BIOCEPT INC

FORM 10-K
(Annual Report)

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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, 2016

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, 2016, was $14,573,995. Shares of common stock held beneficially by stockholders whose ownership exceeds 10% of the Registrant's Common Stock outstanding 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 24, 2017 was 22,280,247.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2017 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 an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or "liquid biopsy." Our assays provide, and our planned future assays will provide, information to oncologists and other physicians that enable them to select appropriate personalized treatment for their patients who have been diagnosed with cancer based on molecular drivers and markers of their disease and when traditional methodologies such as tissue biopsies are insufficient or unavailable. Our assays have potential to provide more contemporaneous information on the characteristics of a patients' disease compared with traditional methodologies such as tissue biopsy and imaging.

Our current assays and our planned future assays focus on key solid tumor indications utilizing our Target-Selector ™ liquid biopsy offering for the biomarker analysis of CTCs and ctDNA from a standard blood sample. Our patented Target-Selector CTC offering is based on an internally developed microfluidics-based cell capture and analysis platform, with enabling features that change how CTC testing is used by clinicians. Our Target-Selector platforms provide both biomarker detection as well as monitoring capabilities, and require only a patient blood sample. Our patent pending Target-Selector ctDNA technology enables mutation detection with enhanced sensitivity and specificity, and is applicable to nucleic acid from ctDNA or other sample types, such as CTCs, red blood cells, or cerebrospinal fluid. We believe that our Target-Selector platform technology has potential to be developed and commercialized as in vitro diagnostic (IVD) test kits, and we are currently pursuing this option.

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. We manufacture our microfluidic channels, related equipment and certain reagents to perform our current assays and our planned future assays 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 assays we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations. In addition, we also participate in and have received College of American Pathologists, or CAP, accreditation, which includes requires rigorous bi-annual laboratory inspections and an adherence to specific quality standards.

We have commercialized our Target-Selector assays for a number of solid tumor indications such as: breast cancer, non-small cell lung cancer, or NSCLC, small cell lung cancer, or SCLC, gastric cancer, colorectal cancer, prostate cancer, and melanoma. These assays utilize our dual CTC and ctDNA technology platform and provide biomarker analysis from a patient's blood sample.

In the case of our breast and gastric cancer offering, 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, or ER, protein, as well as androgen receptor, or AR, protein, which are currently commercially available. We plan to include immunocytochemical analysis of progesterone receptor, or PR, proteins as part of the Target-Selector CTC menu in 2017. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin ® or Tykerb ® . ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

The lung cancer biomarker analyses currently include FISH testing for ALK, ROS1, RET, MET and FGFR1 gene rearrangements and our Target-Selector ctDNA platform for mutation analysis of the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor, or EGFR, gene as well as BRAF and KRAS using our Target-Selector ctDNA platform. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are associated with the drugs Tarceva ® , Gilotrif ® and Iressa ® . For lung cancer, we also offer a resistance profile assay consisting of the biomarkers MET, HER2 (both of which we perform using our technology for CTCs), KRAS, and T790M (both of which are performed using ctDNA in plasma). These assays can be used by physicians to identify the mechanism causing disease progression for patients with NSCLC who are being treated with TKI therapy and therefore may qualify for inclusion in a clinical trial. In November 2015, Tagrisso ® was approved by the U.S. Food and Drug Administration, providing another

biomarker-based therapy for the treatment of patients with EGFR related lung cancer. Tagrisso ® is indicated for the treatment of patients with metastatic disease, who have progressed on or after EGFR tyrosine kinase inhibitor therapy,l and who have acquired a T790M resistance mutation.

Fibroblast growth receptor 1, or FGFR1, amplification is offered using our CTC technology. FGFR1 is present in several tumor types, including both NSCLC and SCLC and has been shown to be a prognostic indicator of progression. FGFR1 is also a key target for many drugs which are in clinical development.

Mutations of the BRAF gene are associated with Zelboraf ® and Tafinlar ® , which are both approved for treating patients with melanoma and are in clinical trials for lung cancer. We offer testing for BRAF on blood using our ctDNA offering.

We analytically validated PD-L1 testing utilizing our CTC technology in 2016. PD-L1 is a biomarker that is informative for immuno-oncology therapies currently marketed for lung cancer and melanoma, as well as therapies in development for multiple tumor types. We collaborated with David Rimm, M.D., Ph.D., a pathologist at Yale Medical School, on the analytical development of this assay.

We plan to add other biomarker analyses, such as ESR1 and NRAS, using blood samples to our current ctDNA assays and our planned future Target-Selector assays as their relevance is demonstrated in clinical trials and/or included in guidelines used by physicians to make treatment decisions. In addition, we plan to offer multiplexed assays which allow the detection and quantification of multiple biomarkers in a single assay.

We continue to execute on our strategies intended to expand our business globally as well as engaging with pharmaceutical companies on clinical trials and assay development. We have executed distribution agreements in Mexico with Quest Diagnostics to support testing for a large pharmaceutical partner, as well as an agreement with Progenetics to market our assays in Israel for clinical testing. In addition, we have distribution agreements in place in Turkey, the Czech Republic, the Philippines, Peru, Columbia and Canada.

We announced three additional pharmaceutical collaborations during 2016. The first agreement is to provide testing for a clinical trial that includes patients who have leptomeningeal disease or metastatic lung cancer in the brain. In this exploratory trial, we are testing both cerebral spinal fluid and blood for molecular alterations that could be impacted by treatment. The second agreement is a large milestone-based multi-project assay development collaboration focused on multiple tumor types including breast cancer and on multiple tumor types including breast cancer and hepatocellular carcinoma, or liver cancer, whereby we intend to develop assays utilizing both our CTC and ctDNA technologies for clinical trials. The third collaboration involves a study presented at the European Society for Medical Oncology, or ESMO, Annual Congress in October 2016, whereby collaborators from a large pharmaceutical company, and academic investigators, demonstrated a high concordance between our Target-Selector liquid biopsy and tissue biopsy. Subsequent to this study, we have earned business in both Mexico and Columbia for EGFR testing in blood to qualify patients for a pharmaceutical company’s targeted therapy.

Our revenue generating efforts are focused in three areas:

- providing clinical testing that oncologists 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.

The following table sets forth certain information concerning our commercial cases accessioned for the periods shown:

	Year Ended December 31,		Change	
	2015	2016	#	%
Commercial cases accessioned	1,608	3,676	2,068	129%

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, with multiple payments received per case. For commercial accessions received during the years ended December 31, 2015 and 2016, the average number of tests performed increased

from 2.6 tests per accession to 3.6 tests per accession, respectively, as the number of commer cialized assays we offer has increased. Approximately 41% and 40% of total revenues during the years ended December 31, 2015 and 2016, respectively, were associated with Medicare reimbursement. For commercial accessions received from January 1, 2016 throug h December 31, 2016, we estimate the average value to be approximately $1,100 per accession, when we receive payments from third parties. We have not historically been reimbursed at this average rate for a variety of reasons, including billing challenges r elated to changes in Medicare CPT codes for our FISH assays in 2015, establishing our associated internal processes, and managing an external "out-sourced" billing company. Additionally, a significant amount of our non-Medicare business (private payors) ha s historically not been contracted, and reimbursement for this business has historically not been at "in network" rates and has therefore been inconsistent. We first began to contract private payor networks in 2015, and since then our number of accessions treated as "in network" has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with eight Preferred Provider Organization networks, two large health plans, and three regional Independent Ph ysician Associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans.

Our future average reimbursement per commercial accession is uncertain and will be impacted by several factors, including:

- The mix of our accessions;
- changes in Medicare schedule rates which generally occur annually;
- our ability to successfully contract private payor business in order to be considered "in-network;"
- the mix of business across payors;
- our ability to receive reimbursement from private payors, and the level of reimbursement we are able to negotiate relative to Medicare schedule rates;
- our ability to successfully collect copayments or other amounts from patients using our patient billing module;
- our ability to successfully implement internal billing policies and manage our out-sourced billing company;
- our ability to improve the recognition of the medical value of our assays, through publication of clinical utility study results and/or possible further improvement of the assays;
- our ability to get reimbursed for capturing CTC's;
- introduction of additional assays;
- increased demand generated by our future sales and marketing efforts, and similar commercial factors;
- our ability to successfully implement internal billing and collection processes; and
- coverage policies as determined by each health plan.

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 assays 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 assays such as ours, or for components of such assays; 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.

We have a sales and marketing team to market and sell our commercialized assays and our planned future cancer diagnostic assays directly to oncologists and other physicians. At December 31, 2016, we had a group of 11 sales representatives, and, based on our success and assay volume, we plan to grow this number to 20-30 within two years.

We collaborate with physicians and researchers at Sarah Cannon Research Institute, Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, University of California, Irvine, Washington University, University of Colorado, Yale University, the University of Minnesota, the John Wayne Cancer Institute, 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 our Target-Selector commercialized

assays and our planned future assays. Such relationships help us develop and validate the effectiveness and utility of our commercialized assays and our planned future assays in specific clinical settings and provide us access to patient samples and data.

We completed a study, published in *Cancer Medicine* in February 2013, utilizing our assay, and a version of this assay 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 were involved in a clinical study led by investigators at the Dana-Farber Cancer Institute following up on the *Cancer Medicine* findings in CTCs. This study 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 assays, including biomarker analysis for HER2 using FISH, performed at subsequent time points. In December 2014, we announced findings that were presented at the San Antonio Breast Conference that 22% 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% (included in the 22%) 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 our 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.

In collaboration with the University of California, San Diego, in June 2015 we presented the clinical validation data of our ctDNA assay demonstrating a very high level of concordance to tissue results (88%), and with our >95% analytical sensitivity and 99% analytical specificity we offer a validated, robust non-invasive solution for mutation identification and monitoring in patients with lung cancer. The recent United States Food and Drug Administration, or FDA, approval of Tagrisso ®, a third-generation tyrosine kinase inhibitor, presents an opportunity for patients to be monitored using a ctDNA assay.

We plan to grow our business by directly offering oncologists and other physicians our Target-Selector liquid biopsy CTC and ctDNA assays. Based on our product development data, as well as discussions with our collaborators, we believe that our planned future assays 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 historic clinical CTC test is the 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 assays will become a key component of the standard of care for personalized cancer treatment.

According to the National Cancer Institute, there were approximately 249,000 new cases of breast cancer and approximately 224,000 new cases of lung cancer diagnosed in the United States in 2016, with over 3.5 million patients who have had a diagnosis of these cancers and are either 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 commercialized assays and our other planned future assays 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 assays require only

a standard blood sample, th ey can be particularly useful when there is no currently available biopsy or surgical material, as is often the case in lung cancer, even at the time of initial evaluation. For example, up to 25% of patients with stage I NSCLC are not surgically treated fo r 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 o btain 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 commercialized diagnostic assays and offer our clinical trial services at our CLIA-certified, CAP-accredited and state- licensed laboratory. Our current assays and our planned near-term cancer diagnostic assays and clinical trial services include:

- *CTC and ctDNA Testing* . Our current assays and our other planned cancer diagnostic assays are based on our Target-Selector technologies and are currently intended to be performed only in our clinical laboratory. After completing testing, we or our partners 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 assays. Our current assays can, and our other planned cancer diagnostic assays and biomarker assays 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 assays would more easily then move into standard clinical practice, helping physicians select the most appropriate therapy for their patients.

We intend to continue to commercialize cancer diagnostic assays 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 believe the Target-Selector technology can someday be used as a stand-alone test for molecular biomarker screening, marked as IVD test kits. Additionally, we plan to evaluate opportunities for licensing of our products and proprietary technologies to partners in the United States and abroad.

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, and according to the World Health Organization, there were approximately 14 million new cases and 8.8 million cancer related deaths in 2015. The number of new cases is also expected to rise by approximately 70% over the next two decades. According to the World Health Organization, the most common causes of cancer death are cancers of the lung (21%), liver (10%), colon (9%), stomach (9%), and breast (7%). 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 2016, and prevalence in 2013, in the United States for the major solid cancers types:

Cancer Type	Est. Incidence (New Cases/Year-2016)	Est. Mortality (Deaths/Year-2016)	Est. Prevalence (Diagnosed and Alive as of 2013)**
Bladder	76,960	16,390	587,426
Breast*	249,260	40,890	3,069,231
Cervical	12,990	4,120	248,920
Colorectal*	95,270	49,190	1,177,556
Endometrial	66,730	2,940	***
Gastric*	26,370	10,730	79,843
Kidney	62,700	14,120	394,336
Lung*	224,390	158,080	415,707
Melanoma*	76,380	10,130	1,034,460
Ovarian	22,280	14,240	195,767
Pancreatic	53,070	41,780	46,620
Prostate*	180,890	26,120	2,850,139
Thyroid	64,300	1,980	637,115

* Areas where we currently have assays or active development programs.
** Includes active disease and disease-free.
*** National Cancer Institute data is unavailable for 2013. 2010 data indicates an estimated prevalence of 600,346.

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 $1.4 trillion 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 forecasted to rise to over $157 billion by 2020.

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. Only in recent years has technology progressed sufficiently 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 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 or aberrant proteins 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. Assays 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 chemic al 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 aggressiven ess. Often an analysis of biomarkers relevant to that tumor type is also performed on the tissue, ranging from IHC to FISH, to mutation analysis by various means such as microarrays and sequencing. After the diagnosis, a clinical workup is performed accord ing 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 risk, symptoms and patient history, and decides on a treatment plan that may include surgery, watchful waiting, radiation, chemotherapy, or stem cell transplantation.

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 entered 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 ensure 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 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 entire 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 Target-Selector technology provides this necessary sensitivity and specificity and creates an opportunity for ctDNA analy sis to complement CTC analysis, or potentially to serve as the platform for stand-alone assays.

Given the incidence of cancer in the United States, with an estimated 1,260,000 new cases in 2016 for the major solid tumors targeted by our planned future assay products, the markets for our current and planned future cancer diagnostic assays 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 232,000 in 2016, 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 the entire tumor was not removed, according to a Johns Hopkins report. If a CTC assay 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 assay 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 assays, 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 consist of proteins or protein modifications that can be identified by immunocytochemical means, cytogenetic or chromosomal aberrations, which are detected by FISH. Gene mutations in CTCs or ctDNA are detected by molecular diagnostic assays, including Target-Selector techniques and gene sequencing. Specific examples include (i) for ICC, 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 assays, which analyze the same biomarkers in a more convenient standard blood sample test that also permits periodic monitoring, could be used in the same way.

Our Business Strategy

We 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 of the standard of care for personalized cancer treatment.

Our approach is to develop and commercialize CTC and ctDNA assays and services that enable us to offer standard blood sample based, real-time testing solutions for a range o f solid tumor types to oncologists that 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 assays and services, to enable physicians to develop personalized treatment plans. We intend to continue the development of additional prognostic and predictive assays and services to provide information that is essential to personalized cancer treatment. By including predictive information on biomarkers associated with specific therapies in our analysis in addition to CTC enumeration, our assays 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 assays are expected to offer enhanced sensitivity and specificity based on the Target-Selector technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions. We have launched our Target-Selector offering in a number of key indications such as breast cancer, lung cancer, gastric cancer, colorectal cancer, prostate cancer, and melanoma, which are performed in our CLIA-accredited testing facility. We plan to perform the necessary validation studies to allow us to commercialize these assays through our clinical laboratory.
- Scale our internal sales and marketing capabilities. Our direct sales force with specialized experience in cancer diagnostic testing focuses on key identified territories in order to provide geographic coverage throughout the United States. At December 31, 2016, we had 11 sales representatives, and depending on our assay volume, we expect to increase this group to 20-30 within two years and potentially 40-50 within five years. This team will educate physicians directly on the benefits of our assays and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners. In addition to our internal efforts, we are actively seeking commercial partnerships that can increase our market reach.
- 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 Washington University, University of California, Irvine, Sarah Cannon Research Institute, University of Colorado, The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, Yale University, the University of Minnesota, the John Wayne Cancer Institute, and Columbia University. Our collaborations enable us to test new technologies, validate the effectiveness and utility of our planned future assays 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 assays.
- Enhance our efforts in reaching and educating oncologists and other physicians about CTC and ctDNA assays. According to the State of Cancer Care in America 2014 Report, published in the Journal of Oncology Practice in March of 2014, there were approximately 13,400 medical oncologists in the United States or 16,500 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 assays 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 13.4% for leading indications and 8.2% for secondary indications of cancer drug compounds from first administration in humans to approval (2013, Clinical Pharmacology and Therapeutics). 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 assays that specifically address their needs, including the ability to characterize and monitor a patient's tumor over time using CTC and ctDNA assays 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.

- Become an enabling technology to cancer targeted therapies. Biopharmaceutical companies wi ll increasingly focus 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. As targeted therapies move into their next phase, the market is beginning to see next generation of drugs such as Astra Zeneca's Tagrisso (Osimertinib) that work after a patient on targeted therapy begin to progress and show a resistance mechanism that is identifiable / targetable, in this case a mutation in EGFR known as T790M. With these drugs, the original biopsy tissue would not show the resistance mechanism so the patient must either undergo a re-biopsy procedure. In many cases re-biopsy is not medical feasible and liquid biopsy offers a more cost ef fective and safer alternative in this application. Another area of interest for the pharmaceutical industry is in immuno-oncology. This is the challenge of helping the body to counter the cancer cells ability to evade the immune system. Several protein b ased tests are being developed in tissue to work as complimentary or companion diagnostics to these new and promising drugs but the use of these test will be limited as a result of limitations of tissue biopsies. A better solution would be to test for thes e proteins with a liquid biopsy based circulating tumor cells test rather than relying on tissue biopsies.
- Conduct additional clinical studies with our current CTC and ctDNA assays and assays we plan to introduce in various cancer types. Clinical utility and validation studies for our planned ctDNA assays 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 future CTC and ctDNA assays 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 assays and our planned additional CTC assays, including enumeration, immunocytochemical biomarker staining and FISH. We also intend to reduce the costs associated with key material components of these assays, including FISH probes. We have and currently utilize an automation system that significantly reduces the hands-on time of our cytogenetic technologists for microfluidic channel analysis while increasing the uniformity 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, further enhancing efficiency.

