	$ (116)	$ 5,295

Cash Used in Operating Activities. Net cash used in operating activities was $14.6 million for the year ended December 31, 2014, compared to net cash used in operating activities of $6.2 million for the year ended December 31, 2013. In all periods the primary use of cash was to fund our net loss. Additionally, an increase of $3.0 million in cash used to fund operating assets and liabilities, primarily related to the payment of deferred salaries, interest and taxes thereon as well as initial public offering costs, was partially offset by an increase of $1.3 million in non-cash operating expenses during the year ended December 31, 2014 as compared to the same period in 2013.

Cash Used in Investing Activities. Cash used in investing activities was $395,000 for the year ended December 31, 2014, compared to $1,000 for the year ended December 31, 2013. In all periods the primary use of cash was to acquire fixed assets.

Cash Provided by Financing Activities. Net cash provided by financing activities was $20.3 million for the year ended December 31, 2014, compared to net cash provided by financing activities of $6.1 million for the year ended December 31, 2013. Our primary source of financing in the year ended December 31, 2013 consisted of loans received from our major shareholder and members of our Board of Directors and their affiliates in exchange for convertible promissory notes and warrants, as well as proceeds from borrowings on our line of credit. Our primary sources of financing in the year ended December 31, 2014 consisted of proceeds from our initial public offering and borrowings on our credit facility and warrants.

Capital Resources and Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. It may take several years to achieve positive operational cash flow or we may not ever achieve positive operational cash flow. We expect that we will use a portion of the net

proceeds from our public offerings and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our tests, acquire equipment, implement automation and scale our capabilities to prepare for significant test volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with being a public company. We may also use a portion of the net proceeds of our public offerings to acquire or invest in businesses, technologies, services or products, although we do not have any current plans to do so.

As of December 31, 2014, our cash and cash equivalents totaled approximately $5.4 million, and our outstanding indebtedness totaled approximately $5.3 million (including $0.1 million of interest accrued thereon, and excluding $0.3 million of associated debt discounts). On February 13, 2015, we received cash proceeds of approximately $9.1 million as a result of the closing of our second public offering, net of underwriting discounts and additional underwriting costs incurred. As of March 5, 2015, additional cash proceeds of approximately $6.7 million have been received from the exercise of warrants sold in such offering. Management believes that its cash resources should be sufficient to support currently forecasted operations through at least the next twelve months. While we currently are in the commercialization stage of operations, we have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future.

We expect that we may need additional financing in the future to execute on our current or future business strategies. Until we can generate significant cash from operations, we expect to continue to fund operations with the proceeds of offerings of our equity and debt securities. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. In addition to test revenues, such financing may be derived from one or more of the following types of transactions: debt, equity, product development, technology licensing or collaboration. If we are unable to raise a sufficient amount of financing in a timely manner, we would likely need to scale back our general and administrative activities and certain of our research and development activities. Our forecast pertaining to our current financial resources and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

- our ability to secure financing and the amount thereof;
- the costs of operating and enhancing our laboratory facilities;
- the costs of developing our anticipated internal sales and marketing capabilities;
- the scope, progress and results of our research and development programs, including clinical utility studies;
- the scope, progress, results, costs, timing and outcomes of the clinical utility studies for our cancer diagnostic tests;
- our ability to manage the costs for manufacturing our microfluidic channels;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;
- our ability to collect revenues; and
- other risks discussed in the section entitled “Risk Factors”.

We may raise additional capital to fund our current operations and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability or inability to develop additional tests, additional capital may not be available when needed on acceptable terms, or at all. If adequate funds are not available, we will need to curb our expansion plans or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Biocept, Inc.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of **Biocept, Inc.**

We have audited the accompanying balance sheets of **Biocept, Inc.** as of December 31, 2014 and 2013, and the related statements of operations and comprehensive loss, shareholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of **Biocept, Inc.** as of December 31, 2014 and 2013, and the results of its operations and its cash flows the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Mayer Hoffman McCann P.C.
San Diego, California
March 10, 2015

Biocept, Inc.

Balance Sheets

	December 31, 2013	December 31, 2014
Current assets:		
Cash and cash equivalents	$ 69,178	$ 5,364,582
Accounts receivable	9,200	10,600
Inventories, net	92,823	188,728
Prepaid expenses and other current assets	799,131	338,721
Total current assets	970,332	5,902,631
Fixed assets, net	358,887	662,422
Other non-current assets, net	500	23,194
Total assets	$ 1,329,719	$ 6,588,247
Current liabilities:		
Accounts payable	$ 1,540,618	$ 641,406
Accrued liabilities	2,242,058	698,833
Line of credit	1,981,000	—
Notes payable, net	5,200,599	—
Warrant liability	2,140,532	1,070
Supplier financings	218,925	33,674
Current portion of equipment financing	—	55,800
Total current liabilities	13,323,732	1,430,783
Non-current portion of equipment financing, net	—	68,801
Credit facility, net	—	4,754,516
Non-current interest payable	—	54,537
Deferred rent	462,001	500,179
Total liabilities	13,785,733	6,808,816
Commitments and contingencies (see Note 19)		
Shareholders' (deficit):		
Series A convertible preferred stock, $0.0001 par value, 100,000,000 authorized; 69,421,047 issued and outstanding at December 31, 2013; liquidation preference of $41,652,628 at December 31, 2013; 5,000,000 shares authorized; no shares issued and outstanding at December 31, 2014 (see Note 2).	6,942	—
Common stock, $0.0001 par value, 53,000,000 authorized; 185,550 issued and outstanding at December 31, 2013; 40,000,000 authorized; 4,449,603 issued and outstanding at December 31, 2014 (see Notes 2 and 21).	19	445
Additional paid-in capital	109,958,001	138,066,008
Accumulated deficit	(122,420,976)	(138,287,022)
Total shareholders' (deficit)	(12,456,014)	(220,569)
Total liabilities and shareholders' (deficit)	$ 1,329,719	$ 6,588,247

The accompanying notes are an integral part of these financial statements

Biocept, Inc.

Statements of Operations and Comprehensive Loss

	For the year ended December 31,	
	2013	**2014**
Revenues	$ 134,245	$ 133,415
Cost of revenues	2,329,900	2,170,548
Gross loss	(2,195,655)	(2,037,133)
Operating expenses		
Research and development expenses	3,086,737	4,497,790
General and administrative expenses	2,513,136	5,201,997
Sales and marketing expenses	148,903	2,137,004
Loss from operations	(7,944,431)	(13,873,924)
Other income/(expense)		
Interest expense, net	(2,070,064)	(1,789,680)
Change in fair value of warrant liability	782,112	(200,936)
Total other income/(expense)	(1,287,952)	(1,990,616)
Loss before income taxes	(9,232,383)	(15,864,540)
Income tax expense	(800)	(1,506)
Net loss & comprehensive loss	$ (9,233,183)	$ (15,866,046)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:		
Basic	181,762	3,997,797
Diluted	181,762	3,997,797
Net loss per common share:		
Basic	$ (50.80)	$ (3.97)
Diluted	$ (50.80)	$ (3.97)

The accompanying notes are an integral part of these financial statements

Biocept, Inc.

Statements of Shareholders' Deficit

	Series A Preferred Stock		Common Stock		Additional	Accumulated	
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Total
Balance at December 31, 2012	27,175,213	$ 2,718	160,393	$ 16	$ 85,800,164	$ (113,187,793)	$ (27,384,895)
Stock-based compensation expense	—	—	—	—	952,521	—	952,521
Stock issuance for RSU	—	—	21,846	2	(2)	—	—
Exercise of stock options	—	—	4,021	1	20,104	—	20,105
Repurchase of common shares	—	—	(710)	—	(4,111)	—	(4,111)
Shares issued for conversion of notes payable and accrued interest of $20.2 million and $2.6 million, respectively	42,245,834	4,224	—	—	22,808,180	—	22,812,404
Reclassification of warrant liability derivative due to triggering event	—	—	—	—	381,145	—	381,145
Net loss	—	—	—	—	—	(9,233,183)	(9,233,183)
Balance at December 31, 2013	69,421,047	6,942	185,550	19	109,958,001	(122,420,976)	(12,456,014)
Stock-based compensation expense	—	—	—	—	1,822,661	—	1,822,661
Shares issued for conversion of Series A Preferred Stock	(69,421,047)	(6,942)	1,652,851	165	6,777	—	—
Shares issued for conversion of notes payable and accrued interest of $6.6 million and $0.5 million, respectively	—	—	711,202	71	7,111,928	—	7,111,999
Reclassification of warrant liability derivative due to triggering event	—	—	—	—	2,475,620	—	2,475,620
Shares issued for initial public offering	—	—	1,900,000	190	16,457,914	—	16,458,104
Warrants issued in connection with credit facility	—	—	—	—	233,107	—	233,107
Net loss	—	—	—	—	—	(15,866,046)	(15,866,046)
Balance at December 31, 2014	—	$ —	4,449,603	$ 445	$ 138,066,008	$ (138,287,022)	$ (220,569)

The accompanying notes are an integral part of these financial statements

Biocept, Inc.

Statements of Cash Flows

	For the year ended December 31,	
	2013	2014
Cash Flows From Operating Activities		
Net loss	$ (9,233,183)	$ (15,866,046)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	266,554	251,203
Inventory reserve	(70,004)	(13,779)
Stock-based compensation	952,521	1,822,661
Non-cash interest expense related to convertible debt, credit facility and other financing activities	2,066,287	1,445,068
Change in fair value of warrant liability	(782,112)	200,936
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable	9,685	(1,400)
Inventory	38,464	(82,126)
Prepaid expenses and other current assets	(37,691)	(401,355)
Other non-current assets	268,583	(28,894)
Accounts payable	(175,280)	(981,869)
Accrued liabilities	233,852	(1,042,160)
Non-current interest payable	—	54,537
Deferred rent	259,961	38,178
Net cash used in operating activities	(6,202,363)	(14,605,046)
Cash Flows From Investing Activities		
Purchases of fixed assets	(711)	(394,925)
Net cash used in investing activities	(711)	(394,925)
Cash Flows From Financing Activities		
Proceeds from exercise of stock options	20,105	—
Payments for repurchase of shares	(4,111)	—
Principal payments on equipment financing	—	(23,250)
Net proceeds from issuance of common stock	—	17,390,240
Payments on supplier and other third party financings	(154,998)	(192,511)
Payments on line of credit	—	(2,346,000)
Proceeds from borrowings on line of credit	1,981,000	365,000
Proceeds from issuance of convertible notes and warrants	4,245,000	175,000
Net proceeds from borrowings on credit facility and warrants	—	4,926,896
Net cash provided by financing activities	6,086,996	20,295,375
Net increase/(decrease) in Cash and Cash Equivalents	(116,078)	5,295,404
Cash and Cash Equivalents at Beginning of Period	185,256	69,178
Cash and Cash Equivalents at End of Period	$ 69,178	$ 5,364,582
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 3,777	$ 402,075
Taxes	$ 800	$ 800

The accompanying notes are an integral part of these financial statements

Non-cash Investing and Financing Activities:

During the year ended December 31, 2013, 21,846 shares of common stock, with a par value of $0.0001, were issued for restricted stock units.

During the year ended December 31, 2013, convertible notes with a principal balance of $20,231,000 and accrued interest of approximately $2,581,000 were converted into 42,245,834 shares of preferred stock with a par value of $0.0001. In conjunction with this conversion, $236,799 of derivative warrant liabilities were reclassified to additional paid-in capital, as the underlying exercise prices on the warrants were determined by the debt conversion. Also during the year ended December 31, 2013, an additional $144,346 of derivative warrant liabilities were reclassified to additional paid-in capital when their underlying exercise price was fixed.

During the year ended December 31, 2013, the Company issued to its landlord a warrant to purchase common shares with a warrant coverage amount of $502,605 and an exercise price equal to the price per share of the Company's common stock sold in the Company's initial public offering ("IPO") (see Note 2). The fair value of the warrant as calculated under the Company's probability weighted Black-Scholes valuation model was approximately $309,000 at issuance in September 2013, which was recorded on the Company's balance sheet as a component of deferred rent and warrant liability.

During the year ended December 31, 2013, the Company incurred $538,318 in costs directly associated with its IPO, which are reflected on the balance sheet as a component of prepaid expenses and other current assets at December 31, 2013. A liability of $328,221 for associated unpaid invoices is recorded as a component of accounts payable at December 31, 2013.

During the years ended December 31, 2013 and 2014, the Company financed insurance premiums of $122,777 and $62,774, respectively, through third party financings. Such financings occur on an annual basis during the three months ended December 31 of each year. During the year ended December 31, 2014, the Company cancelled its private company directors and officers liability insurance policy financed during the year ended December 31, 2013. The previously financed premium balance of $44,559 was cancelled and a partial refund of $10,955 was received.

During the year ended December 31, 2014, common stock warrants with an estimated aggregate grant date fair value of $135,222 were issued in conjunction with guarantees on the Company's additional borrowings under its line of credit and additional borrowings made under its convertible notes issued in 2013, and were recorded as a discount to outstanding debt at the date of issuance.

An IPO of the Company's common stock was effected on February 5, 2014, the closing of which occurred on February 10, 2014 (see Note 2). On February 4, 2014, as contemplated by the registration statement covering the IPO, 69,421,047 shares of outstanding Series A Preferred Stock were automatically converted into 1,652,851 shares of common stock. In connection with the closing of the IPO on February 10, 2014, (i) the underwriters of the IPO were granted a 45 day option from the closing date of the IPO to purchase up to 285,000 shares of common stock at $9.30 per share to cover overallotments with a grant date fair value of $202,143 (see Note 5), which was not exercised and is recorded as an offset to additional paid-in capital within common stock issuance costs at December 31, 2014, (ii) certain designees of the representative of the underwriters were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock at $12.50 per share with a term of five years and a grant date fair value of $544,116 (see Note 5), and is recorded as an offset to additional paid-in capital within common stock issuance costs at December 31, 2014, (iii) underwriter IPO costs and discounts of $279,760 and $1,330,000, respectively, were netted against the proceeds from the IPO and are reflected as an offset to additional paid-in capital, (iv) the $1,400,000 principal amount and $233,982 of accrued interest related to the convertible note issued in 2008 were converted at $10.00 per share into a total of 163,399 shares of common stock, (v) the $5,165,000 principal amount and $313,017 of accrued interest related to the convertible notes issued in 2013 were converted at $10.00 per share into a total of 548,803 shares of common stock, (vi) derivative warrant liabilities of $2,475,620 associated with an aggregate of 387,152 common stock warrants related to the convertible notes issued in 2013 and line of credit were reclassified to additional paid-in capital when their underlying exercise price was fixed at $10.00 per share, and (vii) additional costs associated with the IPO of $932,136 were reclassified from prepaid expenses and other current assets to additional paid-in capital.