Our Competitive Advantages

We believe that the competitive advantages of our molecular assays, including our assays which are still under development, would include the following.

Our current Target-Selector molecular assays enable, and we anticipate our planned future CTC and ctDNA assays 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 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. A key advantage to using Biocept is our ability to interrogate both CTC and ctDNA biomarker targets.

Our current Target-Selector assays each provide, and we anticipate our planned future assays will each provide, more information than competitors' existing tests, including predictive information on biomarkers associated with 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 assays and our planned future assays are designed to provide a more complete profile of a patient's disease than existing CTC or ctDNA. We intend for our assays to contain actionable information to assist physicians in selecting appropriate therapies for individual patients. Our ctDNA assays are expected to offer enhanced sensitivity and specificity based on our technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions.

Our current Target-Selector and our planned future assays 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 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-mesenchyma l 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 have introduced additional staining which would enable detection of cells specifically captured with our antibody cocktail, including EMT cells lacking cytokeratin. We believe that through our enhanced staining, more CTCs and different types of CTCs will be able to be identified and potentially at earlier stages of dise ase, resulting in fewer non-informative cases and more information for physicians.

Our current and planned CTC and ctDNA Target-Selector assays will be, flexible and readily configurable to accommodate new biomarkers with clinical relevance as they are identified. In theory, our platforms permit 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 assays 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 Washington University, University of California, Irvine, Sarah Cannon Research Institute, University of Colorado, The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, Yale University, the University of Minnesota, the John Wayne Cancer Institute, and Columbia University . We have worked closely with a number of physicians at institutions 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 assays. 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 Target-Selector mutation assays would not be platform dependent. These assays 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 assays 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 Assays and Services

We have launched our Target-Selector offering for breast cancer, lung cancer, gastric cancer, colorectal cancer, prostate cancer, and melanoma, and plan to continue to launch a series of assays for different predictive biomarkers. Our current assays and our planned future assays under the Target-Selector offering would be LDTs. FDA clearance or approval is not currently required to offer these types of assays 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 LDTs, 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 assays. We are currently in the process of addressing the requirements for licensure in New York, and we have obtained all required licenses and approvals from all other states requiring licensure of out-of-state laboratories.

Our Marketed Assays

Breast Cancer. Our breast cancer assay was the first test developed, and is currently offered to physicians through our CLIA laboratory. This assay 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 an alysis or replacing it when a tumor biopsy is not available. The assay currently includes the determination of HER2 status by FISH and ICC analysis of ER and Androgen Receptor, or AR. 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. AR status is of emerging predictive value in triple-negative breast cancer. We plan to add ICC analy sis for progesterone receptor, which will also provide information on the suitability of breast cancer patients for endocrine or hormonal therapies.

Lung Cancer. Approximately 22% 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 assays are alternatives for obtaining more detailed information about the molecular status of the tumor that can help the physician select appropriate therapy. The Target-Selector assay's biomarker specific analysis currently includes FISH testing for ALK and ROS gene rearrangements and molecular analysis of the mutations of the EGFR (in exons 19, 20 and 21), KRAS and BRAF genes. The EGFR T790M mutation in exon 20 is a resistance mutation seen in ~50% of patients undergoing treatment with tyrosine kinase inhibitors. In addition, we offer lung cancer resistance testing to analyze for the presence of the T790M mutation as well as FISH analysis for C-MET and HER2 gene amplification and RET gene rearrangements.

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 associated with non-responsiveness to the EGFR kinase inhibitors, and the codon 600 mutations of the B-RAF gene have a prevalence of ~ 3% in lung cancer.

In June 2016, we commercialized our liquid biopsy test for PD-L1 protein expression. The determination of PD-L1 status is necessary to qualify patients for certain targeted immuno-oncology therapeutics in several cancers types including NSCLC. The quantification of protein expression for tests like PD-L1 is performed on CTCs and cannot be determined from ctDNA. This is an example of how the Target-Selector dual-platform, which analyzes cancer biomarkers found on both CTCs and in ctDNA, can provide relevant information beyond the capabilities of technology that only works by analyzing ctDNA.

Gastric Cancer. Our Target-Selector assay for gastric cancer is based on the identification of HER2 as a biomarker for this disease. We employ our CTC HER2 FISH assay, 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 assays circumvent this need for tissue, and can provide straightforward monitoring of HER2 status from a standard blood sample, on a real-time basis during treatment.

Melanoma. Our Target-Selector melanoma assay is performed on a standard blood sample, and provides 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.

Colon Cancer. Our Target-Selector assay for colorectal cancer offers mutation testing analogous to that performed in lung cancer, namely detection of key mutations in the K-RAS and B-RAF genes. Testing on the K-RAS gene focuses on codons 12 and 13 mutations, while testing on the B-RAF gene focuses on V600 mutations.

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. For each of codons 12 and 13 in the K-RAS oncogene, up to 15-20 mutations have been reported. However, there are reports in the scientific literature that patients with one particular mutation, G13D, do respond well and there may be variability in response to different chemotherapies based on the specific K-RAS mutation. This suggests that detailed information on mutation status is clinically relevant.

Prostate Cancer. Our Target-Selector assay for prostate cancer is based on the analysis of CTCs found in a standard blood sample. We currently offer testing for AR.

The AR 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 the inhibition of androgen synthesis.

We also plan to validate testing for PTEN gene deletions by FISH. PTEN, 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 PTEN is mutated, deleted or disrupted, chemotherapy or polytherapy is usually recommended.

Laboratory Testing

From our CLIA-certified laboratory in San Diego, California, we provide test results from our current and planned CTC and ctDNA assays 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 the Centers for Medicare and Medicaid Services, or 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 LDTs, 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 assays. We are currently in the process of addressing the requirements for licensure in New York, and we have obtained all required licenses and approvals in all other states requiring licensure of out-of-state laboratories.

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 a third 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 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 assays and techniques utilizing CTC and ctDNA technologies to provide sensitive, real-time characterization of an individual patient's tumors using a standard blood sample. These assays 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 assays.

Assay Development Process

Our Target-Selector assays were, and our planned additional CTC and ctDNA assays 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 an assay, 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 associated with 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 assay.

- **Stage 2, Assay Development** . We design the assay, which typica lly 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 coul d include development of specific Target-Selector mutation assays or testing of FISH probes. The assay will be used on normal control specimens and clinical samples to assure performance and the process includes defining the performance characteristics of the assay as well as developing standard protocols for our CLIA-certified, CAP accredited, and state-licensed laboratory, where the assay will ultimately be performed. This assessment includes such features as reproducibility, accuracy, sensitivity, and sp ecificity.
- **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 assays, from sample banks, where clinical information on the patients, including outcomes, is already available.
- **Stage 4, Availability for Commercialization** . Upon the completion of clinical validation and before launch, we take several steps to prepare an assay for marketing as an 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.

We currently offer 13 assays that are available for clinical use that have completed all four stages of the development protocol. Other assays for both CTCs and ctDNA are in earlier stages of development. Markers for such assays include, but are not limited to ESR1, NRAS, and a multiplexed assay.

We may be required to seek FDA clearance or approval to expand the commercial use of assays to other laboratories and testing sites in the United States. We may also need to complete additional activities to submit each of these assays for regulatory clearance or approval before commercialization in each of the international markets where introduction is planned.

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 assay development process. In November 2016, the FDA put the process to review and issue this guidance on hold, and has not yet provided further information as to when the process will move forward.

Research and Development

We incurred research and development expenses of $2.9 million and $2.7 million, which represented 469% and 84% of our net revenue, for the years ended December 31, 2015 and 2016, respectively. Research and development expenses represented 17% and 13% of our total costs and expenses for the years ended December 31, 2015 and 2016, respectively. Major components of research and development expenses were direct personnel costs, laboratory equipment, consumables and overhead expenses.

Technology Development

In addition to developing new CTC and ctDNA assays for different cancers to be offered through our CLIA laboratory, and adapting additional predictive biomarkers to these assays as their importance is demonstrated by the scientific and clinical research communities, we continue to focus on improving the base technologies underlying our assays 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 assay 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 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 Assay Process**

  Development of automation throughout the assay process, but particularly at the visual evaluation steps, which include enumeration, any ICC 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 implemented an automation solution for the visual analysis, which has been validated and implemented 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 has also been validated and implemented 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**

  We are continuing to evaluate and develop techniques for CTC capture that take advantage of our antibody enrichment cocktail and our staining technology to modify our current CTC process into a simpler IVD testing kit format. In addition to reducing internal costs, such an advance would enable us to offer a testing kit format that can access the worldwide CTC testing market. The distribution of such kits could create a new business opportunity for us.

- **Utilization of ctDNA Technology for Highly Multiplexed Mutation Testing**

  The ctDNA 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 ctDNA 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 assays, relying on our ctDNA 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 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 and analyzed thousands of normal control and cancer patient samples. Our initial focus has been on breast cancer, where validation studies for our CTC assay, including enumeration of CTCs on the Biocept platform 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 our 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, our 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 the use of our antibody enrichment cocktail enabled recovery of more CTCs compared to using only anti-EpCAM antibodies. This data served as a clinical validation study for CTC enumeration. When our staining is applied to detect cytokeratin-negative CTCs, w e 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* .

Our system has the added advantage of post-capture immunofluorescent, cytogenetic and molecular genomic analyses of the CTCs. Cells captured by Biocept's proprietary Target-Selector system can be analyzed directly within the microfluidic channel, removing the need to re-deposit cells on a slide and thereby minimizing cell loss or damage. Furthermore, given the transparency of the microfluidic channel, captured cells 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 directed towards evaluation of biomarkers, are particularly important and valuable to physicians and patients since 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. Positive HER2 status would indicate eligibility for HER2-targeted therapies like Herceptin ® , a potentially life-saving treatment. These results were 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) involving 95 patients, HER2 positive CTCs and/or DTCs were identified in 18.9% of cases in which the primary tumor was HER2 negative. In the same cohort of patients, only 12.6% were HER2 positive in their primary tumor. In other words, beyond the 12 (of the 95) which traditional tumor tissue analysis had indicated could benefit from Herceptin-based therapy, the Target-Selector assay detected 18 (of the 95 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 assay performed on blood and bone marrow samples. Tumor heterogeneity indicates an important clinical application for the CTC analysis with the Target-Selector assay. Our technology can use a standard blood sample to confirm and crosscheck tissue analysis performed by the pathologist at the time of biopsy or surgery, especially if HER2 negative.

Our Target-Selector platform is well suited towards blood-based analysis of breast cancer biomarkers. A 24-patient study published with Columbia University (*Clinical and Translational Oncology* , 2015, 17(7):539-46) demonstrated the feasibility of CTC testing to evaluate ER and PR status in metastatic breast cancer (mBC) patients. Results showed a concordance of 83% and 68% in ER/PR status between CTCs vs. metastatic tissue tumor, and CTCs vs. primary tissue, respectively. More recently, a December 2016 San Antonio Breast Cancer Symposium poster presentation featured the evaluation of 74 mBC patients. This collaborative work with the Sarah Cannon Research Institute, demonstrated detection of CTCs in 99% of mBC patient samples. In addition, ER protein expression concordance was 84% in cytokeratin positive cells and 18% in cytokeratin negative cells. FISH-based analysis of captured CTCs displayed tissue concordances of 93% and 68% for HER2 gene amplification in cytokeratin positive CTCs and cytokeratin negative CTCs, respectively; FGFR1 amplification concordances to tissue were 79% and 67% for cytokeratin positive CTCs and cytokeratin negative CTCs, respectively. While further investigation is needed to elucidate the significance of cytokeratin negative cells as a possible prognostic indicator to evaluate ER, HER2 and FGFR1 biomarkers in mBC patients, our ability to assess cytokeratin positive and negative CTCs affords a distinct advantage over other CTC technologies that rely solely upon characterization of cytokeratin positive CTCs.

We have also developed proprietary and robust technology to detect and quantify mutant ctDNA in plasma originating from the same blood sample that is used for the previously described CTC analyses. In collaboration with Mexico's Instituto Nacional de Cancerologia and AstraZeneca, a clinical evaluation of blood-based liquid biopsy mutational profiling was performed on 60 advanced stage non-small cell lung cancer patients. This poster discussion presentation at the European Society for Molecular Oncology in October 2016 demonstrated EGFR mutation detection (exon 19 deletions, L858R, and T790) by Target-Selector with 90% sensitivity, 100% specificity, 100% positive predictive value and 90.9% negative predictive value. Target-Selector assays are highly sensitive with the ability to detect EGFR mutations down to one mutant copy per milliliter of plasma. The high concordance of ctDNA versus tissue exhibited in this work highlights Target-Selector

plasma ctDNA assays as a viable and practical means to detect EGFR activating and acquired resistance mutations relevant for guiding targeted therapy decisions.

Clinical utility studies, which demonstrate the specific clinical setting in which a particular CTC or ctDNA assay 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 health plans and government payors now ask for peer-reviewed publications describing such studies and results before agreeing to coverage of a specific assay. We are involved in and plan to become involved in numerous studies to further demonstrate the clinical utility of our assays.

Sales and Marketing

At December 31, 2016, our sales organization consisted of 11 sales representatives placed in strategic locations around the country that have high concentrations of cancer patients, and we may, depending on assay volume, potentially grow this number to 20-30 sales representatives within two years and to 40-50 within five years. We have defined sales territories and have hired sales professionals with extensive 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 assays. 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 liquid biopsy testing services. The key value proposition for these customers will be focused on clinical utility and cost savings by offering our assays as alternatives to expensive surgeries when tumor biopsy tissue is insufficient or 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 assays provide for better information, allowing them to select the most appropriate therapy for their patients, and how and when these assays are most effectively used;
- build relationships with key thought leaders in oncology, specifically in the cancer types for which we are offering or plan to offer assays, to educate and support community oncologists;
- collaborate with leading research universities and institutions that enable the validation of our new assays, 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 delivering clinically actionable information and providing a cost-effective alternative to access clinically actionable information through the use 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 secure and 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 assays into 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 coop erate 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 IVD test kits and/or test systems, including instrumentation.

Competition

As a cancer diagnostics company focused on current and planned assays 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 frequent testing of patients frequently through the course of their disease in addition to, or 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. This clinically actionable information can assist physicians in selecting more personalized treatment plans for individual patients;
- our current and planned future CTC assays' 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 future assays, 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 assays based on our 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 assays that perform better than our current and planned future assays and services will not be introduced. We believe that our continued success depends on our ability to:

- Expand and enhance our current and planned Target-Selector assays 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 including development, regulatory approvals, and commercialization of Target-Selector IVD test kits;
- successfully market and sell assays;
- 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 assays;
- conduct or collaborate with clinical utility studies to demonstrate the application and medical value of our assays;
- 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, assays 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. The methods or behavior of oncologists and other physicians may be difficult to change regarding the use of 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. CTC and ctDNA testing is a new area of science and we cannot predict what assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the assays we develop. Competitors include but are not limited to companies such as Atossa, Qiagen, Roche, Trovagene, Guardant Health, Janssen Diagnostoric, Alere (Adnagen), Illumina, Apocell, EPIC Sciences, Clearbridge Biomedics, Biodesix, Thermo Fisher Scientific, Foundation Medicine, Neogenomics, Cynvenio Biosystems, Genomic Health, Fluxion Biosciences, RareCells, ScreenCell and Silicon Biosystems. Some 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.

There are a number of companies which are focused on the oncology diagnostic market, such as Cancer Genetics, Caris, Neogenomics, Agendia and Genoptix, who while not currently offering CTC or ctDNA assays are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA assays. Large laboratory services companies such as Quest and LabCorp provide more generalized cancer diagnostic testing but could also offer a CTC or ctDNA testing services. Companies like Abbott, Danaher, Qiagen, Thermo Fisher Scientific and others could develop equipment or reagents in the future as well.

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 assays that payors, pathologists and oncologists and other physicians could view as functionally equivalent to our current or planned future assays, which could force us to lower the list price of our assays 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 assays 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 future assays, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that 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 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. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests such as ours would be considered an off-label use and this may limit our access to this market segment.

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 future

assays 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 assay by physicians or patients i n other countries.

Third-Party Suppliers and Manufacturers

Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist but we have not validated the products of such alternative suppliers, 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 any one of our 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.

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, see the section entitled “Risk Factors – Intellectual Property Risks Related to Our Business.”

As of December 31, 2016, we owned 19 issued patents worldwide, including 7 patents in the U.S., as well as pending U.S. patent applications and corresponding patents and patent applications internationally related to our current business. In addition, as of December 31, 2016, we co-owned 2 pending U.S. patent applications as well as corresponding foreign patents and applications. In addition, Biocept has 3 issued U.S. patents related to its earlier microarray business. The patent portfolios for our leading programs as of December 31, 2016 are summarized below.

Microfluidic Channels . We have 3 issued U.S. patents that are related to our current business, and in 2016 we received an additional issued patent on our microfluidic channel in China, in addition to our earlier allowances in Japan, Hong Kong, Europe, China, and South Korea, which cover our microfluidic channel technology. Further U.S. and foreign patent application are pending.

Blood Collection Tubes . In 2015, we received a U.S. patent related to our 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.

Antibody Enrichment Cocktail . We have 1 issued and 1 pending U.S. patent application, and 1 broadly issued European patent, as well as other corresponding foreign patent applications directed to our antibody capture cocktail technology. This

technology includes using antibodies to a number of tumor-associated antig ens from cancer cells of both epithelial and mesenchymal phenotype, as well as cancer stem cells.