During the year ended December 31, 2014, a common stock warrant with an estimated grant date fair value of $233,107 was issued in conjunction with borrowings made under a loan and security agreement (the "April 2014 Credit Facility") with Oxford Finance LLC, and was recorded as a discount to outstanding debt at the date of issuance (see Note 7).

Fixed assets purchased totaling $19,546 during the year ended December 31, 2014 remained unpaid as of December 31, 2014, and are excluded from cash purchases in the Company's statement of cash flows.

A fixed asset purchased for $140,267 during the year ended December 31, 2014 is recorded as an equipment financing obligation and is excluded from cash purchases in the Company's statement of cash flows.

Costs associated with the Company's February 2015 public offering totaling $63,111 were incurred during the year ended December 31, 2014 and remained unpaid as of December 31, 2014, and are excluded from changes in prepaid expenses and other current assets and accounts payable in the Company's statement of cash flows.

The accompanying notes are an integral part of these financial statements

1. The Company and Business Activities

Biocept, Inc. ("the Company") was founded in California in May 1997 and is a commercial-stage cancer diagnostics company developing and commercializing proprietary circulating tumor cell (CTC) and circulating tumor DNA (ctDNA) tests utilizing a standard blood sample to improve the treatment that oncologists provide to their patients by providing better, more detailed information on the characteristics of their tumor.

The Company operates a clinical laboratory that is CLIA-certified (under the Clinical Laboratory Improvement Amendment of 1988) and CAP-accredited (by the College of American Pathologists), and manufactures CEE microfluidic channels, related equipment and certain reagents to perform the Company's diagnostic tests in a facility located in San Diego, California. CLIA certification and accreditation are required before any clinical laboratory may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, treatment of disease, or assessment of health. The tests the Company offers are classified as laboratory developed tests (LDTs), under the CLIA regulations.

In July 2013, the Company effected a reincorporation to Delaware by merging itself with and into Biocept, Inc., a Delaware corporation, which had been formed to be and was a wholly-owned subsidiary of the Company since July 23, 2013.

2. Initial Public Offering

Pursuant to an underwriting agreement dated February 4, 2014 between the Company and Aegis Capital Corp. ("Aegis"), as representative of the several underwriters named therein, an IPO of 1,900,000 shares of common stock at $10.00 per share was effected on February 5, 2014. The closing of the sale of these shares to the underwriters occurred on February 10, 2014. The Company received, after deducting underwriting discounts and additional costs paid to the underwriters, approximately $17.4 million of net cash proceeds from the sale of these 1,900,000 shares. The total increase in capital as a result of the sale of these shares was approximately $16.5 million after deducting $0.9 million of additional non-underwriter costs incurred that are netted against these proceeds under applicable accounting guidance. Additionally, the underwriters were granted a 45 day option from the closing date of the IPO to purchase up to 285,000 shares of common stock at $9.30 per share to cover overallotments with a grant date fair value of approximately $202,000 (see Note 5), which was not exercised. In addition, designees of Aegis were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock at $12.50 per share with a term of five years and a grant date fair value of approximately $544,000 (see Note 5).

On February 4, 2014, as contemplated by the registration statement covering the IPO, 69,421,047 shares of outstanding Series A Preferred Stock were converted into 1,652,851 shares of common stock and the Company's certificate of incorporation was amended to provide for an authorized capitalization of 40,000,000 shares of common stock and 5,000,000 shares of preferred stock.

In connection with the closing of the Company's IPO on February 10, 2014, (i) the $1,400,000 principal amount and $233,982 of accrued interest related to the convertible note issued in 2008 were converted at $10.00 per share into a total of 163,399 shares of common stock, (ii) the $5,165,000 principal amount and $313,017 of accrued interest related to the convertible notes issued in 2013 were converted at $10.00 per share into a total of 547,794 shares of common stock, (iii) the exercise price of the warrants associated with the convertible notes issued in 2013 was fixed at $10.00 per share for an aggregate 258,249 shares of common stock, (iv) the exercise price of the warrants associated with the $2,578,104 of collateral provided to secure the Company's line of credit was fixed at $10.00 per share for an aggregate 128,903 shares of common stock, (v) 73,151 shares of common stock vested as settlement of certain restricted stock units (which were previously expressed in shares of preferred stock) and became issuable subsequent to the expiration of the 180 day lock-up period, (vi) the Company's Executive Chairman ceased to be an employee and continues to serve as non-executive Chairman, (vii) the number of shares of common stock covered by the Company's 2013 Equity Incentive Plan increased by 800,000, (viii) all but 1,587 of the preferred warrants previously outstanding were canceled due to early termination clauses associated with the IPO, (ix) derivative warrant liabilities of $2,475,620 associated with the aggregate of 387,152 common stock warrants related to the convertible notes issued in 2013 and line of credit were reclassified to additional paid-in capital when their underlying exercise price was fixed, (x) unamortized discounts of $996,024 related to the warrants associated with the convertible notes issued in 2013 and line of credit were reclassified to interest expense, and (xi) offering costs associated with the IPO of $932,136 were reclassified from prepaid expenses and other current assets to additional paid-in capital, while additional underwriter IPO costs and discounts of $279,760 and $1,330,000, respectively, were netted against the proceeds from the IPO and are reflected as an offset to additional paid-in capital.

Subsequent to December 31, 2013, the maximum amount of the Company's line of credit was increased to approximately $2.6 million and common stock warrants were issued to four shareholders in conjunction with their guarantees on the Company's additional borrowings under the line of credit. On February 10, 2014, the current outstanding balance under the line of credit of $2,346,000 plus accrued interest of $27,043 was paid in full using the net proceeds from the IPO.

On February 13, 2014, the Compensation Committee of the Company's Board of Directors approved the payment of an aggregate $1,009,552 in deferred salary obligations, including contractual interest, to current and former named executive officers pursuant to previously existing agreements, which was fully disbursed by April 2014 using the net proceeds from the IPO. An additional $344,883 in deferred salary obligations and interest thereon was paid to former employees other than named executive officers. Also on February 13, 2014, in connection with the closing of the IPO and pursuant to a resolution for a director compensation policy adopted in 2013, the Company's Board of Directors approved annual cash retainers to non-employee directors, and granted 238,500 stock options under the Company's 2013 Equity Incentive Plan to non-employee directors. These option awards vest in equal annual installments over 3 years from the date of grant with a 10 year term, subject to continuing service requirements. In February 2014, the Company's Board of Directors approved grants of 54,298 stock options as a result of the closing of the IPO pursuant to the terms of underlying employment agreements. Included in the stock options granted pursuant to the terms of underlying employment agreements are 53,108 option awards granted to the Company's non-executive Chairman, which vested fully on the date of grant.

Under the terms of certain employment agreements with executive officers, the Company incurred additional cash compensation expense of $150,000 immediately, and $225,000 annually, upon the closing of its IPO. All payments required under these agreements as a result of the closing of the Company's IPO on February 10, 2014 were subsequently made in February and March 2014, using the net proceeds from the IPO.

During the year ended December 31, 2014, the Company repaid in full the remaining amounts outstanding of approximately $70,000 due for laboratory equipment under financing agreements with a supplier, which is a business owned by a member of the Company's Board of Directors, using the net proceeds from the IPO.

3. Liquidity

At December 31, 2013 and December 31, 2014, the Company had accumulated deficits of approximately $122.4 million and $138.3 million, respectively. For the years ended December 31, 2013 and 2014, the Company incurred net losses of approximately $9.2 million and $15.9 million, respectively. The Company borrowed a total of $6.2 million and $0.5 million during the years ended December 31, 2013 and 2014, respectively, under note agreements with certain shareholders and a line of credit. In addition, the Company borrowed $5.0 million during the year ended December 31, 2014 under the April 2014 Credit Facility. While the Company is currently in the commercialization stage of operations, the Company has not yet achieved profitability and anticipates that it will continue to incur net losses in the foreseeable future.

Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred stock, proceeds from the issuance of debt, and revenues from clinical laboratory testing through contracted partners. The Company's principal uses of cash have included cash used in operations, payments relating to purchases of property and equipment and repayments of borrowings. The Company expects that the principal uses of cash in the future will be for continuing operations, hiring of sales and marketing personnel and increased sales and marketing activities, funding of research and development, capital expenditures, and general working capital requirements. The Company expects that, as revenues grow, sales and marketing and research and development expenses will continue to grow, albeit at a slower rate and, as a result, the Company will need to generate significant net revenues to achieve and sustain income from operations.

As of December 31, 2014, cash and cash equivalents totaled approximately $5.4 million. On February 13, 2015, the Company received cash proceeds of approximately $9.1 million as a result of the closing of a second public offering, net of underwriting discounts and additional underwriting costs incurred. Subsequent to the closing of the second public offering on February 13, 2015, additional cash proceeds of approximately $6.7 million were received from the exercise of warrants sold in such offering (see Note 21). Management believes that its cash resources should be sufficient to support currently forecasted operations through at least the next twelve months. Management expects that the Company may need additional financing in the future to execute on its current or future business strategies beyond the next twelve months. Until the Company can generate significant cash from operations, the Company expects to continue to fund its operations with the proceeds of offerings of the Company's equity and debt securities. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all. In addition to test revenues, such financing may be derived from one or more of the following types of transactions: debt, equity, product development, technology licensing or collaboration.

4. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America.

Use of Estimates

The preparation of financial statements 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. On an ongoing basis, management evaluates these estimates and judgments, including those related to inventories, long-lived assets, convertible debt, derivative liabilities, income taxes, and stock-based compensation. The Company bases its estimates on various assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Reverse Stock Split and Change in Par Value of Common Stock and Preferred Stock

In July 2013, in conjunction with its reincorporation in the state of Delaware, the Company initiated par values for preferred and common shares equal to $0.0001. In November 2013, the Company effected a 1:14 reverse stock split for all common shares. All references to share and per share amounts in the financial statements and accompanying notes to the financial statements have been retroactively restated to reflect the 1:14 reverse stock split and the change in par value.

Revenue Recognition

Revenue is recognized in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, *Revenue Recognition*, and ASC 954-605 *Health Care Entities, Revenue Recognition* which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. For contract partners, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, the Company considers whether there is sufficient payment history to reliably estimate a payor's individual payment patterns. For new tests where there is limited evidence of payment history at the time the tests are completed, the Company recognizes revenue equal to the amount of cash received until such time as reimbursement experience can be established.

The Company's main source of revenue for the year ended December 31, 2013, and a significant source of revenue for the year ended December 31, 2014, is through contracted partners. This revenue is derived from clinical laboratory testing performed in the Company's laboratories under agreements with such partners. As there is a contractually agreed upon price, and collectability from the partners is reasonably assured, revenues for these tests are recognized at the time the test is completed.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. The Company places its cash and cash equivalents with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation (FDIC). At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company has not experienced any losses in its cash and cash equivalents and believes they are not exposed to any significant credit risk.

Fair Value Measurement

The Company uses a three-tier fair value hierarchy to prioritize the inputs used in the Company's fair value measurements. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets for identical assets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company believes the carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximate their estimated fair values due to the short-term maturities of these financial instruments. See Note 5 for further details about the inputs and assumptions used to determine fair value measurements.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company has not experienced losses in such accounts. Management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

In 2012, the Company launched commercial operations in partnership with a commercial partner, Clarient Diagnostic Services, Inc. ("Clarient"), a GE Healthcare Company. During the years ended December 31, 2013, the final year of this partnership, and December 31, 2014, when subsequent cash collections were made, 10% and 6%, respectively, of the revenues earned were billed through this relationship.

In 2013, the Company entered into a research support agreement with a not-for-profit tax-exempt organization, Dana-Farber Partners Cancer Care, Inc. ("Dana-Farber"). For the years ended December 31, 2013 and 2014, 77% and 32%, respectively, of the revenues earned were billed through this relationship. In addition, 100% and 72% of the receivables were due from Dana-Farber at December 31, 2013 and 2014, respectively.

In 2014, the Company entered into a research support agreement with a not-for-profit tax-exempt organization, The University of Texas MD Anderson Cancer Center ("MD Anderson"). For the year ended December 31, 2014, 2% of the revenues earned were billed through this relationship. In addition, 28% of the receivables were due from MD Anderson at December 31, 2014.

Concentrations of credit risk with respect to revenues and accounts receivable are primarily limited to certain clients including Clarient, Dana-Farber, and MD Anderson, and geographies to which the Company provides a significant volume of its services, and to specific payers of our services such as Medicare and individual insurance companies. The Company's client base consists of a large number of geographically dispersed clients diversified across various customer types. For the year ended December 31, 2013, revenues derived from clients within the states of Massachusetts, California, and Texas accounted for approximately 77%, 22% and 1%, respectively, of total revenues. For the year ended December 31, 2014, revenues derived from clients within the states of Massachusetts, California, and Texas accounted for approximately 32%, 15% and 34%, respectively, of total revenues.

All of the Company's sales for all periods presented were generated in the United States of America.

Certain components used in the Company's current or planned products are available from only one supplier, and substitutes for these components cannot be obtained easily or would require substantial design or manufacturing modifications or identification and qualification of alternative sources.