Enhanced Staining . We have 1 issued U.S. patent, 1 issued Chinese patent, as well as corresponding foreign patent applications directed to this technology.

Target-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 rights for oncology basic and clinical research. Aegea is responsible for the prosecution of 1 U.S. application, while we are responsible for the prosecution of the second U.S. application and its 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.

Operations and Production Facilities

Our research and development laboratory, 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 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 assays 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 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 the Health Insurance Portability and Accountability Act, or 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 currently 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, to produce consistent high quality testing services. The Quality Management Program documen ts the quality assurance and performance improvement plans and policies, and the laboratory quality assurance and quality control procedures necessary to ensure that we offer the highest quality of diagnostic testing services. This program is designed to s atisfy 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, instructions 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 assays, FISH, ICC 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 assay. 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 servi ces. 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 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 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, which is contracted with CMS to administer the MolDx program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore, the enumeration portion of our testing is not currently covered and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Although approximately 72% and 84% of all billable cases received in 2015 and 2016, respectively, relate to our Target-Selector biomarker assays, we continue to receive orders for our traditional enumeration testing, which counts disease burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. On November 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of CTC 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 enumeration portion of our testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The CTC enumeration counts disease burden and is a prognostic test, and although oncologists find the information valuable, it does not currently meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector assays.

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 assay 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 billing 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 steps in our testing process. We currently use a combination of codes to bill for our testing and analysis.

In order to ensure our coding is compliant, we have engaged industry experts to provide guidance on the proper coding of our assays. These experts include consultants at Codemap, LLC and ADVI Health, LLC. However, coding can be complex and payors may require differing codes for a given assay to effect payment. Changes in coding and reimbursement could adversely impact our revenues going forward, or payors could request that we reimburse them for payments we have already received. There can be no guarantees that Medicare and other payors will establish new positive or adequate coverage policies or reimbursement rates, or not change existing positive coverage policies, in the future.

We are moving forward with plans to obtain reimbursement coverage for the capture components of our assays. For other tests, we are able to utilize existin g CPT codes from the Medicare Physician Fee Schedule and Clinical Laboratory Fee Schedule. For these established CPT codes (for example, the codes for molecular testing, FISH and ICC), positive coverage determinations have been adopted as part of national Medicare policy or under applicable Local Coverage Determinations. Specific codes for our assays, however, do not assure an adequate coverage policy or reimbursement rate. Please see the section entitled "Legislative and Regulatory Changes Impacting Clinic al 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 Assays and our Planned Future Assays

Our Medicare Administrative Contractor has issued a negative coverage determination for the enumeration component of all CTC assays. We have received reimbursement for the enumeration component of our assays 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 planned future CTC assays, however, CMS, Palmetto or Noridian could adopt specific negative coverage policies for CTCs or ctDNA analysis in the future.

We expect these analysis components to have a significantly greater reimbursement value than the enumeration components of our current and anticipated CTC assays, based on a comparison of what we believe CellSearch ® 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 assays will have Medicare as their primary medical insurance. We cannot assure you that, even if our current and our planned future assays are otherwise successful, reimbursement for the currently Medicare-covered portions of our current and our planned future assays would, without Medicare reimbursement for the 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 assays. 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 assays.

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 Clinical Laboratory Fee Schedule, or CLFS, and the Physician Fee Schedule, or PFS. Annually, CMS releases the payment amounts under the Medicare fee schedules. The rates 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.

In accordance with Section 1833 (h)(2)(A)(i) of the Social Security Act, the annual update to the CLFS for calendar year 2017 is 0.10% (see 42 CFR405.509(b)(1)). With respect to our diagnostic services for which we expect to be reimbursed under PFS, CMS issues a Final Rule on an annual basis. The 2015, 2016 and 2017 PFS Final Rules have 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 ou r current assays and our planned future assays. These codes describe services that we must perform in connection with our assays and we bill for these codes in connection with the services that we provide.

Under the Protecting Access to Medicare Act of 2014, which was signed to law in April 2014, there were major changes to the payment formula under the 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 is 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. The impact of this federal legislation on reimbursement for our products is too early to predict.

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 MACs for California, respectively. Palmetto GBA is contracted with CMS to administer the MolDx program, which sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays. Palmetto GBA has issued a Local Coverage Determination, whereby Palmetto GBA will not cover many molecular diagnostic assays, such as the enumeration component of our current assays, 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 assay (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. Palmetto GBA currently has a negative coverage determination for the enumeration component of CTC assays, but there is no such negative coverage determination for the analysis component of such CTC assays. Denial (or continuation of denial) of coverage for the enumeration component of our current and anticipated CTC assays by Palmetto GBA or its successor MAC, Noridian Healthcare Solutions, which adopts coverage policies set by the MolDx program, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our current assays and our planned future assays. Noridian Healthcare Solutions intends to follow, for CTC assays, the positive or negative coverage determinations which from time to time Palmetto GBA makes as well as any coverage policy changes set by the MolDx program. On November 27, 2013, Palmetto GBA denied our request for coverage for the enumeration/detection portion of our testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The CTC enumeration counts disease burden and is a prognostic test, and although oncologists find this information valuable, it does not meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector assays.

Additionally, the Centers for Disease Control and Prevention, CMS and the Office of Civil Rights 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 th e 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 Health and Human Services, or 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 statut e 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 fr om 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 jurisdi ction 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 an d/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 requirement s.

U.S. Food and Drug Administration

We provide our assays as 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 since indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. The timing of when, or if, the draft guidance documents will be finalized is unclear, 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 derive the majority of our revenues from sources within the United States.

Employees

As of December 31, 2016, we had a total of 70 full-time employees and 3 part time employees, 5 of whom hold doctorate degrees and 10 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 are 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. Inform ation 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 molecular oncology diagnostics 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 $16.9 million and $18.4 million for the years ended December 31, 2015 and 2016, respectively, and we have never been profitable. At December 31, 2016, our accumulated deficit was approximately $173.6 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.

We need to raise additional capital to continue as a going concern.

We expect to continue to incur losses for the foreseeable future and will have to raise additional capital to fund our planned operations and to meet our long-term business objectives. As a result, there is substantial doubt about our ability to continue as a going concern unless we are able to successfully raise additional capital. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund our operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. 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. Failure to raise additional capital in sufficient amounts would significantly impact our ability to continue as a going concern. The actual amount of funds that we will need and the timing of any such investment will be determined by many factors, some of which are beyond our control.

An event of default under our credit facility may have a material adverse effect on our financial condition.

On April 30, 2014, we borrowed $5.0 million pursuant to the terms of a credit facility, or the April 2014 Credit Facility, with Oxford Finance LLC, or Oxford. At December 31, 2016, a principal balance of approximately $3.1 million was outstanding under the April 2014 Credit Facility, of which approximately $1.9 million was due within one year in the absence of subjective acceleration of the April 2014 Credit Facility by Oxford. The April 2014 Credit Facility includes events of default, the occurrence and continuation of which provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the 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.

Accordingly, the occurrence of an event of default under our April 2014 Credit Facility, unless cured or waived, may have a material adverse effect on our results of operations.

Risks Relating to Our Business and Strategy

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

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

If we are unable to execute our sales and marketing strategy for cancer diagnostic assays 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 molecular oncology diagnostics company and have engaged in only limited sales and marketing activities for the cancer diagnostic assays we currently offer through our CLIA-certified, CAP accredited, and state-licensed laboratory. To date, we have received limited revenue.

Although we believe that our current assays and our planned future assays represent a promising commercial opportunity, our assays 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 assays 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 assays and/or our planned future assays. 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 assays and our planned future assays.

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

- Conducting clinical utility studies of such assays 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 assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions;
- our ability to continue to fund planned sales and marketing activities; and
- whether private health insurers, government health programs and other third-party payors will cover such cancer diagnostic assays and, if so, whether they will adequately reimburse us.

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

If we cannot develop assays 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 incre ase 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 assays and enhance any existing assays to k eep pace with evolving standards of care. Our current assays and our planned future assays could become obsolete unless we continually innovate and expand them to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with cancer. New ca ncer therapies typically have only a few years of clinical data associated with them, which limits our ability to develop cancer diagnostic assays based on, for example, biomarker analysis related to the appearance or development of resistance to those the rapies. If we cannot adequately demonstrate the applicability of our current assays and our planned future assays to new treatments, by incorporating important biomarker analysis, sales of our assays could decline, which would have a material adverse effec t on our business, financial condition and results of operations.

If our current assays and our planned future assays 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 assay results. We believe that our customers are likely to be particularly sensitive to assay defects and errors. As a result, the failure of our current or planned future assays, which capture and analyze CTCs and/or ctDNA, to perform as expected regarding the sensitivity, specificity, concordance or reproducibility of such assays, would significantly impair our reputation and the public image of our cancer assays, 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 assays and pursue our research and development efforts may be jeopardized.

We currently derive our revenues from our cancer diagnostic assays 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 assays for some period of time. The inability to perform our current assays and our planned future assays or the backlog of assays 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 assay 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 assays and our planned future assays could be performed. Even if we find a facility with such qualifications to perform our assays, 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. The methods or behavior of oncologists and other

physicians may be difficult to change regarding the use of 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 repres ent 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. CTC and ctDNA testing is a new area of science and we cannot predict what assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the assays we develop. Competitors include but are not limited to companies such as Atossa, Qiagen, Roche, Trovagene, Guardant, Janssen Diagnostoric, Alere (Adnagen), Illumina, Apocell, EPIC Sciences, Clearbridge Biomedics, Biodesix, Thermo Fisher Scientific, Foundation Medicine, Neogenomics, Cynvenio Biosystems, Genomic Health, Fluxion Biosciences, RareCells, ScreenCell and Silicon Biosystems. Some 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.

There are a number of companies which are focused on the oncology diagnostic market, such as Cancer Genetics, Caris, Neogenomics, Agendia and Genoptix, who while not currently offering CTC or ctDNA assays are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA assays. Large laboratory services companies such as Quest and LabCorp provide more generalized cancer diagnostic testing but could also offer a CTC or ctDNA test service. Companies like Abbott, Danaher, Qiagen, Thermo Fisher Scientific and others could develop equipment or reagents in the future as well.

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 assays that payors, pathologists and oncologists and other physicians could view as functionally equivalent to our current or planned future assays, which could force us to lower the list price of our assays 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 assays 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 future assays, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect that 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 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. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests such as ours would be considered an off-label use and this may limit our access to this market segment.

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 future assays 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 assay by physicians or patients in other countries.

We expect to continue to incur significant expenses to develop and market cancer diagnostic assays, 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 assays. For the year ended December 31, 2015, our research and development expenses were $2.9 million and our sales and marketing expenses were $3.9 million. For the year ended December 31, 2016, our research and development expenses were $2.7

million an d our sales and marketing expenses were $5.1 million. We expect our expenses to continue to increase for the foreseeable future as we conduct studies of our current assays and our planned future assays, establish a sales and marketing organization, drive a doption of and reimbursement for our diagnostic assays and develop new assays. 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 current assays or our planned future assays, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current assays and our planned future assays, we will need to educate oncologists, pathologists, and other health care professionals on the clinical utility, benefits and value of the assays 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 assays and our planned future assays, 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 an assay'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 an assay provides clinically meaningful information and value, commercial adoption of such assay 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 an assay, helping to assure there is appropriate reimbursement.

We need to conduct additional studies for our assays, increase assay 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 assays could be impaired and we may not be able to obtain coverage and adequate reimbursement for them.

We are undergoing management transitions, which could adversely affect our business.

We recently hired Timothy C. Kennedy, who serves as our Chief Financial Officer, Senior Vice President of Operations and Secretary, and Michael Terry, who serves as our Senior Vice President Commercial Operations. We intend to recruit and hire other senior executives. Such management transitions subject 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, any of which could adversely affect our business.

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, Veena M. Singh, M.D., our Senior Vice President and Senior Medical Director, Michael Terry, our Senior Vice President Commercial Operations, and Timothy C. Kennedy, our Chief Financial Officer, Senior Vice President of Operations and Secretary. 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, assays 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

te am 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. Ou r executive management team each 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 o r 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 assays, to expand geographically and to successfully commercialize any other assays or products we may develop.

To succeed in selling our diagnostic assays and any other assays 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 assays 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 assays and our planned future assays, and to do so we must enter into agreements with these partners to sell, market or commercialize our assays. 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 assays. These partners may not commit the necessary resources to market and sell our cancer diagnostics assays 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.

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 sam ples 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 assays and our planned future assays. 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 assays and our planned future assays 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 assays 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 assays in a timely manner.

Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist but we have not validated the products of such alternative suppliers, 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 any one of our 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 assays and our planned future assays could lead to the filing of product liability claims against us if someone alleges that our assays 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 assays, 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 re gulations, 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 assays and our planned future assays, including successfully managing the evolution of our laboratory service, our business could suffer.

As our assay 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. Examples of challenges we may face include, but are not limited to, maintaining the same validated sensitivity if our testing for both CTC and ctDNA analysis as our assay volume increases. We will also need additional clinical laboratory scientists and other scientific and technical personnel to process these additional assays. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional assays 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 or maintain 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 assays 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 assays and our planned future assays, which capture and analyze CTCs and/or ctDNA and would need to continue to perform as expected regarding their sensitivity, specificity, concordance and reproducibility, 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 assays and our planned future assays 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 certai n 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 reage nts 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 fact ors, it could have a significant negative impact on our ability to perform assays 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 increased international expansion, including partnering with academic and commercial testing laboratories, and introducing our technology outside the United States as part of IVD test kits and/or testing systems utilizing our 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 assays and our planned future assays 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 assays and our planned future assays 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; and
- 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.

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 assays 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 assays, 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:

- 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 assays and our planned future assays. 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. Recently, the U.S. House of Representatives and Senate passed legislation, which, if signed into law by President Trump, would repeal certain aspects of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

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 is 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 was required to 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 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 i n 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 reim bursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations.

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, and changes to the reimbursement amounts paid by Medicare and other payors for our current assays and our planned future assays, 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 assays 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 assays and our planned future assays.

Oncologists and other physicians may not order our current assays and our planned future assays 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 assays, seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current assays and our planned future assays 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 assays, or new assays or assay 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 flo w.

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 assays and our planned future assays, our revenues could decline.

Approximately 41% and 40% of total revenues during the years ended December 31, 2015 and 2016, respectively, were associated with Medicare reimbursement. For commercial accessions received from January 1, 2016 through December 31, 2016, we estimate the average value to be approximately $1,100 per accession, when we receive payments from third parties. We have not historically been reimbursed at this average rate for a variety of reasons, including billing challenges related to changes in Medicare CPT codes for our FISH assays in 2015, establishing our associated internal processes, and managing an external "out-sourced" billing company. We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare-covered portions of our current assays and our planned future assays 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 assays 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 assays and our planned future assays 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 many private payors because we have not entered into a specific contract to provide cancer diagnostic assays to their insured patients at specified rates of reimbursement. Additionally, a significant amount of our non-Medicare business (private payors) has historically not been contracted, and reimbursement for this business has historically not been at "in network" rates and has therefore been inconsistent. We first began to contract private payor networks in 2015, and since then our number of accessions treated as "in network" has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with eight Preferred Provider Organization networks, two large health plans, and three regional Independent Physician Associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans. 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 assay 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 assays 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 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 enumeration portion of our testing. Because our laboratory is in California, the regional MAC for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto GBA, LLC, which is contracted with CMS to administer the MolDx program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore, the enumeration portion of our testing is not currently covered and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Although approximately 72% and 84% of all billable cases received in 2015 and 2016, respectively, relate to our Target-Selector biomarker assays, we continue to receive orders for traditional enumeration testing, which counts disease

burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. On Nove mber 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of the enumeration testing in order to seek to persuade the MACs to allow coverage for this portion of our testing. Palmetto GBA responded on November 2 7, 2013, denying our request for Medicare coverage for the CTC enumeration portion of our testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The CTC enumeration counts disease burden an d is a prognostic test, and although valuable, it does not meet many of the medical necessity requirements of Medicare and the payors. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing fo r some of our Target-Selector assays.

We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare-covered portions of our current assays and our planned future assays 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 our current assays and our planned future assays, 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 LDTs, 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 distribu tion 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 assays and our planned future assays, 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 assays.

We provide our assays as 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. The timing of when, if at all, the draft guidance documents will be finalized is unclear, 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.

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 assays 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 assays pending pre-market clearance or approval. If the FDA allows our assays to remain on the market but there is uncertainty about our assays, 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 assays 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 assays 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 assays, 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 c linical studies or trials before continuing to offer assays 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 commercializ ing 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 assays or our planned future assays, 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 assays outside our CLIA laboratory; however, we would need to conduct additional clinical validation activities on our assays 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 assays. 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 assays and our planned future assays 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 assay 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 assays and our planned future assays are effective for the proposed indicated uses, which could cause us to abandon an assay candidate and may delay development of other assays.

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 assays and our planned future assays. 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 assays 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;

- 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, 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 significan t 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 t o 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 th e 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 o n 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. The possibility exists 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 rele vant 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 produ cts 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 ha ve 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 United States Patent and Trademark Office, or 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 i ndependently 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 st eps 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.

For example, in August 2016, we received a letter from MolecularMD Corp. offering a license to two U.S. Patents owned by the Memorial Sloan-Kettering Cancer Center, and licensed to MolecularMD Corp., that are relevant to one of the biomarkers we detect in our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector™ assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector™ assay. One of the two patents is expected to expire in 2026. The other patent is expected to expire in 2028. Although we believe that the claims of both patents relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector Assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector Assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

In addition, we are aware of a U.S. Patent owned by Amgen, Inc. that is relevant to one of the biomarkers we detect in our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector assay. The patent is expected to expire in 2028. Although we believe that the claims of the patent relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Non-Small Cell Lung Cancer Profile Target-Selector assay and our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could materially and adversely affect our business.

We are also aware of a U.S. Patent owned by Genentech, Inc. that is relevant to one of the biomarkers we detect in our Liquid Biopsy Lung Cancer Resistance Profile Target-Selector assay and our Liquid Biopsy Colon Cancer Profile Target-Selector assay. The patent is expected to expire in 2025. Although we believe that the claims of the patent relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Lung Cancer Resistance

Profile Target-Selector assay and our Liquid Biopsy Colon Cancer Profile Target-Selector assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could material ly and adversely affect our business.

In addition, in July 2016, we received a communication from the Mayo Foundation for Medical Education and Research ("Mayo") offering a license to a U.S. Patent owned by Mayo that is relevant to an antibody that we use in our Liquid Biopsy Immuno-Oncology PD-L1 Test. The patent is expected to expire in 2021. At present, we believe that we will need a license to this patent to continue commercializing our Liquid Biopsy Immuno-Oncology PD-L1 Test. We are currently in discussions with Mayo and believe a license can be obtained on commercially reasonable terms. However, if we are unable to secure such a license, we may be liable for past damages, and our business could be materially and adversely affected.

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 produ cts 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 commonplac e. 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 connecte d 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 ri ghts 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 tha t 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 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 assays and our planned future assays;

- favorable or unfavorable decisions about our assays from government regulators, insurance companies or other third-party payors;
- our ability to remain compliant with the terms of our April 2014 Credit Facility;
- 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 herein; 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, the minimum closing bid price requirement, or the minimum stockholders' equity requirement, NASDAQ may take steps to de-list our common stock. For example, in May 2016, we received a letter from NASDAQ indicating that we are not in compliance with the minimum stockholders' equity requirement of NASDAQ Listing Rule 5550(b)(1), and in both June and November 2016, we received letters from NASDAQ indicating that we are not in compliance with the minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2). If we fail to maintain compliance with these, or any other of the continued listing requirements of The NASDAQ Capital Market, 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, 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 wr itten 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 assays and our planned future assays 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 assays; and
- regulatory developments affecting our assays.

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 stoc k to fluctuate substantially.

Future sales of our common stock or other securities, 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 other securities, 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 rais e capital through the sale of additional equity securities. For example, in May 2015, the SEC declared effective a shelf registration statement filed by us. This shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to $50 million, subject to certain limitations for so long as our public float is less than $75 million. To date, we have sold 1,662,191 shares of our common stock and warrants to purchase up to an aggregate of 1,163,526 shares of common stock under this registration statement. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under this shelf registration statement may cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this shelf registration statement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

We had outstanding 22,280,247 shares of common stock as of March 24, 2017, of which no more than 1,555,289 are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of March 24, 2017, we had outstanding options to purchase 868,573 shares of our common stock, 174,249 shares of common stock were issuable upon the settlement of outstanding restricted stock units, or RSUs, and 6,843,666 shares of our common stock were issuable upon the exercise of outstanding warrants. Shares issued upon the exercise of stock options or upon the settlement of outstanding RSUs 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.

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 man agement 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 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 estimated net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our estimated 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 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 estimated 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, 2016, we had estimated federal and state net operating loss carryforwards of approximately $5.3 million and $8.6 million, respectively, and estimated federal and California research and development credits of approximately $0.0 million and $3.4 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, however, we believe ownership changes likely occurred in both 2015 and 2016. As a result, we have estimated that the use of our net operating loss is limited and the amounts above represent the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future, which remain fully offset by a valuation allowance to reduce the net asset to zero.

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.

I tem 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 $116,800 per month. This lease expires in July 2020.

Pursuant to a sublease agreement dated March 30, 2015, we subleased 9,849 square feet, plus free use of an additional area, of our San Diego facility to an entity affiliated with our non-executive Chairman for $12,804 per month, with a refundable security deposit of $12,804 due from the subtenant. The initial term of the sublease expired on July 31, 2015, and is subject to renewal on a month-to-month basis thereafter. On February 1, 2017, we received notice from the subtenant terminating the sublease effective March 31, 2017.

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 is traded on The NASDAQ Capital Market under the symbol "BIOC." The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Capital Market for the periods indicated. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

	For the year ended December 31, 2016	
	High	Low
First Quarter	$ 5.64	$ 3.15
Second Quarter	$ 4.29	$ 1.68
Third Quarter	$ 2.40	$ 1.42
Fourth Quarter	$ 1.60	$ 0.74

	For the year ended December 31, 2015	
	High	Low
First Quarter	$ 14.73	$ 3.27
Second Quarter	$ 12.33	$ 6.18
Third Quarter	$ 9.27	$ 5.04
Fourth Quarter	$ 7.68	$ 3.78

The last sale price for our common stock as reported by The NASDAQ Capital Market on March 24, 2017 was $2.23 per share.

Holders of Record

As of March 24, 2017, there were 201 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.

Item 6. Selected Financial Data.

Not applicable.

I tem 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 molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or "liquid biopsy." Our assays provide, and our planned future assays will provide, information to oncologists and other physicians that enable them to select appropriate personalized treatment for their patients who have been diagnosed with cancer based on molecular drivers and markers of their disease and when traditional methodologies such as tissue biopsies are insufficient or unavailable. Our assays have potential to provide more contemporaneous information on the characteristics of a patients' disease compared with traditional methodologies such as tissue biopsy and imaging.

Our current assays and our planned future assays focus on key solid tumor indications utilizing our Target-Selector ™ liquid biopsy offering for the biomarker analysis of CTCs and ctDNA from a standard blood sample. Our patented Target-Selector CTC offering is based on an internally developed microfluidics-based cell capture and analysis platform, with enabling features that change how CTC testing is used by clinicians. Our Target-Selector platforms provide both biomarker detection as well as monitoring capabilities, and require only a patient blood sample. Our patent pending Target-Selector ctDNA technology enables mutation detection with enhanced sensitivity and specificity, and is applicable to nucleic acid from ctDNA or other sample types, such as CTCs, red blood cells, or cerebrospinal fluid. We believe that our Target-Selector platform technology has potential to be developed and commercialized as in vitro diagnostic (IVD) test kits, and we are currently pursuing this option.

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. We manufacture our microfluidic channels, related equipment and certain reagents to perform our current assays and our planned future assays 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 assays we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations. In addition, we also participate in and have received College of American Pathologists, or CAP, accreditation, which includes requires rigorous bi-annual laboratory inspections and an adherence to specific quality standards.

We have commercialized our Target-Selector assays for a number of solid tumor indications such as: breast cancer, non-small cell lung cancer, or NSCLC, small cell lung cancer, or SCLC, gastric cancer, colorectal cancer, prostate cancer, and melanoma. These assays utilize our dual CTC and ctDNA technology platform and provide biomarker analysis from a patient's blood sample.

In the case of our breast and gastric cancer offering, 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, or ER, protein, as well as androgen receptor, or AR, protein, which are currently commercially available. We plan to include immunocytochemical analysis of progesterone receptor, or PR, proteins as part of the Target-Selector CTC menu in 2017. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin ® or Tykerb ® . ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

The lung cancer biomarker analyses currently include FISH testing for ALK, ROS1, RET, MET and FGFR1 gene rearrangements and mutation analysis of the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor, or EGFR, gene as well as BRAF and KRAS using our Target-Selector ctDNA platform. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are associated with the drugs Tarceva ® , Gilotrif ® and Iressa ® . For lung cancer, we also offer a resistance profile assay consisting of the biomarkers MET, HER2 (both of which we perform using our technology for CTCs), KRAS, and T790M (both of which are performed using ctDNA in plasma). This

assay could be used by physicians to identify the mechanism causing disease progression for patients with NSCLC who are be ing treated with TKI therapy and therefore could qualify for inclusion in a clinical trial. In November 2015, Tagrisso ® was approved by the U.S. Food and Drug Administration, providing another biomarker-based therapy for the treatment of patients with EGFR related lung cancer. Tagrisso ® is indicated for the treatment of patients with metastatic EGFR T790M mutation-positive NSCLC, who have progressed on or after EGFR tyrosine kinase inhibitor therapy.

Fibroblast growth receptor 1, or FGFR1, amplification is offered using our CTC technology. FGFR1 is present in several tumor types, including both NSCLC and SCLC and has been shown to be a prognostic indicator of progression. FGFR1 is also a key target for many drugs which are in clinical development.

Mutations of the BRAF gene are associated with Zelboraf ® and Tafinlar ® , which are both approved for treating patients with melanoma and are in clinical trials for lung cancer. We offer testing for BRAF on blood using our ctDNA offering.

We analytically validated PD-L1 testing utilizing our CTC technology in 2016. PD-L1 is a biomarker that is informative for immuno-oncology therapies currently marketed today for lung cancer and melanoma, as well as for therapies in development for multiple tumor types. We collaborated with David Rimm, M.D., Ph.D., a pathologist at Yale Medical School, on the analytical development of this assay.

We plan to add other biomarker analyses, such as ESR1 and NRAS, on blood samples to our current assays and our planned future Target-Selector assays as their relevance is demonstrated in clinical trials and/or included in guidelines used by physicians to make treatment decisions. In addition, we plan to offer multiplexed assays which allow the detection and quantification of multiple biomarkers in a single assay.

We continue to execute on our strategies intended to expand our business globally as well as engaging with pharmaceutical companies on clinical trials and assay development. We have executed distribution agreements in Mexico with Quest Diagnostics to support testing for a large pharmaceutical partner, as well as an agreement with Progenetics to market our assays in Israel for clinical testing. In addition, we have distribution agreements in place in Turkey, the Czech Republic, the Philippines, Peru, Columbia and Canada.

We announced three additional pharmaceutical collaborations during 2016. The first agreement is to provide testing for a clinical trial that includes patients who have leptomeningeal disease or metastatic lung cancer in the brain. In this exploratory trial, we are testing both cerebral spinal fluid and blood for molecular alterations that could be impacted by treatment. The second agreement is a large milestone-based multi-project assay development collaboration focused on multiple tumor types including breast cancer and on multiple tumor types including breast cancer and hepatocellular carcinoma, or liver cancer, whereby we intend to develop assays utilizing both our CTC and ctDNA technologies for clinical trials. The third collaboration involves a study presented at the European Society for Medical Oncology, or ESMO, Annual Congress in October 2016, whereby collaborators from a large pharmaceutical company, and academic investigators, demonstrated a high concordance between our Target-Selector liquid biopsy and tissue biopsy. Subsequent to this study, we have earned business in both Mexico and Columbia for EGFR testing in blood to qualify patients for a pharmaceutical company’s targeted therapy.

Our revenue generating efforts are focused in three areas:

- providing clinical testing that oncologists 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 continue to develop and commercialize assays through our CLIA-certified, CAP-accredited, and state-licensed laboratory. We have launched our Target-Selector offering for breast cancer, lung cancer, gastric cancer, colorectal cancer, prostate cancer, and melanoma, and plan to continue to launch a series of cancer diagnostic assays for different predictive biomarkers assays in the United States as LDTs performed in our laboratory, and enhance revenue for these products through the efforts of our sales and marketing organization, which we plan to expand. Our sales strategy is to engage oncologists and other physicians in the United States at private and group

practices, hospitals and cancer centers. We also plan to evaluate potential opp ortunities for the commercialization of our products in other countries. In addition to testing for physicians and their patients, we offer clinical trials testing and research services to help increase the efficiency and economic viability of clinical tri als for pharmaceutical and biopharmaceutical companies and clinical research organizations both within and outside of the United States. We are currently exploring the possibility of introducing ctDNA technology outside the United States as part of IVD tes t kits and/or testing systems utilizing our Target-Selector technologies. 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 dev elopment of IVDs and/or test systems, including instrumentation. 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 differe nt cancer types and clinical settings.

To facilitate market adoption of our assays, 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 Sarah Cannon Research Institute, Baylor College of Medicine, The University of Texas MD Anderson Cancer Center, the Dana-Farber Cancer Institute, the University of California, San Diego, University of California, Irvine, Washington University, University of Colorado, Yale University, the University of Minnesota, the John Wayne Cancer Institute, 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 our Target-Selector commercialized assays and our planned future assays. Such relationships help us develop and validate the effectiveness and utility of our commercialized assays and our planned future assays 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

The following table sets forth certain information concerning our commercial cases accessioned for the periods shown:

	Year Ended December 31,		Change	
	2015	2016	#	%
Commercial cases accessioned	1,608	3,676	2,068	129%

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, with multiple payments received per case. For commercial accessions received during the years ended December 31, 2015 and 2016, the average number of tests performed increased from 2.6 tests per accession to 3.6 tests per accession, respectively, as the number of commercialized assays we offer has increased. Approximately 41% and 40% of total revenues during the years ended December 31, 2015 and 2016, respectively, were associated with Medicare reimbursement. For commercial accessions received from January 1, 2016 through December 31, 2016, we estimate the average value to be approximately $1,100 per accession, when we receive payments from third parties. We have not historically been reimbursed at these average rates for a variety of reasons, including billing challenges related to changes in Medicare CPT codes for our FISH assays in 2015, establishing our associated internal processes, and managing an external “out-sourced” billing company. Additionally, a significant amount of our non-Medicare business (private payors) has historically not been contracted, and reimbursement for this business has historically not been at “in network” rates and has therefore been inconsistent. We first began to contract private payor networks in 2015, and since then our number of accessions treated as “in network” has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with eight Preferred Provider Organization networks, two large health plans, and three regional Independent Physician Associations, and expect to continue to gain contracts in order to be considered as an “in-network” provider with additional plans.

During the years ended December 31, 2015 and 2016, approximately $69,000 and $221,000 or 11% and 7%, respectively, of our total annual revenues were billed to clinical partners. 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.

Costs and Expenses

We classify our costs and expenses into four categories: cost of revenues, research and development, sales and marketing, and general and administrative. Our costs and expenses principally consist of facility costs and overhead, personnel costs, outside services and consulting costs, laboratory consumables, development costs, and legal fees.

Cost of Revenues. Our cost of revenues consists principally of facility costs and overhead, personnel costs, and laboratory and manufacturing supplies. 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 and volume discounts with our suppliers and exploring relocating our operations to a lower-cost facility.

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 remain consistent in the near-term, principally 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, third party billing provider fees, 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 expanded commercial activities.

Seasonality

We expect our test volume to decrease during vacation and holiday seasons, and also during the winter season in colder climates experiencing prolonged adverse weather conditions, when patients are less likely to visit their health care providers. We also expect relatively lower cash receipts in the first quarter of each year, as annual patient deductibles generally reset on January 1 of each year. We expect these trends 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 in cluded 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; and
- stock-based compensation.

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.

Stock-Based Compensation

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 RSUs is determined by the price of our 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.

Results of Operations

Years Ended December 31, 2015 and 2016

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

	For the year ended December 31,		Change	
	2015	2016	$	%
(dollars in thousands)				
Revenues	$ 610	$ 3,223	$ 2,613	428%
Cost of revenues	4,596	6,920	2,324	51%
Research and development expenses	2,858	2,713	(145)	(5%)
General and administrative expenses	5,687	6,561	874	15%
Sales and marketing expenses	3,880	5,054	1,174	30%
Loss from operations	(16,411)	(18,025)	(1,614)	10%
Interest expense, net	(639)	(526)	113	(18%)
Other income	102	154	52	51%
Loss before income taxes	(16,948)	(18,397)	(1,449)	9%
Income tax expense	(2)	(2)	—	—
Net loss	$ (16,950)	$ (18,399)	$ (1,449)	9%

Revenues

Revenues were approximately $3,223,000 for the year ended December 31, 2016, compared with approximately $610,000 for the same period in 2015, an increase of $2,613,000, or 428%. The increase was due to an increase of approximately $2,427,000 in commercial assay revenues resulting primarily from increases in both commercial accession volume and collections made thereon, as well as an increase of approximately $186,000 in development services revenues with 535 development services accessions received during the year ended December 31, 2016 as compared to 216 accessions received during the same period in 2015.

Costs and Expenses

Costs of Revenues. Cost of revenues was approximately $6,920,000 for the year ended December 31, 2016, compared with approximately $4,596,000 for the year ended December 31, 2015, an increase of $2,324,000, or 51%. The increase was primarily attributable to an increase of approximately $1,052,000 in personnel costs mainly related to higher assay volume as the average number of laboratory and other direct employees increased from an average of 20 employees during the year ended December 31, 2015 to 28 employees during the same period in 2016, an increase of approximately $988,000 in direct materials costs also related to higher assay volume, as well as an increase of approximately $219,000 related to fewer laboratory costs charged to research and development.

Research and Development Expenses . Research and development expenses were approximately $2,713,000 for the year ended December 31, 2016, compared with approximately $2,858,000 for the year ended December 31, 2015, a decrease of $145,000, or 5%. The decrease was primarily attributable to a decrease of approximately $219,000 related to fewer laboratory costs charged to research and development, a decrease of approximately $34,000 in third party consulting fees, and a decrease of approximately $31,000 in depreciation expense, partially offset by an increase of approximately $138,000 related to an increase in the average number of employees included in the research and development function from 8 employees during the year ended December 31, 2015 to 10 employees during the same period in 2016 .

General and Administrative Expenses . General and administrative expenses were approximately $6,561,000 for the year ended December 31, 2016, compared with approximately $5,687,000 for the year ended December 31, 2015, an increase of $874,000, or 15%. The increase was primarily due to an increase of approximately $237,000 in third party billing fees associated with increased cash collections, an increase of approximately $227,000 in consulting and other third party service provider costs mainly related to expanded commercial activities, an increase of approximately $229,000 in personnel costs related to an increase in the average number of employees included in the general and administrative function from 7 employees during the year ended December 31, 2015 to 9 employees during the same period in 2016, an increase of

approximately $87,000 due to increased allocated facility costs and depreciation, as well as an increase of approximately $81,000 in legal fees.