Accounts Receivable

Accounts receivable are carried at original invoice amounts, less an estimate for doubtful receivables, based on a review of all outstanding amounts on a periodic basis. The estimate for doubtful receivables is determined from an analysis of the accounts receivable on a quarterly basis, and is recorded as bad debt expense. As the Company only recognizes revenue to the extent collection is expected and reasonably assured, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the statement of operations and comprehensive loss. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received. As of December 31, 2013 and 2014, management determined that all of the amounts recorded as accounts receivable were collectible, and no allowance for doubtful accounts was needed.

Inventories

Inventories are valued at the lower of cost or market value. Cost is determined by the average cost method. The Company records adjustments to its inventory for estimated obsolescence or diminution in market value equal to the difference between the cost of the inventory and the estimated market value. At the point of loss recognition, a new cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Fixed Assets

Fixed assets consist of machinery and equipment, furniture and fixtures, computer equipment and software, leasehold improvements, capital leased equipment and construction in process. Fixed assets are stated at cost less accumulated depreciation and amortization. Additions, improvements, and major renewals are capitalized. Maintenance, repairs, and minor renewals are expensed as incurred. Depreciation is determined using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the life of the lease or the asset, whichever is shorter. Depreciation expense for the years ended December 31, 2013 and 2014 was approximately $267,000 and $251,000, respectively.

Upon sale, retirement or disposal of fixed assets, the accounts are relieved of the cost and the related accumulated depreciation or amortization with any gain or loss recorded to the statement of operations.

Fixed assets are reviewed for impairment whenever changes in circumstances indicate that the carrying amount of an asset may not be recoverable. These computations utilize judgments and assumptions inherent in the estimates of future cash flows to determine recoverability of these assets. If the assumptions about these assets were to change as a result of events or circumstances, the Company may be required to record an impairment loss.

Warrant Liability

Warrants for shares that are contingently redeemable and for which the exercise price is not fixed are classified as liabilities on the accompanying balance sheets and carried at their estimated fair value, determined through use of a Black-Scholes valuation model. As of and for the years ended December 31, 2013 and 2014, the Company evaluated and concluded that the fair value obtained from the Black-Scholes method of valuing the warrant liability does not materially differ from the valuation of such warrants using the Monte Carlo or binomial lattice simulation models, and therefore the use of the Black-Scholes valuation model was considered a reasonable method to value the warrants. At the end of each reporting period, any changes in fair value are recorded as a component of other income (expense). As of the closing of the Company's IPO on February 10, 2014, the exercise price underlying the majority of the Company's outstanding warrants was fixed and the fair value of those warrants was reclassified to shareholders' deficit, while a preferred stock warrant to purchase an equivalent of 1,587 shares of common stock remains liability-classified at December 31, 2014.

Stock-based Compensation

The Company accounts for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model ("Black-Scholes valuation model"), while the fair value of restricted stock unit awards is determined by the Company's stock price on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. The Company estimates forfeitures at the time of grant and revises these estimates in subsequent periods if actual forfeitures differ from those estimates. See additional information in Note 13.

The Company accounts for stock-based compensation awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"). Under ASC 505-50, the Company determines the fair value of the warrants or stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. All issuances of equity instruments issued to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. These awards are recorded in expense and additional paid-in capital in shareholders' equity over the applicable service periods based on the fair value of the options at the end of each period.

Calculating the fair value of stock-based awards requires the input of highly subjective assumptions into the Black-Scholes valuation model. Stock-based compensation expense is calculated using the Company's best estimates, which involves inherent uncertainties, and the application of management's judgment. Significant estimates include the fair value of the Company's common stock at the date of grant for awards granted prior to its IPO, the expected life of the stock option, stock price volatility, risk-free interest rate and forfeiture rate.

Research and Development

Research and development costs are expensed as incurred. The amounts expensed in the years ended December 31, 2013 and 2014 were approximately $3,087,000 and $4,498,000, respectively, which includes salaries of research and development personnel.

Income Taxes

The Company provides for income taxes utilizing the liability method. Under the liability method, current income tax expense or benefit is the amount of income taxes expected to be payable or refundable for the current year. A deferred income tax asset or liability is computed for the expected future impact of differences between the financial reporting and tax bases of assets and liabilities and for the expected future tax benefit to be derived from tax credits. Tax rate changes are reflected in the computation of the income tax provision during the period such changes are enacted.

Deferred tax assets are reduced by a valuation allowance when, in management's opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. The Company's valuation allowance is based on available evidence, including its current year operating loss, evaluation of positive and negative evidence with respect to certain specific deferred tax assets including evaluation sources of future taxable income to support the realization of the deferred tax assets. The Company has established a full valuation allowance on the deferred tax assets as of December 31, 2013 and 2014, and therefore has not recognized any income tax benefit or expense in the periods presented.

ASC 740, *Income Taxes* ("ASC 740"), clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC 740 provides that a tax benefit from uncertain tax positions may be recognized when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. ASC 740 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties for income taxes on the balance sheets at December 31, 2013 and 2014, and the Company has not recognized interest and/or penalties in the statements of operations for the years ended December 31, 2013 and 2014.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued authoritative guidance that requires netting unrecognized tax benefits against deferred tax assets for a loss or other carryforward that would apply in settlement of uncertain tax positions. This guidance is effective for annual reporting periods beginning after December 15, 2013, and was effective for the Company's fiscal year beginning January 1, 2014. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In May 2014, the FASB issued authoritative guidance that requires entities to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early adoption is not permitted. The Company is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

In June 2014, the FASB issued authoritative guidance requiring share-based payments with a performance target which affects vesting and that could be achieved after the requisite service period be treated as a performance condition. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company does not expect adoption of this guidance to have a material impact on its financial statements or disclosures.

In August 2014, the FASB issued authoritative guidance requiring management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. This guidance is effective for the annual reporting period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

In November 2014, the FASB issued authoritative guidance requiring entities to consider all of a hybrid instrument's stated and implied substantive terms and features, including any embedded derivative features being evaluated for bifurcation. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. Early adoption is permitted. The Company does not expect adoption of this guidance to have a material impact on its financial statements or disclosures.

5. Fair Value Measurement

Warrant Liability Derivatives

The Company classified the fair value measurements of the Company's warrant liability derivatives as Level 3 in all periods presented. The Company adjusted the carrying value of the warrants classified as liabilities until the completion of its IPO on February 10, 2014, at which time the exercise price was fixed at $10.00 per share and the fair value of the warrants was reclassified to shareholders' deficit, except for a warrant for 1,587 preferred shares that remains outstanding at December 31, 2014 (see Note 2).

As of December 31, 2013, the aggregate common stock warrant liability of approximately $2,132,000 was estimated using a probability weighted Black-Scholes valuation model with the following assumptions for both the five-year and two-year common stock warrant terms separately:

	Five-year term	Two-year term
Stock price	$ 1.48 – 7.69	$ 1.48 – 7.69
Exercise price	$ 1.48 – 7.69	$ 1.48 – 7.69
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	1.73%	0.38%
Expected life (in years)	5.00	2.00
Expected volatility	100.0%	90.0%

At December 31, 2013 the values of both the five-year and two-year common stock warrants using the probability weighted Black-Scholes valuation models accounted for a probability of 75%, while a fair value of $0 was weighted 25%.

As of closing of the Company's IPO on February 10, 2014, the aggregate common stock warrant liability of approximately $2,476,000 was estimated using a Black-Scholes valuation model with the following assumptions for both the five-year and two-year common stock warrant terms separately:

	Five-year term	Two-year term
Stock price	$ 8.91	$ 8.91
Exercise price	$ 10.00	$ 10.00
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	1.48%	0.32%
Expected life (in years)	5.00	2.00
Expected volatility	90.0%	90.0%

The fair value attributed to the common and preferred share warrants as of December 31, 2013 and 2014 is as follows:

	Fair Value Measurements Using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities			
Warrant Liability at December 31, 2013	—	—	2,140,532
Warrant Liability at December 31, 2014	—	—	1,070

The following table includes a summary of changes in the fair value of the common and preferred share warrants for the years ended December 31, 2013 and 2014:

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2012	$ 981,747
Warrant liability incurred in 2013	2,322,042
Change in fair value included in expense in 2013	(782,112)
Warrant liability reclassified to additional paid-in capital in 2013	(381,145)
Balance at December 31, 2013	2,140,532
Warrant liability incurred in 2014	135,222
Change in fair value included in expense in 2014	200,936
Warrant liability reclassified to additional paid-in capital in 2014	(2,475,620)
Balance at December 31, 2014	$ 1,070

The change in the estimated fair value of the total liability outstanding for all outstanding warrants of approximately $782,000 and ($201,000) was recognized as a non-cash gain/(loss) and included in total other income/(expense) in the Company's statements of operations and comprehensive loss for the years ended December 31, 2013 and 2014, respectively.

Other Fair Value Measurements

In connection with the closing of the Company's IPO on February 10, 2014, the IPO's underwriters were granted a 45 day option to purchase up to 285,000 shares of common stock to cover overallotments with a grant date fair value of $202,143, which was not exercised. Additionally, certain designees of the representative of the underwriters were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock with a grant date fair value of $544,116. The fair values of these stock option and common stock warrants were estimated using Black-Scholes valuation models with the following assumptions:

	Options	Warrants
Stock price	$ 8.91	$ 8.91
Exercise price	$ 9.30	$ 12.50
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.07%	1.46%
Expected life (in years)	0.12	5.00
Expected volatility	70.0%	90.0%

The estimated grant date fair values of these non-cash equity classified instruments were recorded as an offset to additional paid-in capital within common stock issuance costs.

In connection with the closing of the April 2014 Credit Facility on April 30, 2014, the lender was granted a warrant to purchase 52,966 shares of common stock with a 10 year term and an estimated grant date fair value of $233,107 (see Note 7). The fair value of this warrant was estimated using a Black-Scholes valuation model with the following assumptions:

Stock price	$ 4.74
Exercise price	$ 4.72
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	2.67%
Expected life (in years)	10.00
Expected volatility	110.0%

The estimated grant date fair value of this non-cash equity classified instrument was recorded as a discount to outstanding debt and is amortized to interest expense utilizing the effective interest method over the underlying term of the loan.

The estimated fair value of the April 2014 Credit Facility at December 31, 2014 approximated carrying value, which was determined using a discounted cash flow analysis. The analysis considered interest rates of instruments with similar maturity dates, which involved the use of significant unobservable Level 3 inputs (see Note 7).

6. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2013	December 31, 2014
Fixed Assets		
Machinery and equipment	$ 2,761,560	$ 2,922,303
Furniture and office equipment	209,844	209,844
Computer equipment and software	681,508	681,508
Leasehold improvements	373,653	506,328
Financed equipment	677,000	878,447
Construction in process	12,299	72,172
	4,715,864	5,270,602
Less accumulated depreciation and amortization	4,356,977	4,608,180
Total fixed assets, net	$ 358,887	$ 662,422
Accrued Liabilities		
Accrued interest	$ 524,885	$ 33,125
Accrued payroll	125,299	82,241
Deferred wages	1,377,987	—
Accrued vacation	213,601	276,574
Accrued bonuses	—	302,763
Other	286	4,130
Total accrued liabilities	$ 2,242,058	$ 698,833

As of December 31, 2013, the Company incurred $538,318 in costs directly associated with its IPO, which are reflected on the Company's balance sheet as a component of prepaid expenses and other current assets. A liability of $328,221 for associated unpaid invoices is recorded as a component of accounts payable at December 31, 2013. As of December 31, 2014, a balance of $1,211,896 of such costs, in addition to underwriting discounts of $1,330,000 and an aggregate $746,259 of associated stock option and restricted stock awards, are offset against additional paid-in capital as a result of the closing of the Company's IPO on February 10, 2014 (see Note 2).

Costs associated with the Company's February 2015 public offering totaling $63,111 were incurred during the year ended December 31, 2014, which are reflected on the Company's balance sheet as a component of prepaid expenses and other current assets at December 31, 2014. A liability of $63,111 for associated unpaid invoices is recorded as a component of accounts payable at December 31, 2014.

7. April 2014 Credit Facility

On April 30, 2014, the Company received net cash proceeds of approximately $4,927,000 pursuant to the execution of its April 2014 Credit Facility with Oxford Finance LLC. A second term loan of up to a principal amount of $5 million will be funded at the Company's request prior to December 31, 2015, subject to the achievement of product and services revenues of at least $9 million for the trailing six months, with such six-month period ending no later than November 30, 2015. Upon the entry into the April 2014 Credit Facility, the Company was required to pay the lenders a facility fee of $50,000 in conjunction with the funding of the first term loan. Another $50,000 facility fee will be due and payable to the lenders on the funding date of the second term loan (if such date occurs). The April 2014 Credit Facility is secured by substantially all of the Company's personal property other than its intellectual property. Each term loan under the April 2014 Credit Facility bears interest at an annual rate equal to the greater of (i) 7.95% or (ii) the sum of (a) the three-month U.S. LIBOR rate reported in the Wall Street Journal three business days prior to the funding date of the applicable term loan, plus (b) 7.71%, such rate to be fixed at the time of borrowing. The first term loan bears interest at an annual rate of 7.95%. The Company is required to make interest-only payments on the first term loan through February 1, 2016 if the funding date of the second term loan occurs before June 30, 2015, or through August 1, 2015 otherwise. If the Company requests and the lenders fund the second term loan, the Company is required to make interest-only payments on the second term loan through February 1, 2016 if the funding date of the second term loan occurs before June 30, 2015, or through the seventh month following the funding date of

the second term loan otherwise. All outstanding term loans under the April 2014 Credit Facility will begin amortizing at the end of the applicable interest-only period, with monthly payments of principal and interest being made by the Company to the lenders in consecutive monthly installments following such interest-only period. The first term loan under the April 2014 Credit Facility matures on July 1, 2018, and the second term loan matures on the first day of the 29th month following the end of the applicable interest-only period. Upon repayment of each term loan, the Company is also required to make a final payment to the lenders equal to 5.50% of the original principal amount of such term loan funded. At its option, the Company may prepay the outstanding principal balance of the term loans in whole but not in part, subject to a prepayment fee of 3% of any amount prepaid if the prepayment occurs on or prior to April 30, 2015, 2% of the amount prepaid if the prepayment occurs after April 30, 2015 but on or prior to April 30, 2016, and 1% of any amount prepaid after April 30, 2016.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to the Company and any subsidiaries the Company creates in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on the Company's transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject to certain exceptions. The April 2014 Credit Facility also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the term loans under the April 2014 Credit Facility, including foreclosure against the Company's properties securing the April 2014 Credit Facility, including the Company's cash. These events of default include, among other things, the Company's failure to pay any amounts due under the April 2014 Credit Facility, a breach of covenants under the April 2014 Credit Facility, the Company's insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than $250,000, and a final judgment against the Company in an amount greater than $250,000.

A warrant to purchase up to 52,966 shares of the Company's common stock at an exercise price of $4.72 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014 (see Note 5). Additional warrants for shares of the Company's common stock will be issued upon execution of the second term loan under the April 2014 Credit Facility in an amount equal to 5.0% of the funded amount divided by the exercise price, which will be equal to the lower of (i) the closing price per share of the Company's common stock on the NASDAQ on the date prior to the funding date of the second term loan or (ii) the ten-day average closing price per share prior to the funding date of the second term loan. Issuance costs of $73,104 associated with the first term loan under the April 2014 Credit Facility were deducted from the gross proceeds by the lender and were recorded as a discount to outstanding debt as of the closing date, resulting in net proceeds of $4,926,896. Other issuance costs of $28,932 directly related to the April 2014 Credit Facility but not associated with the lender were recorded as a component of other non-current assets in the Company's balance sheet. The estimated fair value of the warrant issued of $233,107 was recorded as a discount to outstanding debt as of the closing date. The discounts and other issuance costs are amortized to interest expense utilizing the effective interest method over the underlying term of the loan. The total amount of interest expense recorded during the year ended December 31, 2014 related to the April 2014 Credit Facility was $380,264. Approximately $61,000 related to accretion of the discount was recognized as interest expense during the year ended December 31, 2014, with approximately $245,000 remaining unamortized and reflected as a discount to the debt. The April 2014 Credit Facility bears an effective annual interest rate of 10.81% at both April 30, 2014 and December 31, 2014.

8. Line of Credit

In July 2013, the Company entered into a revolving line of credit with UBS Bank USA in the initial amount of $1.5 million. Interest accrued daily on the outstanding balance and was paid monthly at a variable rate which, as of December 31, 2013, was 2.75% over the 30 day LIBOR rate or a nominal annual interest rate of 2.92%. As of December 31, 2013, the amount outstanding under this revolving line of credit was approximately $2.0 million. Subsequent to December 31, 2013, the maximum amount of the line of credit was increased to approximately $2.6 million. Five of the Company's affiliated parties guaranteed the loan and pledged financial assets to the bank to secure their guaranties, as approved by the Company's Board of Directors. In return, the Company issued common stock warrants to the guarantors. The number of shares subject to the common stock warrants was determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to the bank, by the exercise price set at the price per share of the Company's common stock sold in its IPO. See Note 5 for further discussion of the warrant liabilities. The Company entered into an agreement with the guarantors that provided for reimbursement of any amounts paid by them on their guaranties. This reimbursement obligation was secured by a security interest in the Company's assets.

In connection with the closing of the Company's IPO on February 10, 2014, the current outstanding balance under the line of credit of $2,346,000 plus accrued interest of $27,043 was paid in full, and the exercise price of the warrants associated with the $2,578,104 of collateral provided was fixed at $10.00 per share for an aggregate 128,903 shares of common stock, with associated derivative warrant liabilities of $513,603 reclassified to additional paid-in capital.

9. Notes Payable

The following is a summary of the Company's short-term and long-term debt obligations:

	December 31,	
	2013	2014
Secured convertible note to a major shareholder. As of February 10, 2014, the secured convertible note was converted into common shares. ("2008 Convertible Note") (See Note 10)	$ 1,400,000	$ —
Unsecured convertible notes, issued under a note and warrant purchase agreement dated as of June 28, 2013, net of discounts related to warrants aggregating $874,158 and $0 at December 31, 2013 and 2014, respectively. Includes notes of $2,505,000 and $0 to a major shareholder at December 31, 2013 and 2014, respectively. As of February 10, 2014, the unsecured convertible notes were converted into common shares. ("2013 Convertible Bridge Notes") (See Note 10)	4,115,842	—
Secured term loan agreement, net of discounts related to warrants and lender fees aggregating $0 and $245,484 at December 31, 2013 and 2014, respectively. ("April 2014 Credit Facility") (see Note 7)	—	4,754,516
Other debt discount. As of February 10, 2014, the remaining unamortized portion of the other debt discount was reclassified to interest expense. (See Notes 8 and 10)	(315,243)	—
Total notes payable	5,200,599	4,754,516
Less current portion	5,200,599	—
Long-term portion	$ —	$ 4,754,516

The Company was unable to make principal and interest payments on all outstanding notes payable and convertible notes payable except for the non-current balance of the 2013 Convertible Bridge Notes prior to the conversion of certain of the notes as of June 28, 2013. None of the lenders had sought any remedy for this default prior to the conversion of the notes as of June 28, 2013.

On June 28, 2013, approximately $20,231,000 of outstanding notes payable and $2,581,000 of accrued interest were converted into 42,245,834 preferred shares, in accordance with the provisions of the debt conversion agreements of that date.

In connection with the closing of the Company's IPO on February 10, 2014, (i) the $1,400,000 principal amount and $233,982 of accrued interest related to the 2008 Convertible Note were converted at $10.00 per share into a total of 163,399 shares of common stock, (ii) the $5,165,000 principal amount and $313,017 of accrued interest related to the 2013 Convertible Bridge Notes were converted at $10.00 per share into a total of 547,794 shares of common stock, and (iii) derivative warrant liabilities of $1,562,968 associated with an aggregate of 258,249 common stock warrants related to the 2013 Convertible Bridge Notes were reclassified to additional paid-in capital when their underlying exercise price was fixed at $10.00 per share.

Total interest expense incurred for all notes, convertible notes, and the line of credit, including amortization of debt discounts, for the years ended December 31, 2013 and 2014 was approximately $1,964,000 and $1,768,000, respectively, of which approximately $516,000 and $88,000 was recorded as accrued interest as of December 31, 2013 and 2014, respectively.

10. Convertible Notes and Warrants

Preferred Shares

Goodman Note

During April 2005, the Company entered into an unsecured loan agreement for $15,000,000 (the "Goodman Note"). The note required interest payments and principal settlement upon maturity at the earliest of (a) April 20, 2010, (b) the Company being acquired, or (c) the Company having a change in control, other than through the sale of preferred shares.

During January 2009, the Company entered into an amendment and restatement of the unsecured amended loan, whereby the parties agreed that the principal amount would be reduced to $3,000,000. The amended and restated unsecured note accrued interest at a variable rate per annum based on prime plus 25 basis points. 25% of the accrued interest was due and payable quarterly in arrears on the last business day of each three-month quarter beginning February 1, 2009. The remaining 75% of the accrued interest was not to be compounded by becoming part of the principal, and was due and payable in a lump-sum payment on the maturity date. The principal and any interest amounts that remain outstanding was set to mature at the earlier of (a) April 20, 2010, or (b) the date immediately prior to the Company's closing of an acquisition or asset transfer as defined by the Company's amended and restated articles of incorporation.

In conjunction with the 2009 amendment, the Company issued a warrant to purchase preferred shares issued in the first equity financing to occur subsequent to the execution of the note, and in which the Company receives at least $2,000,000 in gross aggregate proceeds. The exercise price of the warrant would have been equal to the per share price of preferred shares sold in that equity financing, and the number of shares that may have been exercised was equal to 10% of the principal amount of the convertible loan divided by the exercise price. Early termination of the warrant could occur upon an IPO, or if the Company was acquired. The holder of the warrant was to be given 20 days advance notice of such an event, and the warrant would terminate if not exercised before the date of the event.

A qualifying equity financing occurred during February 2009, which set the warrant exercise price at $0.60 per share.

During May 2010, the Company entered into a second amendment and restatement of the Goodman Note in order to extend the maturity date and amend the timing of payments to be made to the lender and to secure the Company's obligations under the note. The secured amended and restated note accrued interest at a per annum fixed rate of 3.25% and was due and payable quarterly in arrears on the last business day of each three-month quarter beginning May 1, 2010. On the effective date of the second amendment, the Company paid the lender $750,000 which was applied to the principal balance of $3,000,000. Beginning May 1, 2010, principal payments were due and payable quarterly in advance. For principal payments due and payable during the period of May 1, 2010 through January 31, 2011, the quarterly principal payment was equal to $45,000; for principal payments due and payable during the period of February 1, 2012 through January 31, 2014, the quarterly principal payment was equal to $90,000; and for principal payments due and payable during the period of February 1, 2014 through the maturity date, the quarterly principal payment was equal to $150,000. In addition to the $750,000 principal paid on the effective date of the amendment, the Company paid principal payments of $135,000 and $180,000 during the years ended December 31, 2010 and 2011, respectively. No principal payments were made during the years ended December 31, 2012 or 2013.

As of June 28, 2013 the holder of the Goodman Note agreed to convert the total principal balance owed under the Goodman Note of $1,935,000 and accrued interest of approximately $105,000 into 3,777,324 preferred shares at a conversion price of $0.54 per share. Although the conversion price of the debt was greater than the value of the preferred shares at the time of conversion, the Company did not record a gain on the conversion under the troubled debt restructuring accounting guidance since the transaction occurred between related parties, and thus, was treated as a capital transaction. As of the closing of the Company's IPO on February 10, 2014, such shares of preferred stock automatically converted into 89,936 shares of common stock.

In July 2013, in connection with this conversion, the Company issued to such beneficial owner a warrant to purchase 23,809 shares of common stock at an exercise price of $10.00 per share, which was set at the price of the Company's common stock sold in the Company's IPO. The warrants are exercisable for a two-year period beginning with the closing of the Company's IPO on February 10, 2014. In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants were initially recorded at their fair value and were then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the warrants for common shares issued under the Goodman Note agreement, the Company used a probability weighted Black-Scholes valuation model. The fair value of the Goodman Note warrants was approximately $62,000 at December 31, 2013 and was included in warrant liabilities until the underlying exercise price was fixed at the closing of the Company's IPO on February 10, 2014, when the warranty liability balance of approximately $95,000 was reclassified to additional paid-in capital (see Notes 2 and 5).

2008 Convertible Note

In December 2008, the Company issued the 2008 Convertible Note in the principal amount of $1,400,000 which was secured by all assets of the Company to an affiliate of a major shareholder. The 2008 Convertible Note accrued interest at a variable rate based on prime per annum payable at maturity, and matured at the earliest occurrence of, (a) the passing of 48 months from inception of the note, (b) the closing date of an acquisition or asset transfer as defined by the note, or (c) the closing date of the issuance and sale of shares of common stock of the Company in the Company's IPO.

Upon the closing of a sale by the Company of its preferred shares in which the Company received an aggregate of at least $20,000,000 in cumulative gross proceeds, including conversion of the convertible loan amount before the maturity date, the unpaid principal and accrued interest would automatically be converted into the number of preferred shares, of the series sold by the Company in such sale, equal to the unpaid principal and accrued interest divided by the per share purchase price of the preferred shares in such sale. The 2008 Convertible Note may have also been converted before the maturity date at the option of the holder at the closing of an equity financing involving the sale of the Company's preferred shares in which the Company received an aggregate of at least $2,000,000 in cumulative gross proceeds, with a conversion price equal to the per share price included in that equity financing. In July 2013, the Company amended the 2008 Convertible Note to provide that all principal and accrued interest on the note would automatically convert into common stock upon the closing of an IPO at the price per share at which common stock is sold in such IPO.

Issued with the 2008 Convertible Note was a warrant to purchase preferred shares issued in the first equity financing to occur subsequent to the execution of the 2008 Convertible Note, and in which the Company would have received at least $2,000,000 in gross aggregate proceeds. The exercise price of the warrant would have been equal to the per share price of preferred shares sold in that equity financing, and the number of shares that may have been exercised was equal to 10% of the principal amount of the convertible loan divided by the exercise price. Early termination of the warrant could occur upon an IPO or if the Company was acquired. The holder of the warrant was to be given 20 days advance notice of such an event, and the warrant would terminate if not exercised before the date of the event.

A qualifying equity financing occurred during February 2009, which set the 2008 Convertible Note conversion price and the warrant exercise price at $0.60 per share. In connection with the closing of the Company's IPO on February 10, 2014, the $1,400,000 principal amount and $233,982 of accrued interest related to the 2008 Convertible Note were converted at $10.00 per share into a total of 163,399 shares of common stock (see Note 2).

2011 Convertible Bridge Notes

In February 2011, the Company executed a note and warrant purchase agreement with a major shareholder's affiliates. In exchange for a series of loans in an aggregate amount equal to $5,000,000 over a period through September 1, 2011, the Company issued the 2011 Convertible Bridge Notes and warrants to purchase preferred shares. The aggregate amount was subsequently raised to $6,000,000 and then $15,000,000 during the year and the funding period was first extended to February 2012 and then to December 2012. Other investors, including related parties, also became party to this arrangement and purchased 2011 Convertible Bridge Notes and warrants.

All unpaid principal and interest outstanding was initially payable on December 31, 2011. During 2012, the maturity date was extended to December 31, 2012. The 2011 Convertible Bridge Notes were secured by virtually all of the assets of the Company. The 2011 Convertible Bridge Notes accrued interest at 8%, payable at maturity. The number of preferred shares for which the warrants were exercisable was determined by dividing the warrant coverage amount, which was 20% of the principal amount of the notes issued under the agreement, by the exercise price.