Sales and Marketing Expenses . Sales and marketing expenses were approximately $5,054,000 for the year ended December 31, 2016, compared with approximately $3,880,000 for the year ended December 31, 2015, an increase of $1,175,000, or 30%. The increase was primarily due to an increase of approximately $899,000 in personnel costs and travel expenses associated with an increase in the average number of employees included in the sales and marketing function from 13 employees during the year ended December 31, 2015 to 15 employees during the same period in 2016, as well as an increase of approximately $268,000 in consulting and other third party service provider costs associated with expanded commercial activities .

Income Tax Expense

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 , however, we believe ownership changes likely occurred during both 2015 and 2016 . As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

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 9, 2015 between us, Aegis Capital Corp. and Feltl and Company, Inc., as underwriters named therein, a public offering of 2,666,666 shares of our common stock and warrants to purchase up to an aggregate of 2,666,666 shares of our common stock was effected at a combined offering price of $3.75. The estimated grant date fair value of these warrants of $7.7 million was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering. All warrants sold in this offering have a per share exercise price of $4.68, 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 $8.8 million of net cash proceeds. Additionally, the underwriters were granted a 45-day option to purchase up to 400,000 additional shares of common stock at a price of $3.75 per share and/or additional warrants to purchase up to 400,000 shares of common stock at a price of $0.0003 per warrant, less underwriting discounts and commissions, to cover overallotments, if any, which was not exercised. The estimated grant date fair value of the overallotment options and warrants of $1.6 million was recorded as an offset to additional paid-in capital within common stock issuance costs upon the closing of this offering. Subsequent to the closing of this offering on February 13, 2015, additional cash proceeds of $9.8 million have been received from the exercise of warrants sold in this offering. As such, the aggregate total net increase in capital related to this offering has been approximately $18.6 million.

In May 2015, the SEC declared effective a shelf registration statement filed by us. The shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to $50 million, subject to certain limitations for so long as our public float is less than

$75 million. Pur suant to an exclusive placement agent agreement dated April 25, 2016 between us and H.C. Wainwright & Co., LLC, or Wainwright, and a securities purchase agreement dated April 29, 2016 between us and the purchasers signatory thereto, a public offering of 1, 662,191 shares of our common stock and warrants to purchase up to an aggregate of 1,163,526 shares of our common stock was effected under this registration statement at a combined offering price of $3.00. All warrants sold in this offering have a per share exercise price of $3.90, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the purchasers occurred on May 4, 2016, pursuant to which we received approximately $4.3 million of net ca sh proceeds. Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately $4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at $3.90 per share until their expiration in May 2021. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. The specific terms of additional f uture offerings, if any, under this shelf registration statement would be established at the time of such offerings.

On December 21, 2015, we entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, which committed to purchase up to an aggregate of $15.0 million of shares of our common stock over the 30-month term of the common stock purchase agreement. On November 4, 2016, we voluntarily terminated this common stock purchase agreement. Upon execution of the common stock purchase agreement, we sold to Aspire Capital 208,334 shares of common stock at $4.80 per share for proceeds of $1,000,000, and concurrently also entered into a registration rights agreement with Aspire Capital, pursuant to which we filed a registration statement registering the sale of the shares of our common stock that were issued to Aspire Capital under the common stock purchase agreement. In consideration for entering into, and concurrently with the execution of, the common stock purchase agreement, we issued to Aspire Capital 55,000 shares of our common stock. The proceeds received by us under the common stock purchase agreement were used for working capital and general corporate purposes. During the year ended December 31, 2016, we submitted purchase notices to Aspire Capital for an aggregate of 173,145 shares of common stock for gross proceeds of $544,051. Costs associated with this offering of approximately $42,000 and $79,000 during the years ended December 31, 2015 and 2016, respectively, were recorded as an offset to additional paid-in capital, and as such, the aggregate total net increase in capital related to these transactions was approximately $1.4 million.

Pursuant to an underwriting agreement dated October 14, 2016 between us, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, a public offering of 9,100,000 shares of our common stock and warrants to purchase up to an aggregate of 9,100,000 shares of common stock was effected at a combined offering price of $1.10. The estimated grant date fair value of these warrants of approximately $5.2 million was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering. Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of $1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of $0.0009 per warrant to cover overallotments, if any, of which the underwriters exercised their overallotment option to purchase 627,131 option warrants for total proceeds to us of $564. The estimated aggregate grant date fair value of the overallotment options and warrants of approximately $0.8 million was recorded as an offset to additional paid-in capital within common stock issuance costs upon the closing of this offering. All warrants sold in this offering have a per share exercise price of $1.10, 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 October 19, 2016, when we received $9.0 million of net cash proceeds. Subsequent to December 31, 2016, approximately $5.3 million of additional cash proceeds had been received from the exercise of warrants sold in this offering. As such, the total net increase in capital as a result of the sale of these shares and warrants has been $14.3 million.

Debt Financing

On April 30, 2014, we received net cash proceeds of approximately $4,898,000 pursuant to the execution of the April 2014 Credit Facility with Oxford Finance LLC. Upon the entry into the April 2014 Credit Facility, we were required to pay the lender a facility fee of $50,000 in conjunction with the funding of the term loan. The April 2014 Credit Facility is secured by substantially all of our personal property other than our intellectual property. Amounts due to Oxford Finance LLC under the April 2014 Credit Facility are callable before maturity by the lender under certain subjective acceleration clauses of the underlying agreement, including changes deemed to be materially adverse by the lender. The 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 term loan, plus (b) 7.71%. The term loan bears interest at an annual rate of 7.95%. We were required to make interest-only payments on the term loan

through August 1, 2015. The outstanding term loan under the April 2014 Credit Facility began amortizing at the end of the applicable interest-only period, with monthly payments of principal and interest being made by us to the lender in consecutive monthly installments following such interest-only period. The term loan under the April 2014 Credit Facility matures on July 1, 2018. Under the original terms of the underlying agreement, we are also required to make a final payment to the lender equal to 5.5% of the original principal amount of the term loan funded. At our option, we may prepay the outstanding principal balance of the term loan in whole but not in part, subject to a prepa yment fee of 1% of any amount prepaid.

On June 30, 2016, we entered into an amendment of the April 2014 Credit Facility. This amendment required us to make interest-only payments on the term loan from July 1, 2016 through September 30, 2016, and also requires an additional final payment of $50,000 to the lender. The terms of the amendment require the amortization of the outstanding amount due under the term loan to commence at the end of the applicable interest-only period, with monthly payments of principal and interest, in arrears, being made by us to the lender in consecutive monthly installments following such interest-only period. Additionally, pursuant to the amendment the aggregate outstanding principal amount of our permitted indebtedness, consisting of capitalized lease obligations and purchase money indebtedness outstanding at any time, was increased to $1.2 million. The June 30, 2016 amendment of our April 2014 Credit Facility was accounted for as a modification of debt under applicable accounting guidance.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to us and any subsidiaries created 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 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 loan 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, 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.

A warrant to purchase up to 17,655 shares of our common stock at an exercise price of $14.16 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014. Issuance costs of $102,498 associated with the term loan under the April 2014 Credit Facility were recorded as a discount to outstanding debt as of the closing date, resulting in net proceeds of $4,897,502. The estimated fair value of the warrant issued of $233,107 was also 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 effective annual interest rate associated with the April 2014 Credit Facility was 11.50% and 13.87% at December 31, 2015 and December 31, 2016, respectively.

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,	
	2015	**2016**
(dollars in thousands)		
Cash provided by/(used in):		
Operating activities	$ (15,155)	$ (15,697)
Investing activities	(165)	(451)
Financing activities	18,777	11,936
Net increase/(decrease) in cash	$ 3,457	$ (4,212)

Cash Used in Operating Activities . Net cash used in operating activities was $15.7 million for the year ended December 31, 2016, compared to net cash used in operating activities of $15.2 million for the year ended December 31, 2015. The net

increase of $0.5 million in cash used in operatin g activities for the year ended December 31, 2016 as compared to the same period in 2015 was primarily related to an increase of $1.4 million in cash used to fund our net loss, partially offset by an increase of approximately $0.7 million in cash provided by operating assets and liabilities, as well as an increase of $0.2 million in adjustments to reconcile net loss to net cash used in operating activities primarily related to stock compensation expense, depreciation expense, and non-cash interest expense.

Cash Used in Investing Activities . Net cash used in investing activities of approximately $451,000 and $165,000 during the years ended December 31, 2016 and 2015, respectively, was related to the acquisition of fixed assets.

Cash Provided by Financing Activities . Net cash provided by financing activities was $11.9 million for the year ended December 31, 2016, compared to net cash provided by financing activities of $18.8 million for the year ended December 31, 2015. Our primary sources of cash from financing during the year ended December 31, 2015 consisted of proceeds from our public offering in February 2015 and the exercise of common stock warrants sold in that offering. Our primary sources of cash from financing during the year ended December 31, 2016 consisted of $9.0 million and $4.3 million in net proceeds from our public offerings in October 2016 and May 2016, respectively, as well as $0.5 million in proceeds from the sale of common stock to Aspire Capital under our then-existing common stock purchase agreement, which was partially offset by $1.8 million of principal payments made on indebtedness.

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 the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, 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 assays, acquire equipment, implement automation and scale our capabilities to prepare for significant assay volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with expanded commercial activities. We may also use the net proceeds from our sale of equity securities, if any, 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, 2016, our cash totaled $4.6 million, and our outstanding net indebtedness totaled $4.4 million. 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. Management expects that we will need additional financing to execute on our current or future business strategies beyond July 2017.

On February 13, 2015, we received net cash proceeds of $8.8 million as a result of the closing of a follow-on public offering. Subsequent to the closing of this follow-on public offering on February 13, 2015, additional cash proceeds of approximately $9.8 million have been received from the exercise of warrants sold in this offering, while approximately $2.7 million in gross warrant proceeds remain outstanding and available to be exercised at $4.68 per share until their expiration in February 2020.

In May 2015, the SEC declared effective a shelf registration statement filed by us. The shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to $50 million, subject to certain limitations for so long as our public float is less than $75 million. Pursuant to an exclusive placement agent agreement dated April 25, 2016 between us and H.C. Wainwright & Co., LLC, or Wainwright, and a securities purchase agreement dated April 29, 2016 between us and the purchasers signatory thereto, we received approximately $4.3 million of net cash proceeds upon the sale of our common stock and warrants to purchase our common stock. Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately $4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at $3.90 per share until their expiration in May 2021. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

On December 21, 2015, we entered into a common stock purchase agreement with Aspire Capital, which committed to purchase up to an aggregate of $15.0 million of shares of our common stock over the 30-month term of the common stock

purchase agreement. On November 4, 2016, we voluntarily terminated this c ommon stock purchase agreement . Upon execution of the common stock purchase agreement, we sold to Aspire Capital 208,334 shares of common stock at $4.80 per share for gross proceeds of $1,000,000, before deducting approximately $0.1 million of costs direct ly associated with this offering, and we concurrently also entered into a registration rights agreement with Aspire Capital, pursuant to which we filed a registration statement registering the sale of the shares of our common stock that were issued to Aspi re Capital under the common stock purchase agreement. In consideration for entering into, and concurrently with the execution of, the common stock purchase agreement, we issued to Aspire Capital 55,000 shares of our common stock. During the year ended Dece mber 31, 2016, we submitted purchase notices to Aspire Capital for an aggregate of 173,145 shares of common stock for gross proceeds of $544,051.

On October 19, 2016, we received net cash proceeds of approximately $9.0 million as a result of the closing of a follow-on public offering. Subsequent to the closing of this public offering on October 19, 2016, the underwriters have exercised their overallotment option to purchase 627,131 option warrants for total proceeds of $564. Subsequent to December 31, 2016, approximately $5.3 million of additional cash proceeds had been received from the exercise of warrants sold in this offering, with approximately $5.4 million in gross warrant proceeds remaining outstanding and available to be exercised at $1.10 per share until their expiration in October 2021.

We expect that we will need additional financing to execute on our current or future business strategies. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time, subject to certain restrictions that apply for so long as our public float is less than $75 million. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. 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. 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 assays;
- 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 assays 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 our other filings with the SEC.

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 unp rofitable operating history and our ability or inability to develop additional assays, 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 limi t 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.
Index to Financial Statements

R EPORT 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, 2016 and 2015, and the related statements of operations and comprehensive loss, shareholders' equity 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, 2016 and 2015, 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.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses from operations and is dependent on future financings to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plan regarding these matters is also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Mayer Hoffman McCann P.C.
San Diego, California
March 28, 2017

Biocept, Inc.

Balance Sheets

	December 31, 2015	December 31, 2016
Current assets:		
Cash	$ 8,821,329	$ 4,609,332
Accounts receivable	34,200	128,969
Inventories, net	349,271	549,045
Prepaid expenses and other current assets	435,938	484,649
Total current assets	9,640,738	5,771,995
Fixed assets, net	946,180	1,806,331
Total assets	$ 10,586,918	$ 7,578,326
Current liabilities:		
Accounts payable	$ 632,538	$ 960,486
Accrued liabilities	966,899	1,160,036
Supplier financings	42,369	75,691
Current portion of equipment financings	110,924	262,674
Current portion of credit facility	1,588,058	1,934,665
Total current liabilities	3,340,788	4,393,552
Non-current portion of equipment financings	291,189	778,643
Non-current portion of credit facility, net	2,638,487	1,123,001
Non-current portion of interest payable	153,547	227,177
Non-current portion of deferred rent	470,172	397,292
Total liabilities	6,894,183	6,919,665
Commitments and contingencies (see Note 16)		
Shareholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 authorized; no shares issued and outstanding at December 31, 2015 and 2016.	—	—
Common stock, $0.0001 par value, 40,000,000 authorized; 6,556,685 issued and outstanding at December 31, 2015; 150,000,000 authorized; 17,499,397 issued and outstanding at December 31, 2016.	656	1,750
Additional paid-in capital	158,928,627	174,292,781
Accumulated deficit	(155,236,548)	(173,635,870)
Total shareholders' equity	3,692,735	658,661
Total liabilities and shareholders' equity	$ 10,586,918	$ 7,578,326

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,	
	2015	2016
Revenues:	$ 609,909	$ 3,223,096
Costs and expenses:		
Cost of revenues	4,596,158	6,920,111
Research and development expenses	2,857,770	2,713,367
General and administrative expenses	5,686,398	6,560,425
Sales and marketing expenses	3,880,386	5,054,230
Total costs and expenses	17,020,712	21,248,133
Loss from operations	(16,410,803)	(18,025,037)
Other income/(expense):		
Interest expense, net	(639,547)	(525,880)
Other income	102,432	153,648
Total other income/(expense):	(537,115)	(372,232)
Loss before income taxes	(16,947,918)	(18,397,269)
Income tax expense	(1,608)	(2,053)
Net loss and comprehensive loss	$ (16,949,526)	$ (18,399,322)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:		
Basic	5,512,989	9,578,285
Diluted	5,512,989	9,578,285
Net loss per common share:		
Basic	$ (3.07)	$ (1.92)
Diluted	$ (3.07)	$ (1.92)

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

Biocept, Inc.

Statements of Shareholders' Equity/ (Deficit)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-in Capital	Deficit	Total
Balance at December 31, 2014	1,483,199	$ 148	$ 138,066,305	$ (138,287,022)	$ (220,569)
Stock-based compensation expense	—	—	1,377,824	—	1,377,824
Shares issued for restricted stock units	58,003	6	(6)	—	—
Shares and warrants issued for February 2015 public offering, net of issuance costs	2,666,666	267	8,766,679	—	8,766,946
Shares issued pursuant to stock purchase agreement, net of issuance costs	263,334	26	957,974	—	958,000
Shares issued upon exercise of common stock warrants	2,085,483	209	9,759,851	—	9,760,060
Net loss	—	—	—	(16,949,526)	(16,949,526)
Balance at December 31, 2015	6,556,685	656	158,928,627	(155,236,548)	3,692,735
Stock-based compensation expense	—	—	1,593,947	—	1,593,947
Shares issued for restricted stock units	4,449	1	(1)	—	—
Shares and warrants issued for May 2016 public offering, net of issuance costs	1,662,191	166	4,333,117	—	4,333,283
Shares and warrants issued for October 2016 public offering, net of issuance costs	9,100,000	910	8,971,815	—	8,972,725
Shares issued pursuant to stock purchase agreement, net of issuance costs	173,145	17	465,276	—	465,293
Fractional shares issued upon one-for-three reverse stock split	2,927	—	—	—	—
Net loss	—	—	—	(18,399,322)	(18,399,322)
Balance at December 31, 2016	17,499,397	$ 1,750	$ 174,292,781	$ (173,635,870)	$ 658,661

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

Biocept, Inc.