Upon the closing of the sale by the Company of its preferred stock in which the Company received an aggregate of at least $20,000,000 in cumulative gross proceeds, including conversion of the 2011 Convertible Bridge Notes, before the maturity date, the unpaid principal and accrued interest would automatically have been converted into the number of preferred shares, of the series sold by the Company in such sale, equal to the unpaid principal and accrued interest divided by the per share purchase price of the preferred shares in such sale. At any time before the maturity date the investor could elect to convert all or any amount of the unpaid principal and accrued interest into the Company's Series A preferred shares at $0.54 per share. Early termination of the warrants could occur upon an IPO or if the Company was acquired. The holders of the warrants were to be given 20 days advance notice of such an event, and the warrants would terminate if not exercised before the date of the event.

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants were initially recorded at their fair value and were then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments issued under the note and warrant purchase agreement dated February 2011, the Company used the Black-Scholes valuation model. The Company recorded approximately $1,400,000 related to the fair value of the warrants at the date of issuance, as a discount to the carrying value of the 2011 Convertible Bridge Notes, accreted as interest expense over the life of the debt. The Company valued the warrants at the date of each issuance using the Black-Scholes valuation model with the following underlying assumptions: contractual term of 5 years, an underlying preferred share price between $0.25 and $0.54, an exercise price of $0.54, an average risk-free interest rate between 0.70% and 2.26%, a dividend yield of 0%, and volatilities between 100.0% and 105.0%. The discount was fully accreted as of December 31, 2012.

As of December 31, 2012, the Company had issued the 2011 Convertible Bridge Notes with an aggregate principal amount of approximately $12,336,000. No further note or warrant issuances were made under this agreement during the year ended December 31, 2013. As of December 31, 2012, the Company was in default for payment on the 2011 Convertible Bridge Notes, and no principal payments were made in 2013 prior to their conversion. As of June 28, 2013 the investors under these notes elected to convert the total principal balance owed under the 2011 Convertible Bridge Notes of approximately $12,336,000 and accrued interest of approximately $1,832,000 into 26,237,611 preferred shares at a conversion price of $0.54 per share. Upon the conversion, the exercise price of the related warrants was set at $0.54 per share, and the $236,799 fair value of the warrants was reclassified into additional paid-in capital as of June 28, 2013. Although the conversion price of the debt was greater than the value of the preferred shares at the time of conversion, the Company did not record a gain on the conversion under the troubled debt restructuring accounting guidance since the transaction occurred between related parties, and thus, was treated as a capital transaction. As of the closing of the Company's IPO on February 10, 2014, such shares of preferred stock automatically converted into 624,705 shares of common stock.

2012 Revolver Notes

On January 13, 2012, the Company executed a note and warrant purchase agreement with several shareholders, including a major shareholder, calling for (in addition to the issuance of certain related warrants) the issuance of a series of 2012 Revolver Notes to be issued between January 13, 2012 and April 5, 2012 totaling up to $1,750,000, with an original maturity date in April 2012. The 2012 Revolver Notes were amended on April 5, 2012 to extend the maturity date to May 31, 2012 or July 31, 2012, depending on certain milestones, and to allow the Company to issue up to $5,000,000 in notes payable under this agreement, as needed. The 2012 Revolver Notes were amended again on November 8, 2012 to increase the amount of notes payable the Company could issue to $8,000,000, and to provide that all notes issued under this agreement would have the same maturity date of either November 30, 2012 or December 31, 2012, depending on certain milestones. The 2012 Revolver Notes accrued interest at 10%, payable at maturity.

Beginning on the closing of the sale by the Company of its preferred shares in which the Company received an aggregate of at least $20,000,000 in cumulative gross proceeds, the warrants would have been exercisable for preferred shares of the series sold by the Company in such sale, at an exercise price equal to the purchase price per share of the preferred shares sold by the Company in such sale. The number of preferred shares for which the warrants would have been exercisable was determined by dividing the warrant coverage amount, which was 20% of the principal amount of the notes issued under the agreement on the issuance date of such 2012 Revolver Notes, by the exercise price. At any time prior to the maturity date, the investor could elect to convert all or any amount of the unpaid principal and accrued interest into the Company's Series A preferred stock at $0.54 per share, or if a qualified financing had occurred, at the purchase price per share of the preferred shares sold by the Company in such qualified financing. Early termination of the warrant could occur upon an IPO, or if the Company was acquired. The holders of the warrants were to be given 20 days advance notice of such an event, and the warrants would terminate if not exercised before the date of the event.

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants were initially recorded at their fair value and were then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the 2012 Revolver Notes and warrants issued under the note and warrant purchase agreement dated January 13, 2012, the Company used the Black-Scholes valuation model. The Company recorded approximately $396,000 related to the fair value of the warrants issued, as a discount to the carrying value of the debt, accreted as interest expense over the life of the debt. The Company valued the warrants at the date of each issuance using the Black-Scholes valuation model with the following underlying assumptions: contractual term of 5 years, an underlying preferred share price between $0.24 and $0.30, an exercise price of $0.54, an average risk-free interest rate between 0.62% and 1.02%, a dividend yield of 0%, and volatility of 105.0%. Approximately $396,000 related to accretion of the discount was recognized as interest expense during the year ended December 31, 2012. The discount was fully accreted as of December 31, 2012.

As of December 31, 2012, the Company had issued $5,960,000 in 2012 Revolver Notes. The Company was in default for payment of these notes as of December 31, 2012, and no principal payments were made in 2013 prior to conversion. As of June 28, 2013 the investors under the 2012 Revolver Notes elected to convert the total principal balance of approximately $5,960,000 owed under the 2012 Revolver Notes and accrued interest of approximately $645,000 into 12,230,899 preferred shares at a conversion price of $0.54 per share, pursuant to note conversion agreements of that date. Although the conversion price of the debt was greater than the value of the preferred shares at the time of conversion, the Company did not record a gain on the conversion under the troubled debt restructuring accounting guidance since the transaction occurred between related parties, and thus, was treated as a capital transaction. On September 13, 2013, the exercise price of the warrants was fixed at $0.54 per share, and the fair value of the warrant liability of approximately $144,000 on that date was reclassified to additional paid-in capital. As of the closing of the Company's IPO on February 10, 2014, such shares of preferred stock automatically converted into 291,212 shares of common stock.

Other

On September 10, 2012, the Company issued a warrant to its landlord in exchange for a rent deferral through November 30, 2012. The number of Series A preferred shares exercisable under the warrant agreement is determined by dividing the warrant coverage amount of $40,000 by the exercise price. The exercise price of the warrants is $0.60, or, upon the closing of the sale by the Company of its preferred stock in which the Company receives an aggregate of at least $15,000,000 in cumulative gross proceeds, the warrant's exercise price will be the price per share for which the Company sells its preferred shares in such sale. The term of the warrant is seven years. Early termination of the warrant can occur if the Company is acquired. The holder of the warrant is to be given 20 days advance notice of such an event, and the warrant will terminate if not exercised before the date of the event. The fair value of such liability-classified preferred warrant to purchase an equivalent 1,587 shares of common stock at December 31, 2013 and 2014 is not material to the financial statements.

As of December 31, 2012, warrants to purchase preferred stock were reflected as a liability on the balance sheet, which was adjusted to estimated fair value at the end of each reporting period over the term of the warrants. These warrants were reclassified to additional paid-in capital during the year ended December 31, 2013. The fair value of the warrant liability for warrants to purchase preferred stock as of December 31, 2012 of approximately $982,000 was estimated using the Black-Scholes valuation model with the following assumptions: contractual term between 3.08 and 4.92 years, an underlying preferred share price of $0.25, an exercise price of $0.54, an average risk-free interest rate between 0.35% and 0.70%, a dividend yield of 0%, and volatility of 105.0%.

Common Shares

2013 Convertible Bridge Notes

The Company executed a convertible note and warrant purchase agreement as of June 28, 2013 with several shareholders, including a major shareholder, relating to the Company's borrowing as needed of, and issuance of the 2013 Convertible Bridge Notes for, up to $7,000,000. The Company had borrowed $4,990,000 and $5,165,000 as of December 31, 2013 and as of the closing of the Company's IPO on February 10, 2014, respectively, against the 2013 Convertible Bridge Notes, including $2,505,000 at each date from a major shareholder. As of December 31, 2013, the maturity date of the 2013 Convertible Bridge Notes was May 31, 2014 with the option to extend by the respective note holders for two successive six month periods. The 2013 Convertible Bridge Notes accrued interest at 8.0% per annum, payable at maturity.

The 2013 Convertible Bridge Notes would automatically convert into the Company's common stock upon the closing of an IPO of at least $8,000,000 in cumulative gross proceeds, at a price equal to the price per share of the Company's common stock sold in the IPO. The number of common shares for which the warrants were exercisable was determined by dividing the warrant coverage amount, which was 50% of the principal amount of the notes issued under the agreement, by the exercise price of $10.00, which was the price per share of the Company's common stock sold in the IPO. The warrants are exercisable for a five-year period beginning with the closing of the Company's IPO on February 10, 2014. Early termination of the warrants can occur upon any capital reorganization, any reclassification of the capital stock, or an asset transfer or acquisition of the Company. The holders of the warrants are to be given 20 days advance notice of such an event, and the warrants will terminate if not exercised prior to the date of the event.

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants were initially recorded at their fair value and were then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the warrants for common shares issued together with the 2013 Convertible Bridge Notes, the Company used a probability weighted Black-Scholes valuation model. The Company recorded approximately $1,612,000 related to the fair value of the warrants issued, as a discount to the carrying value of the debt, accreted to interest expense using the effective interest method from the date of issuance over the life of the debt. These warrants to purchase common stock were valued as of their date of issuance, using the following assumptions: exercise price of between $1.48 and $14.28 per share, contractual term of 5 years, a risk-free interest rate between 1.38% and 1.73%, a dividend yield of 0%, and volatility between 100.0%—105.0%. The value of the warrants using the probability weighted Black-Scholes valuation model accounted for a probability between 75% and 80%, while a fair value of $0 was weighted between 20% and 25%. The fair value of the warrants was approximately $1,399,000 at December 31, 2013 and was included in warrant liabilities until the underlying exercise price was fixed at the closing of the Company's IPO on February 10, 2014, when the warranty liability balance of approximately $1,563,000 was reclassified to additional paid-in capital (see Notes 2 and 5). Approximately $685,000 related to accretion of the discount was recognized as interest expense during the year ended December 31, 2013, with approximately $874,000 remaining unamortized and reflected as a discount to the debt at December 31, 2013. Approximately $928,000 related to accretion and write-off of the discount was recognized as interest expense from January 1, 2014 until the closing of the Company's IPO on February 10, 2014, when the $5,165,000 principal amount and $313,017 of accrued interest related to the 2013 Convertible Bridge Notes were converted at $10.00 per share into a total of 547,794 shares of common stock (see Note 2).

Line of Credit

Five of the Company's related parties guaranteed the Company's Line of Credit (see Note 8) and pledged financial assets to the bank to secure their guaranties, as approved by the Company's Board of Directors. In return, the Company issued common stock warrants to the guarantors. The fair market value of the collateral provided by the respective guarantors until the closing of the Company's IPO on February 10, 2014 was $2,578,076. The number of shares subject to the common stock warrants was determined by dividing the warrant coverage amount, which was 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to the bank, by the exercise price of $10.00, which was set at the price per share of the Company's common stock sold in its IPO. The warrants are exercisable for a two-year period beginning with the closing of the Company's IPO on February 10, 2014.

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants were initially recorded at their fair value and were then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the warrants for common shares issued in connection with the Company's Line of Credit, the Company used a probability weighted Black-Scholes valuation model. The Company recorded approximately $536,000 related to the fair value of the warrants issued, as a discount to the carrying value of the debt, accreted to interest expense on a straight line basis from the date of issuance over the life of the debt. These warrants to purchase common stock were valued as of their date of issuance, using the following assumptions: exercise price between $1.48 and $14.28 per share, contractual term of 2 years, a risk-free interest rate between 0.38% and 1.38%, a dividend yield of 0%, and volatility between 90.0% and 105.0%. The value of the warrants using the probability weighted Black-Scholes valuation model accounted for a probability of 75%, while a fair value of $0 was weighted 25%. The fair value of the warrants was approximately $390,000 at December 31, 2013 and was included in warrant liabilities until the underlying exercise price was fixed at the closing of the Company's IPO on February 10, 2014, when the warranty liability balance of approximately $514,000 was reclassified to additional paid-in capital (see Notes 2 and 5). Approximately $139,000 related to accretion of the discount was recognized as interest expense during the year ended December 31, 2013, with approximately $315,000 remaining unamortized and reflected as a discount to outstanding debt at December 31, 2013. Approximately $397,000 related to accretion and write-off of the discount was recognized as interest expense from January 1, 2014 until the closing of the Company's IPO on February 10, 2014, after which the total outstanding $2,346,000 principal amount and $27,043 of accrued interest were repaid using the net proceeds from the IPO.

Other

On September 10, 2013, the Company, as part of a lease amendment for its non-cancellable operating lease for its office, laboratory, and warehouse space at its San Diego, California facility, issued a warrant to its landlord with a coverage amount of $502,605. The warrant is exercisable for a five-year period beginning with the closing of the Company's IPO on February 10, 2014, when such warrant became exercisable for 50,260 shares of common stock and the exercise price was fixed at $10.00 per share.

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrant was initially recorded at fair value and then was re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the warrant for common shares issued to the landlord, the Company used a probability weighted Black-Scholes valuation model. The Company recorded approximately $309,000 related to the fair value of the warrant issued at issuance in September 2013, as a reduction in deferred rent liability, accreted to rent expense on a straight line basis from the date of issuance over the term of the amended lease. The warrant was valued as of the date of issuance, using the following assumptions: exercise price of between $3.08 and $14.28 per share, contractual term of 5 years, a risk-free interest rate of 1.38%, a dividend yield of 0%, and volatility of 105.0%. The value of the warrant using the probability weighted Black-Scholes valuation model accounted for a probability of 75%, while a fair value of $0 was weighted 25%. The fair value of the warrant was approximately $282,000 at December 31, 2013 and was included in warrant liabilities until the underlying exercise price was fixed at $10.00 per share at the closing of the Company's IPO on February 10, 2014, when the warranty liability balance of approximately $304,000 was reclassified to additional paid-in capital (see Notes 2 and 5).

11. Supplier Financing

In 2011, the Company purchased certain laboratory equipment under financing agreements with a supplier, a business owned by a member of the Company's Board of Directors, totaling approximately $256,000. Financing was granted for the purchase of the equipment at a stated interest rate of 0.0%. The Company utilized its average interest rate for 2013 of 8.0% to amortize the payments and record interest expense of approximately $5,000 for the year ended December 31, 2013, utilizing the effective interest expense method. The remaining balance owed under these financing agreements was approximately $66,000 as of December 31 2013 and was due in 2013, and was subsequently paid in full using the net proceeds from the Company's IPO.

In 2011, the Company purchased laboratory software under a financing agreement with a supplier for approximately $177,000. This software financing agreement bears an interest rate of 7.4% per annum. The balance owed under these financing agreements was approximately $62,000 at December 31, 2013 and was subsequently paid in full using the net proceeds from the Company's IPO.

In 2013 and 2014, the Company obtained third-party financing for certain business insurance premiums. The financing bears an interest rate of 5.95% per annum, and all financing is due within one year. The balances due under these annual financing arrangements were approximately $91,000 and $34,000 as of December 31, 2013 and 2014, respectively.

12. Shareholders' Deficit

(a) Common Stock

On November 1, 2013, the Company effected a 1:14 reverse stock split for all common shares. All references to share and per share amounts in the financial statements and accompanying notes to the financial statements have been retroactively restated to reflect the 1:14 reverse stock split.

On July 22, 2013, the Company amended its articles of incorporation to increase the number of authorized shares of common stock from 14,600,000 to 53,000,000. In addition, on July 30, 2013, the Company assigned a par value to its common shares of $0.0001 in conjunction with its reincorporation in Delaware. The new par value per common share has been retroactively reflected in the financial statements for all periods presented. The authorized number of shares of common stock at December 31, 2013 was 53,000,000. On February 4, 2014, as contemplated by the registration statement covering the Company's IPO, the Company's certificate of incorporation was amended to provide for an authorized capitalization of 40,000,000 shares of common stock.

(b) Preferred Stock

As of December 31, 2012, all 36,460,000 authorized shares of preferred stock were designated as Series A preferred stock. On July 22, 2013, the Company amended its articles of incorporation to increase the number of authorized preferred shares from 14,600,000 to 100,000,000. In addition, on July 30, 2013, the Company assigned a par value to its preferred shares of $0.0001 in conjunction with its reincorporation in Delaware. The new par value per preferred share has been retroactively reflected in the financial statements for all periods presented. On February 4, 2014, as contemplated by the registration statement covering the Company's IPO, the Company's certificate of incorporation was amended to provide for an authorized capitalization of 5,000,000 shares of preferred stock.

Holders of the Company's preferred shares were entitled to receive, when and as declared by the Board of Directors and in preference to common shareholders, non-cumulative cash dividends at the rate of 8% per annum of the applicable original issue price on each outstanding preferred share. The original issue price of each share of Series A preferred stock was $0.60. No dividends were declared during 2013 or 2014. Dividends cannot be granted for common shareholders while shares of preferred stock remain outstanding.

The holders of preferred shares had the right to one vote for each common share into which the preferred shares were convertible. Upon the liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the preferred shareholders would have been paid out an amount equal to the original issue price plus all declared and unpaid dividends. If, upon any liquidation, distribution, or winding up of the Company, and the assets of the Company were insufficient to make payment in full to all holders of preferred shares of the liquidation preference, then such assets would have been distributed among the holders of preferred shares ratably in proportion to the full amounts to which they would be entitled.

The convertible preferred shares could have been converted into common shares at any time at the option of the holder utilizing the then effective Series A preferred conversion price. All preferred shares would have been automatically converted into common shares utilizing the then effective Series A preferred conversion price upon a) the election of the holders of a majority of the outstanding shares of Series A preferred stock, or b) the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933 covering the sale of the Company's common stock if gross proceeds are at least $20,000,000 and the per share price is at least $25.20.

The effective conversion price was equal to the original issue price divided by $25.20 and could have been adjusted for dilutive issuances of common shares, common share rights or options, common share splits and combinations, dividends, and distributions. The effective conversion rate would not have been adjusted for issuances of common share options, warrants or rights to employees, directors, or non-employee service providers.

During the year ended December 31, 2013, 42,245,834 shares of Series A preferred stock were issued for the conversion of approximately $20,231,000 of debt and $2,581,000 of accrued interest, primarily to related parties (see Notes 9 and 10).

13. Accounting for Stock-Based Compensation Expense

2007 Equity Incentive Plan

The 2007 Equity Incentive Plan ("2007 Plan") authorizes the grant of the following types of awards: (i) nonstatutory stock options, or NSOs, (ii) incentive stock options, or ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards, or RSUs, (v) stock appreciation rights, or SARs, (vi) performance awards, and (vii) other stock awards. Awards may be granted to employees, officers, non-employee board members, consultants, and other service providers of the Company. However, ISOs may not be granted to non-employees. In conjunction with the 1:14 reverse common stock split in November 2013, the number of shares authorized under the 2007 Plan decreased to 178,571 shares. As of December 31, 2013 and 2014, shares available for grant under the 2007 Plan were 77,061 and 86,001, respectively.

2013 Equity Incentive Plan

In July 2013, the Company adopted a new stock-based compensation plan entitled the 2013 Equity Incentive Plan ("2013 Plan"). The 2013 Plan authorizes the grant of the following types of awards: (i) nonstatutory stock options, (ii) ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards ("RSUs"), (v) stock appreciation rights, and (vi) performance compensation awards. Awards may be granted to employees, officers, non-employee board members, consultants, and other service providers of the Company. However, ISOs may not be granted to non-employees. The Company has authorized a total of 403,571 shares of common stock for issuance pursuant to awards granted under the 2013 Equity Incentive Plan, subject to an increase of 800,000 shares upon the completion of an IPO, and subject to additional increases every January 1 equal to the lesser of (i) 5% of the Company's outstanding common stock on such January 1, or (ii) a number of shares determined by the Company's Board of Directors in its discretion for use on such particular January 1. On February 10, 2014, in connection with the closing of the Company's IPO, the number of shares of common stock covered by the 2013 Plan increased by 800,000. As of December 31, 2014, 1,027,846 stock options and RSUs have been granted under the 2013 Plan, and 175,725 shares are available for grant under the 2013 Plan.

Stock Options

Options granted under either plan vest over a maximum period of four years and expire ten years from the date of grant. Options generally vest either (i) over four years, 25% on the one year anniversary of the date of grant and monthly thereafter for the remaining three years; or (ii) over four years, monthly vesting beginning month-one after the grant and monthly thereafter. Certain options have been granted which vest 50% on the grant date and monthly thereafter for the remaining two years.

The fair value of stock options is determined on the date of grant using the Black-Scholes valuation model. For non-performance awards, such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line method. The amount and timing of compensation expense recognized for performance awards is based on management's estimate of the most likely outcome. The determination of the fair value of stock options is affected by the Company's stock price, as well as assumptions regarding a number of complex and subjective variables. The volatility assumption is based on a combination of the historical volatility of the Company's common stock and the volatilities of similar companies over a period of time equal to the expected term of the stock options. The volatilities of similar companies are used in conjunction with the Company's historical volatility because of the lack of sufficient relevant history for the Company's common stock equal to the expected term. The expected term of employee stock options represents the weighted-average period the stock options are expected to remain outstanding. The expected term assumption is estimated based primarily on the options' vesting terms and remaining contractual life and employees' expected exercise and post-vesting employment termination behavior. The risk-free interest rate assumption is based upon observed interest rates on the grant date appropriate for the term of the employee stock options. The dividend yield assumption is based on the expectation of no future dividend payouts by the Company.

The assumptions used in the Black-Scholes pricing model for options granted during the years ended December 31, 2013 and 2014 are as follows:

	2013	2014
Stock and exercise prices	$ 5.18	$2.79 - $9.11
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	1.38% – 1.69%	1.56% – 2.06%
Expected life (in years)	5.26 – 6.02	5.00 – 6.08
Expected volatility	105.0%	90.0% – 100.0%
Expected forfeiture rate	0.00% – 5.00%	0.00% – 5.00%

Using the assumptions described above, the weighted-average estimated fair value of options granted in 2013 and 2014 were approximately $4.43 and $5.25, respectively.

A summary of stock option activity for 2013 and 2014 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2012	63,518	$ 4.97	6.2
Granted	300,438	$ 5.18	
Exercised	(4,021)	$ 5.00	
Cancelled/forfeited/expired	(26,829)	$ 5.20	
Outstanding at December 31, 2013	333,106	$ 5.14	9.3
Granted	647,298	$ 6.71	
Exercised	—	—	
Cancelled/forfeited/expired	(74,210)	$ 4.77	
Outstanding at December 31, 2014	906,194	$ 6.29	9.0
Vested and unvested expected to vest, December 31, 2014	901,882	$ 6.28	8.9

The intrinsic value of options exercised during the year ended December 31, 2013 was $3,450. The intrinsic value of options outstanding at December 31, 2013 and 2014 was $8,204 and $0, respectively.

The Company received $20,105 in proceeds from stock options exercised during the year ended December 31, 2013. The tax benefit related to stock options exercised during the year ended December 31, 2013 was not significant.

Further information about the options outstanding and exercisable is as follows:

Options Outstanding and Exercisable at December 31, 2013

Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Total Shares Exercisable
$ 4.62	20,208	7.3	13,731
$ 5.04	12,460	5.5	12,455
$ 5.18	300,438	9.6	110,825
	333,106		137,011

Options Outstanding and Exercisable at December 31, 2014

Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Total Shares Exercisable
$ 2.79	52,500	9.8	—
$ 4.42	103,934	8.8	29,715
$ 5.22	413,962	8.8	241,918
$ 7.50	43,000	9.2	—
$ 8.88	238,500	9.1	—
$ 9.11	54,298	9.1	54,298
	906,194		325,931

The intrinsic value of options exercisable at December 31, 2013 and 2014 was $5,575 and $0, respectively.

Restricted Stock

The fair value of restricted stock awarded under either plan is determined by the closing price of the Company's common stock on the date of grant. For non-performance awards, such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line method. The amount and timing of compensation expense recognized for performance-based awards is based on management's estimate of the most likely outcome.

In November 2010, the Company issued to a member of the Board of Directors a restricted stock unit award for 390,000 shares of Series BB preferred stock. In November 2011, these RSUs were modified to be redeemable for Series A preferred stock under the same terms and conditions of the original grant. As of the closing of the Company's IPO on February 10, 2014, 9,285 RSUs with an estimated grant date fair value of $4.62 per share vested in accordance with the terms of the underlying agreement. The common shares underlying this vested RSU award are not yet distributed.

In March 2011, the Company awarded a restricted stock unit award to a member of the Board of Directors for 428,597 shares of Series BB preferred stock. Also in March 2011, the Company awarded an additional performance-based restricted stock unit award for an estimated 574,108 shares of Series BB preferred stock to the same member. In November 2011, these RSUs were modified to be redeemable for Series A preferred stock under the same terms and conditions of the original grant. The number of shares in the RSUs is based on certain milestones to be achieved. As of the closing of the Company's IPO on February 10, 2014, 63,866 RSUs with an estimated grant date fair value of $4.62 per share vested in accordance with the terms of the underlying agreements. The common shares underlying these vested RSU awards are not yet distributed.

The Board of Directors approved a resolution in December 2010, that each January 1 each person (other than two identified individuals) who is serving as a non-employee director on such January 1 shall be automatically granted an annual restricted stock unit award covering a number of common shares equal to 0.25% of the fully diluted outstanding common stock of the Company as of the December 31 immediately preceding such January 1. These RSUs will be granted automatically on each January 1 and will vest in equal monthly installments over 12 months from the date of the grant. Additionally, in January 2012, each person (other than two identified individuals) who is serving as a non-employee director is to be granted a "true up grant" in addition to the annual grant covering a number of common shares equal to 0.25% of the fully diluted outstanding common shares of the Company as of the immediately preceding December 31. These RSUs will vest 100% on the date of the grant. In January 2012, five restricted stock unit awards for a total of 20,930 common shares were granted in accordance with this resolution. In addition, on January 1, 2012, an additional five restricted stock unit awards were granted to non-employee directors for a total of 20,930 common shares, vesting immediately upon grant. Although vested, shares are only delivered on the earlier of (i) the date that is 10 years from the grant date, (ii) the date of a change in control, (iii) the date of termination of the holder from the Company, (iv) the date of death or disability, or (v) the date of an unforeseeable emergency as described in Internal Revenue Code section 409A.

RSU awards for 8,735 shares of common stock each were granted to three directors and an RSU award for 14,285 shares of common stock was granted to another director, on July 31, 2013. All RSUs awarded in July 2013 have an estimated grant date fair value of $5.60 per share and vest in equal monthly installments over five months beginning August 1, 2013. The common shares underlying these vested RSU awards are not yet distributed.

In August 2013, 60,712 RSU awards with an estimated grant date fair value of $5.60 per share were granted to certain executive employees. These awards vest 50% on the date of grant, with the remaining 50% vesting in equal monthly installments over twenty-four months beginning August 31, 2013. The common shares underlying the vested portions of these RSU awards are not yet distributed.