Statements of Cash Flows

	For the year ended December 31,	
	2015	2016
Cash Flows From Operating Activities		
Net loss	$ (16,949,526)	$ (18,399,322)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	261,409	322,029
Inventory reserve	(34,437)	(31,659)
Stock-based compensation	1,377,824	1,593,947
Non-cash interest expense related to credit facility and other financing activities	119,732	100,005
Gain on sale of fixed assets	—	(30,662)
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable	(23,600)	(94,769)
Inventory	(126,106)	(168,115)
Prepaid expenses and other current assets	(80,432)	494,734
Accounts payable	(51,790)	332,732
Accrued liabilities	240,901	165,543
Accrued interest	110,021	55,444
Deferred rent	1,163	(36,965)
Net cash used in operating activities	(15,154,841)	(15,697,058)
Cash Flows From Investing Activities:		
Proceeds from sale of fixed assets	—	30,662
Purchases of fixed assets	(165,160)	(482,065)
Net cash used in investing activities	(165,160)	(451,403)
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock and warrants	9,788,057	13,771,301
Proceeds from exercise of common stock warrants	9,760,060	—
Payments on equipment financings	(74,697)	(86,227)
Payments on supplier and other third party financings	(71,232)	(510,123)
Payments on line of credit	(625,440)	(1,238,487)
Net cash provided by financing activities	18,776,748	11,936,464
Net increase/(decrease) in Cash	3,456,747	(4,211,997)
Cash at Beginning of Period	5,364,582	8,821,329
Cash at End of Period	$ 8,821,329	$ 4,609,332
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ 405,715	$ 358,632
Taxes	$ 2,184	$ 2,053

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

Non-cash Investing and Financing Activities:

A public offering of the Company's common stock and warrants to purchase its common stock was effected on February 9, 2015, the closing of which occurred on February 13, 2015 (see Note 4). In connection with the closing of this offering, (i) warrants were issued to buy (in the aggregate) up to 2,666,666 shares of common stock at an exercise price of $4.68 per share with a term of five years and an estimated grant date fair value of approximately $7.7 million, which was recorded as an offset to additional paid-in capital within common stock issuance costs (see Note 5), (ii) the underwriters were granted a 45 day option from the closing date of this offering to purchase up to 400,000 additional shares of common stock at a price of $3.75 per share and/or additional warrants to purchase up to 400,000 shares of common stock at a price of $0.0003 per warrant, less underwriting discounts and commissions, to cover overallotments, if any, with an aggregate estimated grant date fair value of approximately $1.6 million that was recorded to common stock issuance costs (see Note 5), and (iii) costs of $63,111 directly associated with this offering that were included in prepaid expenses and other current assets at December 31, 2014 were reclassified to common stock issuance costs.

A public offering of the Company's common stock and warrants to purchase its common stock was effected on April 29, 2016, the closing of which occurred on May 4, 2016 (see Note 4). In connection with the closing of this offering, warrants were issued to buy (in the aggregate) up to 1,163,526 shares of common stock at an exercise price of $3.90 per share with a term of five years and an estimated grant date fair value of approximately $2.0 million, which was recorded as an offset to additional paid-in capital within common stock issuance costs (see Note 5). Additionally, approximately $653,000 of fees and costs directly associated with this offering were recorded as an offset to additional paid-in capital within common stock issuance costs in accordance with applicable accounting guidance.

A public offering of the Company's common stock and warrants to purchase its common stock was effected on October 14, 2016, the closing of which occurred on October 19, 2016 (see Note 4). In connection with the closing of this offering, warrants to purchase up to an aggregate of 9,100,000 shares of common stock with estimated grant date fair value of approximately $0.57 per share were issued (see Note 5). Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of $1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of $0.0009 per warrant to cover overallotments, if any (see Note 5). The estimated aggregate grant date fair value of the overallotment options and warrants of approximately $0.8 million, as well as an additional approximate $1.0 million of fees and costs directly associated with this offering, were recorded as an offset to additional paid-in capital within common stock issuance costs in accordance with applicable accounting guidance.

Fixed assets purchased totaling $337,085 and $975,406 during the years ended December 31, 2015 and 2016, respectively, were recorded as equipment financings and were excluded from cash purchases in the Company's statements of cash flows (see Notes 6 and 8). During the year ended December 31, 2016, fixed assets with an aggregate net book value of $270,377, which had previously been recorded as equipment financings with remaining outstanding balances owed totaling $239,994, were effectively disposed of and replaced with upgraded equipment recorded as equipment financings.

The amount of unpaid fixed assets excluded from cash purchases in the Company's statements of cash flows increased from $19,546 at December 31, 2014 to $64,300 at December 31, 2015, and decreased to $58,066 at December 31, 2016.

During the years ended December 31, 2015 and 2016, the Company financed insurance premiums of $79,896 and $547,378, respectively, through third party financings (see Note 9). During the year ended December 31, 2016, the Company received a partial refund of $3,933 related to an insurance premium previously financed.

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

1. The Company and Business Activities

Biocept, Inc., or the Company, was founded in California in May 1997 and is an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample. The Company's assays provide, and its planned future assays will provide, information to oncologists and other physicians that enable them to select appropriate personalized treatment for their patients who have been diagnosed with cancer based on molecular drivers and markers of their disease and when traditional methodologies such as tissue biopsies are insufficient or unavailable. The Company's assays have potential to provide more contemporaneous information on the characteristics of a patients' disease compared with traditional methodologies such as tissue biopsy and imaging.

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 cell enrichment and extraction microfluidic channels, related equipment and certain reagents to perform the Company's diagnostic assays 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 assays the Company offers are classified as laboratory developed tests 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. Liquidity and Going Concern Uncertainty

As of December 31, 2016, cash totaled $4.6 million and the Company had an accumulated deficit of $173.6 million. For the years ended December 31, 2015 and 2016, the Company incurred net losses of $16.9 million and $18.4 million, respectively. At December 31, 2016, the Company had aggregate net interest-bearing indebtedness of approximately $4.4 million, of which approximately $2.3 million was due within one year in the absence of subjective acceleration of amounts due under a credit facility entered into in April 2014 with Oxford Finance LLC, or the April 2014 Credit Facility, in addition to approximately $2.1 million of other non-interest bearing current liabilities. Additionally, in February 2016, the Company signed a firm, noncancelable, and unconditional commitment in an aggregate amount of $1,062,500 with a vendor to purchase certain inventory items, payable in minimum quarterly installments of $62,500 through May 2020, under which $812,500 remained outstanding at December 31, 2016 (see Note 16). These factors raise substantial doubt about the Company's ability to continue as a going concern for the one year period following the date that these financial statements were issued. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

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 for 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 exercise of warrants to purchase common stock, proceeds from the issuance of debt, and revenues from laboratory services. 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 growth in net revenues to achieve and sustain income from operations.

Subsequent to the closing of the Company's public offering in February 2015, cash proceeds of approximately $9.8 million have been received by the Company from the exe rcise of warrants sold in this offering, while approximately $2.7 million in gross warrant proceeds remain outstanding and available to be exercised at $4.68 per share until their expiration in February 2020. In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to $50 million, subject to certain limitations for so long as the Company's public float is less than $75 million. A public offering of the Company's common stock and warrants to purchase its common stock was effected under this shelf registration statement on April 29, 2016, the closing of which occurred on May 4, 2016, pursuant to which the Company received net cash proceeds of approximately $4.3 million (see Note 4). Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately $4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at $3.90 per share until their expiration in May 2021. In connection with its public offering in May 2016, the Comp any has agreed to certain contractual terms that limit its ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the ti me of such offerings. A public offering of the Company's common stock and warrants to purchase its common stock was effected under an underwriting agreement dated October 14, 2016 between the Company, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, the closing of which occurred on October 19, 2016, pursuant to which the Company received net cash proceeds of approximately $9.0 million (see Note 4). Subsequent to December 31, 2016, cash proceeds of approximately $5.3 mil lion have been received by the Company from the exercise of warrants sold in this offering, while approximately $5.4 million in gross warrant proceeds remain outstanding and available to be exercised at $1.10 per share until their expiration in October 202 1.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Until the Company can generate significant cash from operations, including assay revenues, management's plans to obtain such resources for the Company include proceeds from offerings of the Company's equity securities or debt, or transactions involving product development, technology licensing or collaboration. 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.

3. 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. Certain prior period amounts have been reclassified to conform to the current period presentation.

On September 27, 2016, the Company's stockholders approved, and the Company filed, an amendment to the Company's amended and restated certificate of incorporation to effect a one-for-three reverse stock split of the Company's outstanding common stock, and to increase the authorized number of shares of the Company's common stock from 40,000,000 to 150,000,000 shares. The one-for-three reverse stock split was effected on September 29, 2016 . As such, all references to share and per share amounts in these financial statements and accompanying notes have been retroactively restated to reflect the one-for-three reverse stock split, except for the authorized number of shares of the Company's common stock of 150,000,000 shares , which was not affected by the one-for-three reverse stock split.

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, 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.

Revenue Recognition

Four basic criteria must be met before the Company recognizes revenue: (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.

Approximately 11% and 7% of the Company's revenues for the years ended December 31, 2015 and 2016, respectively, resulted from agreements with contracted partners not associated with third party insurance or payor reimbursement. 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 and results are delivered.

Cash

The Company places its cash with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation, or 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 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, 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.

Concentrations of credit risk with respect to revenues are primarily limited to geographies to which the Company provides a significant volume of its services, and to specific third party payors of the Company's services such as Medicare and individual insurance companies and other third party payors. The Company's client base consists of a large number of geographically dispersed clients diversified across various customer types. Approximately 41% and 40% of the Company's total revenues during the years ended December 31, 2015 and 2016, respectively, were associated with Medicare reimbursement. For the year ended December 31, 2015, the first, second, and third most significant third party payors not associated with Medicare reimbursement accounted for approximately 21%, 7%, and 6%, respectively, of total revenues. For the year ended December 31, 2016, the first, second, and third most significant third party payors not associated with Medicare reimbursement accounted for approximately 19%, 11%, and 9%, respectively, of total revenues. For the year ended December 31, 2015, the first, second, and third most significant individual clients or practices accounted for approximately 12%, 9%, and 5%, respectively, of total revenues. For the year ended December 31, 2016, the first, second, and third most significant individual clients or practices accounted for approximately 10%, 7%, and 4%, respectively, of total revenues.

The Company operates in one reportable business segment and historically has derived most revenues only from the United States.

Certain components used in the Company's current or planned products are currently sourced from one supplier for which alternative suppliers exist, but the Company has not validated the product(s) of such alternative supplier(s), and substitutes for these components may not be obtained easily or may require substantial design or manufacturing modifications.

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, 2015 and 2016, 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. In addition, the Company records a liability for firm, noncancelable, and unconditional purchase commitments with contract manufacturers and suppliers for quantities in excess of the Company's future demand forecasts consistent with its valuation of excess and obsolete inventory.

Fixed Assets

Fixed assets consist of machinery and equipment, furniture and fixtures, computer equipment and software, leasehold improvements, financed 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 seven 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, 2015 and 2016 was approximately $261,000 and $322,000, respectively.

Upon sale 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 and comprehensive loss.

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.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees and directors based on their grant date fair values. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model, while the fair value of restricted stock unit awards, or RSUs, 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 Note 10).

The Company determines the fair value of the 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.

C alculating 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 uncertain ties, and the application of management's judgment. Significant estimates include 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, 2015 and 2016 were approximately $2,858,000 and $2,713,000, 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, 2015 and 2016, and therefore has not recognized any income tax benefit or expense in the periods presented.

A tax benefit from uncertain tax positions may be recognized by the Company 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.

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, 2015 and 2016, and the Company has not recognized interest and/or penalties in the statements of operations and comprehensive loss for the years ended December 31, 2015 and 2016.

Recent Accounting Pronouncements

In May 2014, and as subsequently updated and amended from time to time, 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 proposed guidance has been deferred and would be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. As the Company has not yet completed its final review of the impact of the new guidance but expects to during 2017, the Company has not determined whether the adoption of this guidance will have a material impact on its financial statements or disclosures. The Company is still evaluating disclosure requirements under the new guidance, and will continue to evaluate additional changes, modifications or interpretations to the guidance which may impact the current conclusions. The Company expects to adopt the new standard for the fiscal year beginning January 1, 2018 and has not yet determined whether the full or modified retrospective application method will be applied.

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. T he Company adopted this guidance for the reporting period beginning on January 1, 2016. The adoption of this guidance did not have a material impact on the Company's 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 adopted this guidance during the year ended December 31, 2016. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In July 2015, the FASB issued authoritative guidance requiring entities that do not measure inventory using the retail inventory method or on a last-in, first-out basis to record inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This guidance is effective on a prospective basis for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In January 2016, the FASB issued authoritative guidance requiring, among other things, that certain equity investments be measured at fair value with changes in fair value recognized in net income, that financial assets and financial liabilities be presented separately by measurement category and form of financial asset on the balance sheet or the accompanying notes to the financial statements, that the prior requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet be eliminated, and that a reporting organization is to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption of the instrument-specific credit risk amendment is permitted. The Company expects to adopt this guidance for the fiscal year beginning on January 1, 2018, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently have any equity method investments.

In February 2016, the FASB issued authoritative guidance requiring, among other things, that entities recognize the assets and liabilities arising from leases on the balance sheet under revised criteria, while the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria in the previous leases guidance. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company anticipates that the adoption of this guidance will materially affect its statement of financial position and will require changes to its processes. The Company has not yet made any decision on the timing of adoption or method of adoption with respect to the optional practical expedients, but expects to during 2018.

In March 2016, the FASB issued authoritative guidance clarifying that a change in the counterparty to a derivative instrument that has been designated as the hedging instrument does not necessarily require dedesignation of that hedging relationship, provided that all other applicable hedge accounting criteria continue to be met. This guidance is effective on either a prospective basis or modified retrospective basis for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In March 2016, the FASB issued authoritative guidance requiring entities to assess whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts, and clarifies what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts. This guidance is effective on a modified retrospective basis for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early

adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material im pact on the Company's financial statements or disclosures.

In March 2016, the FASB issued authoritative guidance simplifying the accounting for stock compensation. This guidance, among other things, amends existing accounting and classification requirements primarily around income taxes, forfeitures, and cash payments associated with share-based payment awards to employees. This guidance is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In August 2016, the FASB issued authoritative guidance clarifying the classification of certain cash receipts and cash payments in the statement of cash flows. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, on a retrospective transition method to each period presented. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2018, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company has not historically engaged in the transactions encompassed by the proposed guidance.

In January 2017, the FASB issued authoritative guidance clarifying the definition of a business when evaluating transactions involving acquisitions or disposals of assets or businesses. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Certain applications of this guidance are permitted for early adoption. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2018, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company has not historically acquired or disposed of material assets or businesses.

4. Sales of Equity Securities

Pursuant to an underwriting agreement dated February 9, 2015 between the Company, Aegis Capital Corp. and Feltl and Company, Inc., as underwriters named therein, a public offering of 2,666,666 shares of the Company's common stock and warrants to purchase up to an aggregate of 2,666,666 shares of common stock was effected at a combined offering price of $3.75. The estimated grant date fair value of these warrants of $7.7 million was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering. All warrants sold in this offering have a per share exercise price of $4.68, 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 $1.2 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, $8.8 million of net cash proceeds. Additionally, the underwriters were granted a 45-day option to purchase up to 400,000 additional shares of common stock at a price of $3.75 per share and/or additional warrants to purchase up to 400,000 shares of common stock at a price of $0.0003 per warrant, less underwriting discounts and commissions, to cover overallotments, if any, which was not exercised. The estimated grant date fair value of the overallotment options and warrants of $1.6 million was recorded as an offset to additional paid-in capital within common stock issuance costs upon the closing of this offering. Subsequent to the closing of this offering on February 13, 2015, additional cash proceeds of $9.8 million have been received from the exercise of warrants sold in this offering. As such, the aggregate total net increase in capital related to this offering has been approximately $18.6 million.

In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to $50 million, subject to certain limitations for so long as the Company's public float is less than $75 million. Pursuant to an exclusive placement agent agreement dated April 25, 2016 between the Company and H.C. Wainwright & Co., LLC, or Wainwright, and a securities purchase agreement dated April 29, 2016 between the Company and the purchasers signatory thereto, a public offering of 1,662,191 shares of the Company's common stock and warrants to purchase up to an aggregate of 1,163,526 shares of common stock was effected under this registration statement at a combined offering price of $3.00. All warrants sold in this offering have a per share exercise price of $3.90, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the purchasers occurred on May 4, 2016, pursuant to which the Company received, after deducting $0.7 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, approximately $4.3 million of net cash proceeds. Subsequent to the closing of this public offering on May 4, 2016,

no warrants sold in this offering have been exercised, with approximately $4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at $3.90 per share until their expiration in May 2021. In connection with its public offering in May 2016, the Company has agreed to certain contractual terms that limit its ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at t he time of such offerings.

On December 21, 2015, the Company entered into a common stock purchase agreement with Aspire Capital Fund, LLC, or Aspire Capital, which committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 30-month term of the common stock purchase agreement. On November 4, 2016, the Company voluntarily terminated this common stock purchase agreement. Upon execution of the common stock purchase agreement, the Company sold to Aspire Capital 208,334 shares of common stock at $4.80 per share for proceeds of $1,000,000, and concurrently also entered into a registration rights agreement with Aspire Capital, pursuant to which the Company filed a registration statement registering the sale of the shares of the Company's common stock that were issued to Aspire Capital under the common stock purchase agreement. In consideration for entering into, and concurrently with the execution of, the common stock purchase agreement, the Company issued to Aspire Capital 55,000 shares of its common stock. The proceeds received by the Company under the common stock purchase agreement were used for working capital and general corporate purposes. During the year ended December 31, 2016, the Company submitted purchase notices to Aspire Capital for an aggregate of 173,145 shares of common stock for gross proceeds of $544,051. Costs associated with this offering of approximately $42,000 and $79,000 during the years ended December 31, 2015 and 2016, respectively, were also recorded to common stock issuance costs under applicable accounting guidance, and as such, the total net increase in capital related to these transactions were approximately $1.4 million.

Pursuant to an underwriting agreement dated October 14, 2016 between the Company, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, a public offering of 9,100,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 9,100,000 shares of common stock was effected at a combined offering price of $1.10. The estimated grant date fair value of these warrants of approximately $5.2 million was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering (see Note 5). Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of $1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of $0.0009 per warrant to cover overallotments, if any, of which the underwriters have exercised their overallotment option to purchase 627,131 option warrants for total proceeds to the Company of $564. The estimated aggregate grant date fair value of the overallotment options and warrants of approximately $0.8 million was recorded as an offset to additional paid-in capital within common stock issuance costs upon the closing of this offering (see Note 5). All warrants sold in this offering have a per share exercise price of $1.10, 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 October 19, 2016, when the Company received, after deducting $1.0 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, $9.0 million of net cash proceeds. Subsequent to December 31, 2016, approximately $5.3 million of additional cash proceeds had been received from the exercise of warrants sold in this offering (see Note 18). As such, the total net increase in capital as a result of the sale of these shares and warrants has been $14.3 million.