On June 12, 2014, the Company's Board of Directors approved the issuance of 44,496 RSUs with a grant date fair value of $5.35 per share to its Chief Executive Officer pursuant to the 2013 Plan. Vesting of these RSUs may occur based on the Company's achievement of specified objectives as determined by the Company's Board of Directors or Compensation Committee, as follows:

	Percentage of Overall RSU Grant Subject to Vesting
Target	
Minimum revenue in 2015	25%
Maximum EBITDA loss in 2015	15%
Attainment of financial plan for fiscal 2015	20%
Minimum value of strategic agreements by December 31, 2015	20%
Implementation of four new diagnostic test panels by December 31, 2015	20%
Total	100%

Stock-based Compensation Expense

The following table presents the effects of stock-based compensation related to equity awards to employees and nonemployees on the statement of operations during the periods presented:

	Years Ended December 31,	
	2013	2014
Stock Options		
Cost of revenues	$ -	$ 20,961
Research and development expenses	298,618	163,229
General and administrative expenses	221,726	1,139,309
Sales and marketing expenses	—	76,204
Total expenses related to stock options	520,344	1,399,703
RSUs		
Research and development expenses	72,500	30,000
General and administrative expenses	359,677	392,958
Total stock-based compensation	$ 952,521	$ 1,822,661

As of December 31, 2014, total unrecognized share-based compensation expense related to nonvested stock option and restricted stock awards, adjusted for estimated forfeitures, was approximately $2,735,000 and $50,000, respectively, and is expected to be recognized over a weighted-average period of approximately 2.6 years and 0.6 years, respectively.

14. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the years ended December 31, 2013 and 2014, the outstanding shares of Series A preferred stock, RSUs, convertible debt, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

In November 2013, the Company effected a 1:14 reverse stock split of all common shares outstanding. The calculation of weighted-average shares outstanding has been adjusted for this reverse split as if it had occurred on January 1, 2013.

The following potentially dilutive securities have been excluded from the computations of diluted weighted-average shares outstanding for the periods presented, as they would be anti-dilutive:

	For the year ended December 31,	
	2013	2014
Series A preferred (number of common stock equivalents)	1,652,851	—
Preferred warrants outstanding (number of common stock equivalents)	192,262	1,587
Preferred share RSUs (number of common stock equivalents)	89,647	73,151
Common warrants outstanding	836,890	609,187
Notes payable convertible into common shares	1,110,649	—
Common share RSUs	133,971	178,467
Common options outstanding	333,106	906,194
Total anti-dilutive common share equivalents	4,349,376	1,768,586

15. 401(k) Plan

The Company sponsors a 401(k) savings plan for all eligible employees. The Company may make discretionary matching contributions to the plan to be allocated to employee accounts based upon employee deferrals and compensation. To date, the Company has not made any matching contributions into the savings plan.

16. Income Taxes

For the year ended December 31, 2013 and 2014, the provision for income taxes was calculated as follows:

	For the year ended December 31,	
	2013	2014
Current:		
Federal	$ —	$ —
State	800	1,506
Total	800	1,506
Deferred		
Federal	—	—
State	—	—
Total	—	—
Provision for income tax	$ 800	$ 1,506

The following table provides a reconciliation between income taxes computed at the federal statutory rate and the Company's provision for income taxes:

	For the year ended December 31,	
	2013	2014
Income tax at statutory rate	$ (3,139,368)	$ (5,393,944)
State liability	(321,058)	(813,039)
Permanent items	6,932	14,374
Stock Compensation	171,003	159,128
Nondeductible Interest	395,089	399,249
Expiration of net operating losses	188,316	1,136,317
Other	(6,723)	339,636
Research and development credit	(103,500)	(127,491)
Valuation allowance	2,810,109	4,287,276
Provision for income tax	$ 800	$ 1,506

Deferred income taxes are provided for temporary differences in recognizing certain income and expense items for financial and tax reporting purposes. The deferred tax assets consisted primarily of the income tax benefits from net operating loss carryforwards, deferred rent, and research and development credits. Valuation allowances have been recorded to fully offset deferred tax assets at December 31, 2013 and 2014, as it is more likely than not that the assets will not be utilized.

At December 31, 2014, the Company had federal net operating loss carryforwards of approximately $124,601,000 expiring beginning in 2020 and California net operating loss carryforwards of approximately $84,764,000 expiring beginning in 2015. California net operating loss carryforwards of approximately $13,655,000, $15,808,000 and $55,301,000 will expire in 2015, 2016, and in 2017 and beyond, respectively. Additionally, at December 31, 2014, the Company had research and development credits of approximately $3,205,000 and $3,087,000 for federal and California purposes, respectively. The federal research and development tax credits will begin to expire in 2018. The California research and development tax credits do not expire.

For the years ended December 31, 2013 and 2014, the Company has evaluated the various tax positions reflected in its income tax returns for both federal and state jurisdictions, to determine if the Company has any uncertain tax positions on the historical tax returns. The Company recognizes the impact of an uncertain tax position on an income tax return at the largest amount that the relevant taxing authority is more-likely-than not to sustain upon audit. The Company does not recognize uncertain income tax positions if they have less than 50 percent likelihood of being sustained. Based on this assessment, the Company believes there are no tax positions for which a liability for unrecognized tax benefits should be recorded as of December 31, 2013 or 2014. The Company is subject to taxation in the United States, California and other states. The Company may earn taxable income in some states in future periods for which there are no net operating loss carryforward credits to offset the resulting taxes owed to these states. The Company's federal filings prior to 2010 and the Company's state filings prior to 2009 are no longer subject to examination. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company is currently not under examination by any taxing authorities and does not believe its unrecognized tax benefits will significantly change in the next twelve months.

The tax effects of carryforwards that give rise to deferred tax assets consist of the following:

	For the year ended December 31,	
	2013	2014
Net operating loss carryforward	$ 43,666,636	$ 47,329,815
Research and development credits	5,114,652	5,242,144
Accruals and other	742,045	1,216,600
Deferred rent	176,893	198,945
	49,700,226	53,987,504
Less valuation allowance	(49,700,226)	(53,987,504)
Net deferred tax assets	$ —	$ —

Utilization of the domestic net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which on its own or combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in such an ownership change, or could result in an ownership change in the future.

Upon the occurrence of an ownership change under Section 382 of the Code as outlined above, utilization of the net operating loss and research and development credit carryforwards are subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, which could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss or research and development credit carryforwards before utilization. The Company has not yet completed an analysis to determine whether an ownership change has occurred.

On September 13, 2013, the U.S. Treasury Department released final income tax regulations on the deduction and capitalization of expenditures related to tangible property. These final regulations apply to tax years beginning on or after January 1, 2014, and may be adopted in earlier years. The Company adopted the tax treatment of expenditures to improve tangible property and the capitalization of

inherently facilitative costs to acquire tangible property for the tax year beginning on January 1, 2014. The impact of these changes to was not material to the Company's financial statements or disclosures.

17. Collaborative Agreements

On August 17, 2011, the Company entered into a three year exclusive collaboration agreement with Clarient to collaborate to promote and maximize the commercialization of the Company's or jointly developed diagnostic tests (together, the "Diagnostic Tests") in the United States. Clarient is responsible for marketing, providing customer service, and for third party billing on all Diagnostic Tests performed under the agreement, and for performing the professional component of the Diagnostic Tests. The Company is responsible for promoting sales of the Diagnostic Tests in the United States, as well as performing all technical components of all Diagnostic Tests sold by either party.

Under this agreement, the Company invoices Clarient for the performance of each of the Diagnostic Tests at a contractually agreed-upon rate. Clarient is responsible for billing the patient, provider and/or payer for each completed test, and bears all collection risk related to such billings. Sales of Diagnostic Tests under this agreement did not commence until 2012. The total amount of revenue the Company earned under this agreement was approximately $14,000 and $8,000 for the years ended December 31, 2013 and 2014, respectively.

The agreement was replaced as of May 2013 to remove exclusivity provisions and to modify the performance obligations of the parties. As a result of the replacement agreement, the Company will be responsible for billing third party payors for tests performed under the Clarient agreement. Revenue derived from the Clarient arrangement after the replacement date is recognized as collected, provided all other revenue recognition criteria are met.

In January 2013, the Company entered into a research support agreement with Dana-Farber, a not-for-profit tax-exempt organization. The Company is responsible for performing all technical components of the diagnostic tests as ordered by Dana-Farber and recognizes revenue as services are delivered, provided all other revenue recognition criteria are met. The total amount of revenue the Company earned under this agreement was approximately $104,000 and $43,000 for the years ended December 31, 2013 and 2014, respectively.

In September 2014, the Company entered into a two year research support agreement with MD Anderson, a not-for-profit tax-exempt organization. The Company is responsible for performing all technical components of the diagnostic tests as ordered by MD Anderson and recognizes revenue as services are rendered, provided all other revenue recognition criteria are met. The total amount of revenue the Company earned under this agreement was approximately $3,000 for the year ended December 31, 2014.

18. Related Party Transactions

During 2005, the Company executed the Goodman Note in favor of an investor which became a beneficial owner of more than 5% of the Company's common stock. As of December 31, 2012, the Company had $1,935,000 outstanding on this note. In June 2013, the investor converted the entire principal amount of $1,935,000 and accrued interest of approximately $105,000 due on the Goodman Note into 3,777,324 shares of Series A preferred stock. As of the closing of the Company's IPO on February 10, 2014, such shares of preferred stock automatically converted into 89,936 shares of common stock.

During 2008, the Company executed the 2008 Convertible Note with an affiliate of a major shareholder who was a member of the Board of Directors in the amount of $1,400,000. A warrant to purchase preferred shares was issued along with the convertible promissory note (see Notes 9 and 10). In July 2013, the Company amended the 2008 Convertible Note with a principal balance of $1,400,000, held by a related party, to provide that all principal of and accrued interest on the note would automatically convert into common stock upon the closing of an IPO at the price per share at which common stock is sold in such IPO. In connection with the closing of the Company's IPO on February 10, 2014, the $1,400,000 principal amount and $233,982 of accrued interest related to the 2008 Convertible Note were converted at $10.00 per share into a total of 163,399 shares of common stock (see Note 2).

As of June 28, 2013, $17,060,000 of principal and $2,339,000 of interest due to affiliates of a major shareholder who was a member of the Board of Directors under several note and warrant purchase agreements was converted into shares of 35,923,845 Series A preferred stock. As of December 31, 2013, the Company had $3,905,000 of such notes payable due to affiliates of this major shareholder (see Notes 9 and 10). In connection with the closing of the Company's IPO on February 10, 2014, the total balance of outstanding notes payable of $3,905,000 together with $433,821 of accrued interest were converted at $10.00 per share into a total of 433,883 shares of common stock, including 163,399 shares associated with the 2008 Convertible Note (see Note 2).

As of June 28, 2013, approximately $975,000 of principal and $101,000 of interest due on a portion of notes payable outstanding with members of the Board of Directors under several different note and warrant purchase agreements were converted into 1,993,591 preferred shares (see Notes 9 and 10). As of December 31, 2013 and the closing of the Company's IPO on February 10, 2014, the Company had approximately $1,479,000 and $1,554,000, respectively, of notes payable outstanding under such note and warrant

purchase agreements. In connection with the closing of the Company's IPO on February 10, 2014, the total aggregate balance of outstanding notes payable of $1,554,000 together with $87,531 of accrued interest were converted at $10.00 per share into a total of 164,104 shares of common stock (see Note 2).

In September and December 2013, and January 2014, the Company issued common stock warrants to five shareholders who were also affiliates in conjunction with their guarantees on the Company's borrowings under the Company's line of credit (see Notes 8 and 10).

During 2011, the Company entered into two supplier financing arrangements with a business owned by a member of the Board of Directors totaling $256,000, of which $66,000 is outstanding as of December 31, 2013 and was subsequently paid in full using the net proceeds from the Company's IPO (see Notes 2 and 11).

A member of the Company's management is the controlling person of Aegea Biotechnologies, Inc. ("Aegea"). On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement with Aegea Biotechnologies, Inc. The total amount of invoices received by the Company from Aegea during the year ended December 31, 2013 was approximately $2,000, which are unpaid and recorded in accounts payable at December 31, 2013 and 2014.

All of the members of the Company's Board of Directors participated in its public offering in February 2015, purchasing an aggregate 142,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 142,000 shares of its common stock for total proceeds of $177,500 (see Note 21).

The Company believes that these transactions were on terms at least as favorable to the Company as could have been obtained from unrelated third parties.

19. Commitments and Contingencies

Operating Leases

The Company leases office, laboratory, and warehouse space at its San Diego, California facility under a non-cancelable operating lease. The initial lease was for an eight-year term expiring in 2012. In November 2011, the Company extended the lease term through October 31, 2018 and expanded the original premises by 9,849 square feet. Under the amended lease, the landlord delivered the expanded premises in May 2013. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent.

For the years ended December 31, 2013 and 2014, rent expense was approximately $1,143,000 and $1,272,000, respectively. As of December 31, 2012 the Company owed rent in arrears of approximately $185,000, and as of December 31, 2013 and 2014, the Company owed no rent in arrears.

In September 2013, the Company amended its non-cancellable operating lease for its office, laboratory, and warehouse space at its San Diego, California facility. The amendment extends the maturity date of the lease through July 31, 2020. As part of this amendment, the landlord waived the lease payments due from August 1, 2013 through December 31, 2013 of approximately $503,000, and the Company forfeited its long-term deposit of approximately $269,000. In conjunction with this amendment, the Company granted to the landlord a warrant to purchase common shares with a warrant coverage amount of $502,605. The warrant is exercisable for a five-year period beginning with the closing of the Company's IPO on February 10, 2014, when such warrant became exercisable for 50,260 shares of common stock and the exercise price was fixed at $10.00 per share (see Notes 2, 5 and 10).

The future minimum lease payments under the amended lease agreement as December 31, 2014 are as follows:

2015	$ 1,270,501
2016	1,307,187
2017	1,348,257
2018	1,388,705
2019	1,430,366
Thereafter	855,136
Total	$ 7,600,152

Employment Agreements

Under the terms of certain employment agreements with executive officers, the Company incurred cash compensation expense of $150,000 immediately, and $225,000 annually, upon the closing of its IPO. All payments required under these agreements as a result of the closing of the Company's IPO on February 10, 2014 were subsequently made in February and March 2014.

Legal Proceedings

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. The Company is not party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on its financial condition, results of operations or liquidity.

The Company's former Vice President of Operations filed an administrative proceeding against the Company with the California Labor Commissioner in April 2013, seeking damages for alleged unpaid wages and penalties. A hearing was held on August 19, 2013 which resulted in a finding against the Company for approximately $65,000, of which $40,000 was paid during the year ended December 31, 2013 and $25,000 was accrued as of December 31, 2013. On February 25, 2014, the aforementioned administrative proceeding was settled in full following payment of the remaining $25,000 due.

20. Selected Quarterly Financial Data (Unaudited)

The following is selected quarterly financial data as of and for the periods ending:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
December 31, 2013				
Balance sheet data:				
Cash & cash equivalents	$ 17,964	$ 4,483	$ 302,908	$ 69,178
Total assets	1,095,023	991,576	1,083,089	1,329,719
Total non-current liabilities	1,252,921	508,527	167,291	462,001
Total shareholders' equity/(deficit)	(29,300,361)	(8,215,261)	(10,272,840)	(12,456,014)
Statement of operations and comprehensive loss data:				
Revenues	$ 35,154	$ 48,369	$ 31,922	$ 18,800
Gross profit/(loss)	(512,097)	(544,868)	(587,158)	(551,532)
Research and development expenses	710,206	690,582	975,104	710,845
General and administrative expenses	451,157	478,163	806,872	776,944
Sales and marketing expenses	96,404	27,932	5,342	19,225
Loss from operations	(1,769,864)	(1,741,545)	(2,374,476)	(2,058,546)
Net loss	$ (1,925,974)	$ (1,975,009)	$ (2,860,191)	$ (2,472,009)
Net loss per common share:[1]				
Basic	$ (10.67)	$ (10.83)	$ (15.72)	$ (13.57)
Diluted	$ (10.67)	$ (10.83)	$ (15.72)	$ (13.57)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	180,540	182,304	181,954	182,203
Diluted	180,540	182,304	181,954	182,203

[1] Basic and diluted net loss per common share are computed independently for each of the components and quarters presented. Therefore, the sum of quarterly basic and diluted per share information may not equal annual basic and diluted net loss per common share.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
December 31, 2014				
Balance sheet data:				
Cash & cash equivalents	$ 10,417,277	$ 12,460,565	$ 8,819,872	$ 5,364,582
Total assets	11,289,508	13,359,982	9,875,039	6,588,247
Total non-current liabilities	473,080	5,203,742	5,339,618	5,378,033
Total shareholders' equity/(deficit)	9,356,778	6,883,269	3,344,897	(220,569)
Statement of operations and comprehensive loss data:				
Revenues	$ 28,275	$ 19,245	$ 10,274	$ 75,621
Gross profit/(loss)	(630,040)	(340,119)	(527,907)	(539,067)
Research and development expenses	1,008,929	1,107,678	1,310,905	1,070,278
General and administrative expenses	1,876,912	1,032,855	1,060,812	1,231,418
Sales and marketing expenses	11,142	423,361	812,005	890,496
Loss from operations	(3,527,023)	(2,904,013)	(3,711,629)	(3,731,259)
Net loss	$ (5,127,871)	$ (2,996,840)	$ (3,859,794)	$ (3,881,541)
Net loss per common share:[1]				
Basic	$ (1.96)	$ (0.67)	$ (0.87)	$ (0.87)
Diluted	$ (1.96)	$ (0.67)	$ (0.87)	$ (0.87)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	2,617,275	4,449,603	4,449,603	4,449,603
Diluted	2,617,275	4,449,603	4,449,603	4,449,603

1 Basic and diluted net loss per common share are computed independently for each of the components and quarters presented. Therefore, the sum of quarterly basic and diluted per share information may not equal annual basic and diluted net loss per common share.

21. Subsequent Events

Pursuant to an underwriting agreement dated February 9, 2015 between the Company, Aegis and Feltl and Company, as underwriters named therein, a public offering of 8,000,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 8,000,000 shares of common stock was effected at a combined offering price of $1.25. All of the members of the Company's Board of Directors participated in this offering, purchasing an aggregate 142,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 142,000 shares of its common stock for total proceeds of $177,500. All warrants sold in this offering have a per share exercise price of $1.56, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the underwriters occurred on February 13, 2015, when the Company received, after deducting underwriting discounts and additional costs paid to the underwriters, approximately $9.1 million of net cash proceeds. The total increase in capital as a result of the sale of these shares and warrants is expected to be approximately $8.9 million after deducting an estimated $0.2 million of additional non-underwriter costs incurred. Additionally, the underwriters were granted a 45-day option to purchase up to 1,200,000 additional shares of common stock at a price of $1.25 per share and/or additional warrants to purchase up to 1,200,000 shares of common stock at a price of $0.0001 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any. Subsequent to the closing of our second public offering on February 13, 2015, additional cash proceeds of approximately $6.7 million were received from the exercise of warrants sold in such offering.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2014, the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer, have concluded that our disclosure controls and procedures were effective as of the end of such period.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management's annual report on internal control over financial reporting is set forth below.

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 Rules 13a-15(f) and 15d-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

We conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (1992 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal Control—Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2014.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in the sections entitled "Election of Directors" and "Executive Officers" in our Proxy Statement for our 2015 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, and is incorporated herein by reference.

We have adopted a code of ethics that applies to our Chief Executive Officer and other senior financial officers (our Chief Financial Officer, Controller and other senior financial officers performing similar functions), which we refer to as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at www.biocept.com under the Corporate Governance section of the Investor Relations portion of the website. Our Code of Business Conduct and Ethics is designed to meet the requirements of Section 406 of Regulation S-K and the rules promulgated thereunder. We will promptly disclose on our website (i) the nature of any amendment to the Code of Business Conduct and Ethics that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of the covered persons.

Item 11. Executive Compensation.

The information required by this item will be set forth in the section entitled "Executed Compensation" in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in the sections entitled "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation" in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in the section entitled "Transactions with Related Persons" in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section entitled "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Report:

1. *Financial Statements.* The following documents are included in Part II, Item 8 of this Report and are incorporated by reference herein:

	Page No.
Report of Independent Registered Public Accounting Firm	73
Balance Sheets at December 31, 2014 and 2013	74
Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2014 and 2013	75
Statements of Shareholders' Deficit for the Years Ended December 31, 2014 and 2013	76
Statements of Cash Flows for the Years Ended December 31, 2014 and 2013	77
Notes to Financial Statements	79

2. *Financial Statement Schedules.*

3. *Exhibits.*

EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Current Report on Form S-1, filed with the SEC on September 23, 2013).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
4.3	Form of Representative's Warrant, dated February 10, 2014 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 20, 2013).
4.4	Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
4.5	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on February 6, 2015).
4.6	Warrant to Purchase Preferred Stock, dated September 10, 2012, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.7	Warrant to Purchase Common Stock, dated September 10, 2013, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.8	Warrant to Purchase Preferred Stock dated as of January 21, 2009, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.9	Warrant to Purchase Common Stock dated as of July 31, 2013, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.10	Form of Warrant to Purchase Preferred Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012 (incorporated by reference to Exhibit 10.19.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.11	Form of Amendment of Warrant to Purchase Preferred Stock, dated as of September 13, 2013 (incorporated by reference to Exhibit 10.19.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.12	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013 (incorporated by reference to Exhibit 10.20.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.13	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various guarantors under the Reimbursement Agreement dated as of July 11, 2013 (incorporated by reference to Exhibit 10.21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.1+	2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.2+	Form of Stock Option Grant Notice and Option Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.3+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.4+	2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 20, 2013).
10.5+	Form of Notice of Stock Option Grant under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).

Exhibit No.	Description of Exhibit
10.6+	Form of Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.7+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.8+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for senior officers: as used August 8, 2013) (incorporated by reference to Exhibit 10.2.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.9+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for non-employee directors: as used August 8, 2013) (incorporated by reference to Exhibit 10.2.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.10+	Restricted Stock Unit Grant Notice / Agreement with David F. Hale, dated as of March 10, 2011 ("Performance-Based") (incorporated by reference to Exhibit 99.3 of the Registrant's Registration Statement on Form S-8 (File No. 333-194930), filed with the SEC on March 31, 2014).
10.11+	Restricted Stock Unit Grant Notice / Agreement with David F. Hale, dated as of March 10, 2011 ("Time-Based") (incorporated by reference to Exhibit 99.4 of the Registrant's Registration Statement on Form S-8 (File No. 333-194930), filed with the SEC on March 31, 2014).
10.12+	Restricted Stock Unit Grant Notice / Agreement with Ivor Royston, dated as of November 8, 2010, as amended on February 15, 2012 (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the Commission on September 23, 2013).
10.13+	2014 Annual Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 8, 2014).
10.14+	Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.15+	Form of Indemnity Agreement between Biocept, Inc., a California corporation, and its officers and directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.16+	Employment Agreement, between the Registrant and Michael W. Nall, effective as of August 26, 2013 (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.17+	Employment Agreement, between the Registrant and Lyle J. Arnold, dated April 30, 2011(incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.18+	Employment Agreement, between the Registrant and William G. Kachioff, dated August 1, 2011(incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.19+	Employment Agreement, between the Registrant and Raaj Trivedi, dated March 1, 2014 (incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on January 9, 2015).
10.20	Lease, between the Registrant and Nexus Equity VIII LLC, dated March 31, 2004 (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
10.21	First Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated November 1, 2011(incorporated by reference to Exhibit 10.11.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.22	Second Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated September 10, 2012 (incorporated by reference to Exhibit 10.11.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.23	Third Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated as of January 31, 2013, and effective as of January 1, 2013 (incorporated by reference to Exhibit 10.11.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).

Exhibit No.	Description of Exhibit
10.24	Fourth Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated as of September 10, 2013, and effective as of August 1, 2013 (incorporated by reference to Exhibit 10.11.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.25	Amended and Restated Investor Rights Agreement, dated as of October 31, 2011, among the Registrant and certain investors named therein (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.26*	Collaboration Agreement dated as of November 2, 2012 between the Registrant and Life Technologies Corporation (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 30, 2014.)
10.27	Collaboration Agreement dated as of August 17, 2011 between the Registrant and Clarient Diagnostic Services, Inc. (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 8, 2014).
10.28	Assignment and Exclusive Cross-License Agreement between the Registrant and Aegea Biotechnologies, Inc. dated June 2, 2012 (incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 30, 2014).
10.29*	Master Laboratory Research Support and Services Agreement dated as of July 9, 2012 between the Registrant and Dana-Farber Partners Cancer Care, Inc. (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
10.30	Laboratory Services Agreement dated July 29, 2013, effective as of May 1, 2013, between the Registrant and Clarient Diagnostic Services, Inc. (incorporated by reference to Exhibit 10.14.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.31	Loan and Security Agreement by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC, dated as of April 30, 2014 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
10.32+	Employment Agreement, between the Registrant and David F. Hale, dated March 10, 2011 (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.33+	Employment Agreement, between the Registrant and Veena Singh, dated December 1, 2014 (incorporated by reference to Exhibit 10.41 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on January 21, 2015).
23.1	Consent of Mayer Hoffman McCann P.C.
31.1	Certification of Michael Nall, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of William Kachioff, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Michael Nall, 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 William Kachioff, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Indicates management contract or compensatory plan.

* Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Rule 406 under the Securities Act of 1933.

** This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

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.

BIOCEPT, INC.

Date: March 10, 2015

By: /s/ Michael W. Nall
Michael W. Nall
Chief Executive Officer, President and Director

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

Signature	Title	Date
/s/ Michael W. Nall Michael W. Nall	Chief Executive Officer, President and Director (Principal Executive Officer)	March 10, 2015
/s/ William G. Kachioff William G. Kachioff	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2015
/s/ David F. Hale David F. Hale	Chairman and Director	March 10, 2015
/s/ Marsha A. Chandler Marsha A. Chandler	Director	March 10, 2015
/s/ Bruce E. Gerhardt Bruce E. Gerhardt	Director	March 10, 2015
/s/ Bruce A. Huebner Bruce A. Huebner	Director	March 10, 2015
/s/ Edward Neff Edward Neff	Director	March 10, 2015
/s/ Ivor Royston Ivor Royston	Director	March 10, 2015
/s/ M. Faye Wilson M. Faye Wilson	Director	March 10, 2015

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the previously filed Registration Statement (No. 333-194930) on Form S-8 of our report dated March 10, 2015, relating to the financial statements of Biocept, Inc., appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 10, 2015

EXHIBIT 31.1

CERTIFICATION

I, Michael W. Nall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biocept, Inc.;

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 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 subsidiary, is made known to us by others within those entities, particularly during the period in which this 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 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 information; 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.

Date: March 10, 2015

/s/ Michael W. Nall

Michael W. Nall
Chief Executive Officer, President and Director
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, William G. Kachioff, certify that:

1. I have reviewed this Annual Report on Form 10-K of Biocept, Inc.;

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 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 subsidiary, is made known to us by others within those entities, particularly during the period in which this 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 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 information; 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.

Date: March 10, 2015

/s/ William G. Kachioff

William G. Kachioff
Senior Vice-President of Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

I, Michael W. Nall, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to my knowledge, the Annual Report on Form 10-K of Biocept, Inc. for the fiscal year ended December 31, 2014 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: March 10, 2015

/s/ Michael W. Nall
Michael W. Nall
Chief Executive Officer, President and Director
(Principal Executive Officer)

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.

EXHIBIT 32.2

CERTIFICATION

I, William G. Kachioff, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to my knowledge, the Annual Report on Form 10-K of Biocept, Inc. for the fiscal year ended December 31, 2014 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: March 10, 2015

/s/ William G. Kachioff
William G. Kachioff
Senior Vice-President of Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934.