5. Fair Value Measurement

The estimated fair value of the April 2014 Credit Facility at December 31, 2016 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.

In connection with the closing of the Company's February 2015 public offering, warrants were issued to buy (in the aggregate) up to 2,666,666 shares of common stock with an estimated grant date fair value of approximately $7.7 million, which was recorded as an offset to additional paid-in capital within common stock issuance costs. Also in connection with the closing of the Company's follow-on public offering on February 13, 2015, the underwriters were granted a 45 day option from the closing date of the offering to purchase up to 400,000 additional shares of common stock at a price of $3.75 per share and/or additional warrants to purchase up to 400,000 shares of common stock at a price of $0.0003 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any. The estimated aggregate grant date fair value of these over-allotment options and warrants of approximately $1.6 million was also recorded to common stock issuance costs

as a component of additional paid-in capital. The fair values of these over-allotment options and all common stock warrants issued in this offering were estimated using Black-Scholes valuation models with the following assumptions:

	Over-allotment Options	Warrants
Stock price	$ 4.23	$ 4.23
Exercise price	$ 3.75	$ 4.68
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.02%	1.53%
Expected life (in years)	0.12	5.00
Expected volatility	168.1%	90.0%

As of the closing of the Company's May 2016 public offering, the estimated grant date fair value of $1.72 per share associated with the warrants to purchase 1,163,526 shares of common stock issued in this offering, or a total of approximately $2.0 million, was recorded as an offset to additional paid-in capital within common stock issuance costs, and was estimated using a Black-Scholes valuation model with the following assumptions:

Stock price	$ 2.70
Exercise price	$ 3.90
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	1.23%
Expected life (in years)	5.00
Expected volatility	90.0%

As of the closing of the Company's October 2016 public offering, the estimated grant date fair value of $0.57 per share associated with the warrants to purchase 9,100,000 shares of common stock issued in this offering, or a total of approximately $5.2 million, was recorded as an offset to additional paid-in capital within common stock issuance costs. Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of $1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of $0.0009 per warrant to cover overallotments, if any. The estimated fair value of the overallotment options of approximately $0.8 million was also recorded as an offset to additional paid-in capital within common stock issuance costs. The fair values of these instruments were estimated using a Black-Scholes valuation model with the following assumptions:

	Overallotment Options	Warrants
Stock price	$ 0.93	$ 0.93
Exercise price	$ 1.0331	$ 1.10
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.25%	1.24%
Expected life (in years)	0.08	5.00
Expected volatility	12.9%	80.0%

6. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2015	December 31, 2016
Fixed Assets		
Machinery and equipment	$ 2,518,158	$ 2,728,468
Furniture and office equipment	143,726	143,726
Computer equipment and software	577,898	620,582
Leasehold improvements	514,614	517,968
Financed equipment	914,179	1,559,690
Construction in process	70,815	169,896
	4,739,390	5,740,330
Less accumulated depreciation and amortization	(3,793,210)	(3,933,999)
Total fixed assets, net	$ 946,180	$ 1,806,331
Accrued Liabilities		
Accrued interest	$ 28,981	$ 20,776
Accrued payroll	128,753	168,727
Accrued vacation	307,845	364,953
Accrued bonuses	376,100	422,868
Accrued sales commissions	76,574	77,844
Current portion of deferred rent	31,170	67,085
Accrued other	17,476	37,783
Total accrued liabilities	$ 966,899	$ 1,160,036

During the years ended December 31, 2015 and 2016, non-financed equipment fixed assets with aggregate gross book values and corresponding accumulated depreciation amounts of approximately $1,076,000 and $77,000, respectively, were disposed of or sold. Total cash proceeds of $30,662 were received upon the sale of fixed assets during the year ended December 31, 2016.

7. April 2014 Credit Facility

On April 30, 2014, the Company received net cash proceeds of approximately $4,898,000 pursuant to the execution of the April 2014 Credit Facility with Oxford Finance LLC. Upon the entry into the April 2014 Credit Facility, the Company was required to pay the lender a facility fee of $50,000 in conjunction with the funding of the term loan. The April 2014 Credit Facility is secured by substantially all of the Company's personal property other than its intellectual property. Amounts due to Oxford Finance LLC under the April 2014 Credit Facility are callable before maturity by the lender under certain subjective acceleration clauses of the underlying agreement, including changes deemed to be materially adverse by the lender. The 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 term loan, plus (b) 7.71%. The term loan bears interest at an annual rate of 7.95%. The Company was required to make interest-only payments on the term loan through August 1, 2015. The outstanding term loan under the April 2014 Credit Facility began amortizing at the end of the applicable interest-only period, with monthly payments of principal and interest being made by the Company to the lender in consecutive monthly installments following such interest-only period. The term loan under the April 2014 Credit Facility matures on July 1, 2018. Under the original terms of the underlying agreement, the Company is also required to make a final payment to the lender equal to 5.5% of the original principal amount of the term loan funded. At its option, the Company may prepay the outstanding principal balance of the term loan in whole but not in part, subject to a prepayment fee of 1% of any amount prepaid.

On June 30, 2016, the Company entered into an amendment of the April 2014 Credit Facility. This amendment required the Company to make interest-only payments on the term loan from July 1, 2016 through September 30, 2016, and also requires an additional final payment of $50,000 to the lender. The terms of the amendment require the amortization of the outstanding amount due under the term loan to commence at the end of the applicable interest-only period, with monthly payments of

principal and interest, in arrears, being made by the Company to the lender in consecutive monthly installments following such interest-only period. Additionally, pursuant to the amendment th e aggregate outstanding principal amount of the Company's permitted indebtedness, consisting of capitalized lease obligations and purchase money indebtedness outstanding at any time, was increased to $1.2 million. The June 30, 2016 amendment of the April 2 014 Credit Facility was accounted for as a modification of debt under applicable accounting guidance. On March 27, 2017, the Company received a waiver from the lender regarding exceeding the permitted indebtedness limit during the month ended January 31, 2 017.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to the Company and any subsidiaries created 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 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 loan under the April 2014 Credit Facility, including foreclosure against the Company's properties securing the April 2014 Credit Facility, including its 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, 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 17,655 shares of the Company's common stock at an exercise price of $14.16 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014. Issuance costs of $102,498 associated with the term loan under the April 2014 Credit Facility were recorded as a discount to outstanding debt as of the closing date, resulting in net proceeds of $4,897,502. The estimated fair value of the warrant issued of $233,107 was also 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, with a total unamortized discount of $78,408 remaining at December 31, 2016. The effective annual interest rate associated with the April 2014 Credit Facility was 11.50% and 13.87% at December 31, 2015 and 2016, respectively. As of December 31, 2016, total principal payments of $1,934,665 and $1,201,409 were due under the April 2014 Credit Facility during the years ending December 31, 2017 and 2018, respectively.

8. Equipment Financings

The Company leases certain laboratory equipment under arrangements accounted for as capital leases and classified as equipment financings. The financed equipment is depreciated on a straight-line basis over periods ranging from 5 to 7 years. The total gross value of fixed assets capitalized under such financing arrangements was $914,179 and $1,559,690 at December 31, 2015 and 2016, respectively. Total accumulated depreciation related to financed equipment was approximately $523,000 and $525,000 at December 31, 2015 and 2016, respectively. Total depreciation expense related to financed equipment was approximately $73,000 and $119,000 for the years ended December 31, 2015 and 2016, respectively. Fixed assets purchased totaling $337,085 and $975,406 during the years ended December 31, 2015 and 2016, respectively, were recorded as equipment financings. During the year ended December 31, 2016, fixed assets with an aggregate net book value of $270,377, which had previously been recorded as equipment financings with remaining outstanding balances owed totaling $239,994, were effectively disposed of and replaced with upgraded equipment recorded as equipment financings. The aggregate weighted average effective annual interest rate related to the equipment financings is 13.18% at December 31, 2016, and the maturity dates on such outstanding arrangements range from July 2017 to May 2023.

The following schedule sets forth the future minimum lease payments outstanding under financed equipment arrangements, as well as corresponding laboratory equipment maintenance obligations that are expensed and accrued as incurred, and due within each respective year ending December 31, as well as the present value of the minimum lease payments as of December 31, 2016:

	Minimum Lease Payments	Maintenance Obligation Payments
2017	$ 274,367	$ 27,495
2018	242,040	27,490
2019	205,067	26,733
2020	203,107	26,664
2021	203,107	26,664
Thereafter	381,354	37,774
Total payments	1,509,042	172,820
Less amount representing interest	467,725	—
Present value of payments	$ 1,041,317	$ 172,820

At December 31, 2016, the present value of minimum lease payments due within one year was $262,674.

9. Supplier Financings

In 2015 and 2016, the Company obtained third-party financing for certain business insurance premiums. The 2015 and 2016 financings bear interest rates ranging from 3.75% to 5.95% per annum, and all financing is due within one year. The balances due under these annual financing arrangements were approximately $42,000 and $76,000 as of December 31, 2015 and 2016, respectively.

10. Stock-Based Compensation

On September 29, 2016, the Company effected a one-for-three reverse stock split of all common shares outstanding. The following per share amounts and share numbers have been adjusted for this reverse stock split as if it had occurred on December 31, 2014.

Equity Incentive Plans

The Company maintains two equity incentive plans: The Amended and Restated 2013 Equity Incentive Plan, or the 2013 Plan, and the 2007 Equity Incentive Plan, or the 2007 Plan. The 2013 Plan includes a provision that shares available for grant under the Company's 2007 Plan become available for issuance under the 2013 Plan and are no longer available for issuance under the 2007 Plan. On July 25, 2016, the Company's Board of Directors approved an amendment to the 2013 Plan to reserve 1,000,000 shares on a pre-reverse stock split basis, or 333,333 shares on a post-reverse stock split basis, of the Company's common stock exclusively for the grant of stock awards to employees who have not previously been an employee or director of the Company, except following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company, as defined under applicable Nasdaq Listing Rules. In conjunction with the one-for-three reverse split of the Company's common stock effected on September 29, 2016, the number of non-inducement shares authorized under all plans decreased from 3,068,865 to 1,022,955 shares, and the number of inducement shares authorized under the 2013 Plan decreased from 1,000,000 shares to 333,333 shares. As of December 31, 2016, under all plans, a total of 1,022,955 non-inducement shares were authorized for issuance, 987,394 shares had been issued, 945,912 non-inducement stock options and RSUs were outstanding, and 35,561 non-inducement shares were available for grant. As of December 31, 2016, a total of 333,333 inducement shares were authorized for issuance, 124,999 inducement stock options and RSUs had been issued and were outstanding, and 208,334 inducement shares were available for grant under the 2013 Plan.

Stock Options

Non-performance options granted under either plan vest over a maximum period of four years and expire ten years from the date of grant. Non-performance 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.

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 recogni zed 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 and when the achievement of the performance objectives is probable. 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 as sumption 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, 2015 and 2016 are as follows:

	2015	2016
Stock and exercise prices	$4.14 - $10.14	$0.775 - $4.02
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	1.52% – 1.94%	0.99% – 2.11%
Expected life (in years)	5.23 – 6.08	5.13 – 6.08
Expected volatility	70.0% – 100.0%	80.0% – 90.0%

Using the assumptions described above, with stock and exercise prices being equal on date of grant, the weighted-average estimated fair value of options granted in 2015 and 2016 were approximately $3.96 and $1.79 per share, respectively.

A summary of stock option activity for the years ended December 31, 2015 and 2016 is as follows:

	Number of Shares		Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2014	302,015	$	18.88	9.0
Granted	441,288	$	6.01	
Exercised	—		—	
Cancelled/forfeited/expired	(29,644)	$	13.83	
Outstanding at December 31, 2015	713,659	$	11.03	8.8
Granted	290,399	$	2.51	
Exercised	—		—	
Cancelled/forfeited/expired	(107,396)	$	7.99	
Outstanding at December 31, 2016	896,662	$	8.80	8.5
Vested and unvested expected to vest, December 31, 2016	801,529	$	9.26	8.0

The intrinsic values of options outstanding at December 31, 2015 and 2016, as well as options vested and unvested expected to vest at December 31, 2016, were zero. The total weighted-average grant date fair values of the 75,455 and 218,688 stock options vested during the years ended December 31, 2015 and 2016, respectively, were $1,185,128 and $1,563,378, respectively.

Further information about the options outstanding and exercisable at December 31, 2016 is as follows:

Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Total Shares Exercisable
$ 0.78	13,771	10.0	—
$ 1.93	184,073	9.6	42,082
$ 4.06	118,342	9.1	67,919
$ 6.37	336,406	8.7	149,981
$ 15.26	139,104	6.8	116,789
$ 26.45	104,966	7.1	78,466
	896,662		455,237

The intrinsic value of options exercisable at December 31, 2016 was zero.

On August 31, 2015, the Company's Board of Directors approved the issuance of 33,333 stock options with an estimated grant date fair value of $4.40 per share and an exercise price of $6.03 per share to its Chief Executive Officer pursuant to the 2013 Plan. On February 29, 2016, the Company's Board of Directors approved the issuance of 33,333 stock options with an estimated grant date fair value of $2.87 per share and an exercise price of $4.02 per share to its Chief Executive Officer pursuant to the 2013 Plan. Vesting of these stock options was based on the Company's achievement of specified objectives by December 31, 2016 as determined by the Company's Board of Directors or Compensation Committee. Subsequent to the year ended December 31, 2016, 6,333 of the performance stock options granted on August 31, 2015 and 10,000 of the performance stock options granted on February 29, 2016 were declared vested by our Board of Directors in satisfaction of these awards, and the remaining 50,333 shares underlying these awards were forfeited.

On July 25, 2016, the Company entered into an employment agreement with its new Chief Financial Officer, Senior Vice President of Operations and Secretary, or CFO. Pursuant to the terms of this employment agreement, on July 29, 2016 the CFO was granted inducement stock option awards with an exercise price of $1.95 per share to purchase up to (i) 66,666 shares of the Company's common stock with an estimated grant date fair value of $1.45 per share, 25% of which will vest on the one-year anniversary of the commencement of the CFO's employment with the Company, and remainder of which will vest in equal monthly installments over the following three years, and (ii) 33,333 shares of the Company's common stock with an estimated grant date fair value of $1.26 per share, which vest upon the Company's achievement of specified corporate goals for 2016 and the consummation of a specified financing transaction. Subsequent to the year ended December 31, 2016, 16,383 stock options were declared vested by our Board of Directors in satisfaction of the 33,333 performance option award granted on July 29, 2016, and the remaining 16,950 shares underlying this award was forfeited.

Restricted Stock

The fair value of RSUs awarded under either plan is determined by the closing price of the Company's common stock on the date of grant. For non-performance RSUs, 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 RSUs is based on management's estimate of the most likely outcome and when the achievement of the performance objectives is probable.

A summary of RSU activity during 2015 and 2016 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2014	83,755	$ 15.43
Granted	—	—
Issued	(58,003)	$ 15.56
Forfeited	—	—
Outstanding at December 31, 2015	25,752	$ 15.12
Granted	165,829	$ 1.96
Issued	(4,449)	$ 16.05
Forfeited	(12,883)	$ 13.34
Outstanding at December 31, 2016	174,249	$ 2.68
Vested and unvested expected to vest, December 31, 2016	171,667	$ 2.69

On June 12, 2014, the Company's Board of Directors approved the grant of 14,832 RSUs with a grant date fair value of $16.05 per share to its Chief Executive Officer pursuant to the 2013 Plan. Vesting of these RSUs was based on the Company's achievement of specified objectives by December 31, 2015 as determined by the Company's Board of Directors or Compensation Committee. During the year ended December 31, 2016, a total of 4,449 RSUs were declared vested by the Company's Board of Directors and issued to its Chief Executive Officer in satisfaction of the June 12, 2014 RSU award, and the remaining 10,383 shares underlying this award were forfeited.

The RSUs granted during the year ended December 31, 2016 vest fully on the one year anniversary of the date of grant, subject to continuing service by the holders of such RSUs. At December 31, 2016, the intrinsic values of RSUs outstanding and RSUs unvested and expected to vest were $135,043 and $133,042, respectively.

On July 6, 2016, the Compensation Committee of the Company's Board of Directors approved retention RSUs for an aggregate of 58,332 shares of common stock to three of the Company's executive officers pursuant to the 2013 Plan, including retention RSUs for 25,000 shares of common stock to its Chief Executive Officer. Each of these retention RSUs has a grant date fair value of $1.86 per share for a grant date fair value of $108,498 to all three officers, in aggregate. These retention RSUs vest fully on the one year anniversary of the date of grant, subject to continuing service by the holders of such RSUs.

Pursuant to the terms of the Company's employment agreement with its CFO dated July 25, 2016, the CFO was granted an inducement RSU award on July 29, 2016 covering 25,000 shares of the Company's common stock with a grant date fair value of $1.95 per share, 100% of which will vest on the one-year anniversary of the commencement of the CFO's employment with the Company.

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,	
	2015	2016
Stock Options		
Cost of revenues	$ 68,660	$ 115,266
Research and development expenses	103,138	123,330
General and administrative expenses	933,018	1,071,490
Sales and marketing expenses	149,917	142,741
Total expenses related to stock options	1,254,733	1,452,827
RSUs		
Cost of revenues	—	32,338
Research and development expenses	10,724	30,261
General and administrative expenses	112,367	38,274
Sales and marketing expenses	—	40,247
Total stock-based compensation	$ 1,377,824	$ 1,593,947

Stock-based compensation expense was recorded net of estimated forfeitures of 0% - 4% and 0% - 8% per annum during the years ended December 31, 2015 and 2016, respectively. As of December 31, 2016, total unrecognized share-based compensation expense related to unvested stock options and RSUs, adjusted for estimated forfeitures, was approximately $1,611,000, and is expected to be recognized over a weighted-average period of approximately 2.1 years.

11. Common Stock Warrants Outstanding

On September 29, 2016, the Company effected a one-for-three reverse stock split of all common shares outstanding. The following per share amounts and share numbers have been adjusted for this reverse stock split as if it had occurred on December 31, 2014.

A summary of equity-classified common stock warrant activity, for warrants other than those underlying unexercised overallotment option warrants, during 2015 and 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2014	203,047	$ 29.79	3.8
Issued	2,666,666	$ 4.68	
Exercised	(2,085,483)	$ 4.68	
Expired	—	—	
Outstanding at December 31, 2015	784,230	$ 11.18	3.8
Issued	10,890,657	$ 1.40	
Exercised	—	—	
Expired	(50,900)	$ 30.00	
Outstanding at December 31, 2016	11,623,987	$ 1.93	4.6

Further information about equity-classified common stock warrants, for warrants other than those underlying unexercised overallotment option warrants, outstanding and exercisable at December 31, 2016 is as follows:

Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)
$ 1.10	9,727,131	4.8
$ 3.90	1,163,526	4.3
$ 4.68	581,183	3.1
$ 14.16	17,655	7.3
$ 30.00	102,826	2.1
$ 37.50	31,666	2.1
	11,623,987	

The intrinsic value of equity-classified common stock warrants outstanding and exercisable at December 31, 2016 was zero.

Subsequent to December 31, 2016, the Company received approximately $5.3 million of cash proceeds upon the exercise of 4,780,850 common stock warrants with an exercise price of $1.10 per share issued in connection with the Company's public offering in October 2016.

12. 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, 2015 and 2016, the outstanding RSUs, 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.

On September 29, 2016, the Company effected a one-for-three reverse stock split of all common shares outstanding. The calculation of weighted-average shares outstanding has been adjusted for this reverse stock split as if it had occurred on December 31, 2014.

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,	
	2015	2016
Preferred warrants outstanding (number of common stock equivalents)	529	529
Common warrants outstanding	784,230	11,623,987
RSUs outstanding	25,752	174,249
Common options outstanding	713,659	896,662
Total anti-dilutive common share equivalents	1,524,170	12,695,427

13. 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.

14. Income Taxes

For the years ended December 31, 2015 and 2016, the provision for income taxes was calculated as follows:

	For the year ended December 31,	
	2015	2016
Current:		
Federal	$ —	$ —
State	1,608	2,053
Total	1,608	2,053
Deferred		
Federal	—	—
State	—	—
Total	—	—
Provision for income tax	$ 1,608	$ 2,053

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,	
	2015	2016
Income tax at statutory rate	$ (5,762,293)	$ (6,255,072)
State liability	(334,494)	(260,835)
Permanent items	34,852	67,151
Stock compensation	334,609	157,250
Nondeductible interest	(316)	21,548
Expiration of net operating losses	796,699	—
Research and development credit	(164,967)	(170,950)
State rate change	746,238	44,421
Estimated section 382 limitation	48,484,354	9,256,295
Other	(1,041)	96,406
Valuation allowance	(44,132,033)	(2,954,161)
Provision for income tax	$ 1,608	$ 2,053

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 estimated net operating loss carryforwards, deferred rent, and estimated research and development credits. Valuation allowances have been recorded to fully offset deferred tax assets at December 31, 2015 and 2016, as it is more likely than not that the assets will not be utilized.

At December 31, 2016, the Company had estimated federal net operating loss carryforwards of approximately $5,303,000 expiring beginning in 2034 and total estimated state net operating loss carryforwards of approximately $8,622,000 expiring beginning in 2022. Additionally, at December 31, 2016, the Company had estimated research and development credits of approximately $16,000 and $3,376,000 for federal and California purposes, respectively. The estimated federal research and development tax credits will begin to expire in 2034. The California research and development tax credits do not expire.

For the years ended December 31, 2015 and 2016, 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, 2015 or 2016. 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 2012 and the Company's state filings prior to 2011 are no longer subject to examination. The Company's policy is to re cognize 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 and other temporary differences that give rise to deferred tax assets consist of the following:

	For the year ended December 31,	
	2015	2016
Estimated net operating loss carryforward	$ 6,204,024	$ 2,218,618
Estimated research and development credits	2,235,914	2,244,047
Accruals and other	1,234,413	2,273,838
Deferred rent	181,134	164,821
	9,855,485	6,901,324
Less valuation allowance	(9,855,485)	(6,901,324)
Net deferred tax assets	$ —	$ —

Utilization of the estimated 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, or the Code, as well as similar state provisions. These ownership changes may limit the amount of estimated 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, likely 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 estimated 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 estimated 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, however, the Company believes ownership changes likely occurred during both 2015 and 2016. As a result, the Company has estimated that the use of its net operating loss is limited and has disclosed in the table above only the amounts it estimates could be used in the future, which remain fully offset by a valuation allowance to reduce the net asset to zero.

15. Related Party Transactions

All of the members of the Company's Board of Directors participated in its public offering in February 2015, purchasing an aggregate 47,331 shares of the Company's common stock and warrants to purchase up to an aggregate of 47,331 shares of its common stock for total proceeds of $177,500 (see Note 4).

Three members of the Company's Board of Directors participated in its public offering in May 2016, purchasing an aggregate of 58,335 shares of the Company's common stock and warrants to purchase up to an aggregate of 40,832 shares of its common stock for total gross proceeds to the Company of $175,000. Additionally, a trust affiliated with a beneficial owner of more than 10% of the Company's outstanding common stock at the time, Claire K.T. Reiss, participated in its public offering in May 2016, purchasing 204,758 shares of its common stock and warrants to purchase up to 143,330 shares of its common stock for total gross proceeds to the Company of $614,273 (see Note 4).

Seven members of the Company's Board of Directors, including its Chief Executive Officer, and all three of the Company's other executive officers participated in the Company's public offering in October 2016, purchasing an aggregate of 534,088 shares of common stock and warrants to purchase up to an aggregate of 534,088 shares of common stock for total gross

proceeds to the Company of $587,497. Additionally, a trust affiliated with a beneficial owner of more than 10% of the Company's outstanding common stock prior to the Company's public offering in October 2016, Claire K.T. Reiss, participated in the Company's public offering in October 2016, purchasing 227,272 shares of its common stock and warrants to purchase up 227,272 shares of its common stock for total gross proceeds to the Company of $249,999. Further, several of the Company's employees and one of its consultants participated in the Company's public offering in October 2016, purchasing an aggregate of 79,090 shares of its common stock and warrants to purchase up to an aggreg ate of 79,090 shares of its common stock for total aggregate gross proceeds to the Company of $86,999.

A member of the Company's management is the controlling person of Aegea Biotechnologies, Inc., or Aegea. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement, or the Cross-License Agreement, with Aegea. The Company received payments totaling $25,763 and $19,047 during the years ended December 31, 2015 and 2016, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement.

Pursuant to a sublease agreement dated March 30, 2015, the Company subleased 9,849 square feet, plus free use of an additional area, of its San Diego facility to an entity affiliated with the Company's non-executive Chairman for $12,804 per month, with a refundable security deposit of $12,804 due from the subtenant. The initial term of the sublease expired on July 31, 2015, and was subject to renewal on a month-to-month basis thereafter. A total of $102,432 and $153,648 in rental income was recorded to other income/(expense) in the Company's statement of operations and comprehensive loss during the years ended December 31, 2015 and 2016, respectively. On February 1, 2017, the Company received notice from the subtenant terminating the sublease effective March 31, 2017.

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.

16. 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. In September 2013, the Company extended the lease term through July 31, 2020. 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. During each of the years ended December 31, 2015 and 2016, total rent expense recorded in the Company's statements of operations and comprehensive loss was approximately $1,272,000.

The future minimum lease payments under the amended lease agreement as December 31, 2016 are as follows:

2017	$	1,348,257
2018		1,388,705
2019		1,430,366
2020		855,136
Thereafter		—
Total	$	5,022,464

Purchase Commitment

In February 2016, the Company signed a firm, noncancelable, and unconditional commitment in an aggregate amount of $1,062,500 with a vendor to purchase certain inventory items, payable in quarterly installments of $62,500 through May 2020. At December 31, 2016, a total of $812,500 remained outstanding under this purchase commitment.

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.

17. 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, 2015				
Balance sheet data:				
Cash	$ 19,294,706	$ 16,523,975	$ 12,541,919	$ 8,821,329
Total assets	20,899,513	18,317,659	14,196,386	10,586,918
Total non-current liabilities	5,083,216	4,234,552	3,877,362	3,553,395
Total shareholders' equity	13,582,795	11,049,961	6,928,277	3,692,735
Statement of operations and comprehensive loss data:				
Revenues	$ 150,002	$ 76,768	$ 164,856	$ 218,283
Cost of revenues [1]	1,147,682	1,013,075	1,159,710	1,275,691
Research and development expenses [1]	651,420	744,242	677,729	784,379
General and administrative expenses	1,292,049	1,359,226	1,630,608	1,404,515
Sales and marketing expenses	709,456	851,109	1,055,653	1,264,168
Loss from operations	(3,650,605)	(3,890,884)	(4,358,844)	(4,510,470)
Net loss	$ (3,800,728)	$ (4,035,105)	$ (4,496,193)	$ (4,617,500)
Net loss per common share: [2]				
Basic	$ (1.10)	$ (0.67)	$ (0.72)	$ (0.73)
Diluted	$ (1.10)	$ (0.67)	$ (0.72)	$ (0.73)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	3,457,556	6,005,145	6,242,604	6,307,316
Diluted	3,457,556	6,005,145	6,242,604	6,307,316

[1] A total of $290,709 and $27,856 of revenue-generating costs previously allocated to research and development expenses during the quarters ended March 31, 2015 and June 30, 2015, respectively, were reclassified to cost of revenues in this current period presentation of selected quarterly financial data.

[2] 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, 2016				
Balance sheet data:				
Cash	$ 4,572,750	$ 3,751,570	$ 678,855	$ 4,609,332
Total assets	6,780,830	6,303,153	3,282,549	7,578,326
Total non-current liabilities	3,132,372	3,134,593	2,793,258	2,526,113
Total shareholders' equity/(deficit)	(489,231)	(419,402)	(4,556,158)	658,661
Statement of operations and comprehensive loss data:				
Revenues	$ 221,369	$ 662,860	$ 1,047,280	$ 1,291,587
Cost of revenues	1,474,790	1,669,571	1,876,288	1,899,462
Research and development expenses	728,076	716,279	600,613	668,399
General and administrative expenses	1,487,224	1,517,664	1,918,543	1,636,994
Sales and marketing expenses	1,304,899	1,291,709	1,278,455	1,179,167
Loss from operations	(4,773,620)	(4,532,363)	(4,626,619)	(4,092,435)
Net loss	$ (4,875,198)	$ (4,594,174)	$ (4,743,076)	$ (4,186,874)
Net loss per common share: [1]				
Basic	$ (0.74)	$ (0.60)	$ (0.57)	$ (0.27)
Diluted	$ (0.74)	$ (0.60)	$ (0.57)	$ (0.27)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	6,566,992	7,702,286	8,370,691	15,620,049
Diluted	6,566,992	7,702,286	8,370,691	15,620,049

[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.

18. Subsequent Events

Subsequent to December 31, 2016, the Company received approximately $5.3 million of cash proceeds upon the exercise of 4,780,850 common stock warrants with an exercise price of $1.10 per share issued in connection with the Company's public offering in October 2016.

On February 1, 2017, the Company received notice from its subtenant terminating the sublease effective March 31, 2017.

Item 9. Changes in and Disagreements with Accoun tants 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, 2016, 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 (2013 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, 2016.

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 2017 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, 2016, 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 "Executive 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:

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 (File No. 333-191323), filed with the SEC on September 23, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	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).
4.3	Specimen Common Stock certificate of Biocept, Inc.
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	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).
4.9	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).
4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).

Exhibit No.	Description of Exhibit
4.15	Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated April 29, 2016, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).
4.16	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.16 of the Registrant's Post-Effective Amendment to Registration Statement on Form S-1 (File No. 333-213111), filed with the SEC on October 14, 2016) .
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+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8	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).
10.9	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).
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).

Exhibit No.	Description of Exhibit
10.15	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).
10.16+	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).
10.17+	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).
10.18+	Employment Agreement Amendment between the Registrant and Michael W. Nall, dated November 6, 2015 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2015).
10.19	Letter Agreement, dated April 25, 2016, by and between Biocept, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).
10.20	Second Amendment to 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 June 30, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's quarterly report on Form 10-Q, filed with the SEC on August 5, 2016).
10.21+	Biocept, Inc. Amended and Restated 2013 Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit agreement for use thereunder (incorporated by reference to Exhibit 99.3 of the Registrant's Current Report on Form 8-K, filed with the SEC on July 27, 2016).
10.22+	Employment Agreement between the Registrant and Timothy Kennedy, dated July 25, 2016 (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 27, 2016).
31.1	Certification of Michael Nall, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Timothy Kennedy, 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 Timothy Kennedy, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

* 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 28, 2017

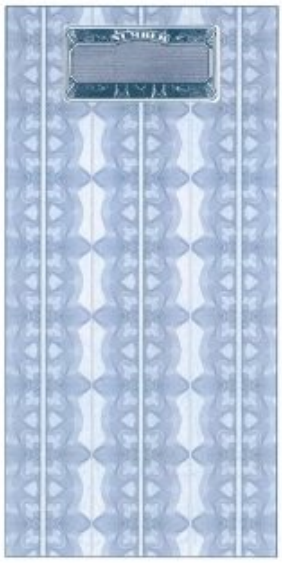
By: /s/ Michael W. Nall
Michael W. Nall
Chief Executive Officer, President and Director

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 28, 2017
/s/ Timothy C. Kennedy Timothy C. Kennedy	Chief Financial Officer, Senior Vice President of Operations (Principal Financial Officer and Principal Accounting Officer)	March 28, 2017
/s/ David F. Hale David F. Hale	Chairman and Director	March 28, 2017
/s/ Marsha A. Chandler Marsha A. Chandler	Director	March 28, 2017
/s/ Bruce E. Gerhardt Bruce E. Gerhardt	Director	March 28, 2017
/s/ Bruce A. Huebner Bruce A. Huebner	Director	March 28, 2017
/s/ Edward Neff Edward Neff	Director	March 28, 2017
/s/ Ivor Royston Ivor Royston	Director	March 28, 2017
/s/ M. Faye Wilson M. Faye Wilson	Director	March 28, 2017

Exhibit 4.3

COMMON STOCK



Biocept

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SHARES

SEE REVERSE SIDE FOR CERTAIN DEFINITIONS

CUSIP 09072V 20 4

THIS CERTIFIES THAT

is the owner of

FULLY PAID AND NON-ASSESSABLE COMMON SHARES, $0.0001 PAR VALUE, OF

BIOCEPT, INC.

transferable on the books of the Corporation by the holder hereof in person or by Attorney upon surrender of this certificate properly endorsed. This certificate is not valid until countersigned and registered by the Transfer Agent and Registrar.

IN WITNESS WHEREOF, the said Corporation has caused this certificate to be signed by facsimile signatures of its duly authorized officers.

Dated:

COUNTERSIGNED AND REGISTERED:
CONTINENTAL STOCK TRANSFER

TRANSFER AGENT
AND REGISTRAR

By

AUTHORIZED SIGNATURE

CHIEF FINANCIAL OFFICER,
SENIOR VICE PRESIDENT OF OPERATIONS
AND CORPORATE SECRETARY

PRESIDENT AND CHIEF EXECUTIVE OFFICER

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations.

TEN COM – as tenants in common

TEN ENT – as tenants by entirety

JT TEN – as joint tenants with right of survivorship and not as tenants in common

UTMA – _____ Custodian _____
(Cust) (Minor)
under Uniform Transfers to Minors

Act _____
(State)

Additional abbreviations may also be used though not in above list.

For value received _____ *hereby sell, assign, and transfer unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING ZIP CODE OF ASSIGNEE)

_____

_____

_____ *Shares*

of the capital stock represented by the within Certificate, and do hereby irrevocably constitute and appoint _____

_____ *Attorney*

to transfer the said stock on the books of the within-named Corporation with full power of substitution in the premises.

Dated _____

X _____

X _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

SIGNATURE GUARANTEED

ALL SIGNATURES MUST BE GUARANTEED BY A FINANCIAL INSTITUTION (BANK, STOCKBROKER, SAVINGS AND LOAN ASSOCIATION AND CREDIT UNION) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15. IF THE SHARES ARE REGISTERED IN THE NAME OF A FIDUCIARY, THE NAME THEREOF MUST BE GIVEN. ALL SIGNATURES MUST BE GUARANTEED, EVEN IF THE SHARES ARE BEING TRANSFERRED TO YOURSELF. SIGNATURES MUST BE GUARANTEED BY A FINANCIAL INSTITUTION (BANK, STOCKBROKER, SAVINGS AND LOAN ASSOCIATION AND CREDIT UNION) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM, PURSUANT TO S.E.C. RULE 17Ad-15. SIGNATURES MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION. NOTARIZATIONS ARE NOT ACCEPTABLE.

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 28, 2017

/s/ Michael W. Nall

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

EXHIBIT 31.2

CERTIFICATION

I, Timothy C. Kennedy, 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 28, 2017

/s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer, Senior Vice President of Operations
(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, 2016 (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 28, 2017

/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, Timothy C. Kennedy, 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, 2016 (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 28, 2017

/s/ Timothy C. Kennedy
Timothy C. Kennedy
Chief Financial Officer, Senior Vice President of Operations
(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.