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

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**Amendment No. 6  
to  
Form S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**BIOCEPT, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**8071**  
(Primary Standard Industrial  
Classification Code Number)

**80-0943522**  
(I.R.S. Employer  
Identification No.)

**5810 Nancy Ridge Drive  
San Diego, CA 92121  
(858) 320-8200**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Chief Executive Officer and President  
Biocept, Inc.  
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San Diego, CA 92121  
(858) 320-8200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
 ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.
 ☐

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

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

The registrant is an “emerging growth company,” as defined in Section 2(a)(19) of the Securities Act. This registration statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE				
Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Aggregate Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee <sup>(1)</sup>
Common Stock, \$0.0001 par value per share <sup>(2)</sup>	2,090,908	\$12.00	\$25,090,896	\$3,406.51*
Representative’s Warrants to Purchase Common Stock <sup>(3)</sup>	—	—	—	—
Common Stock Underlying Representative’s Warrants <sup>(2)(4)</sup>	90,909	\$15.00	\$1,363,635	\$185.13**
<b>Total Registration Fee</b>			\$26,454,531	\$3,591.64***

- (1) The registration fee is calculated in accordance with Rule 457(a) under the Securities Act of 1933, as amended, and includes 272,727 shares of common stock the underwriters have the option to purchase to cover over-allotments, if any.
- (2) Pursuant to Rule 416 under the Securities Act, the shares of common stock registered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of stock splits, stock dividends, recapitalizations or other similar transactions.
- (3) No registration fee pursuant to Rule 457(g) under the Securities Act.
- (4) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price.
- \* \$3,137.20 for \$23,000,000 of shares (equating to 1,916,666 shares at the now-proposed maximum aggregate offering price per share of \$12.00) at the previous rate of \$136.40 per million dollars, and \$269.31 for an additional \$2,070,896 (equating to 174,242 shares) at the new rate of \$128.80 per million dollars.
- \*\* \$170.50 for \$1,250,000 of shares (equating to 83,333 shares at the now-proposed maximum aggregate offering price per share of \$15.00) at the previous rate of \$136.40 per million dollars, and \$14.63 for an additional \$115,635 (equating to 7,576 shares) at the new rate of \$128.80 per million dollars.
- \*\*\* \$3,591.64 was previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED JANUARY 8, 2014

# 1,818,181 Shares Common Stock



This is the initial public offering of shares of common stock of Biocept, Inc. No public market currently exists for our shares. We are offering all of the shares of common stock offered by this prospectus. We expect the public offering price of our shares of common stock to be between \$10.00 and \$12.00 per share.

All common share and per-common-share figures in this prospectus have been adjusted to reflect a 1-for-14 reverse stock split of our outstanding common stock effected on November 1, 2013.

Our shares of common stock have been approved for listing on The NASDAQ Capital Market under the symbol "BIOC."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, we have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

**Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 13 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Offering proceeds to us, before expenses	\$	\$

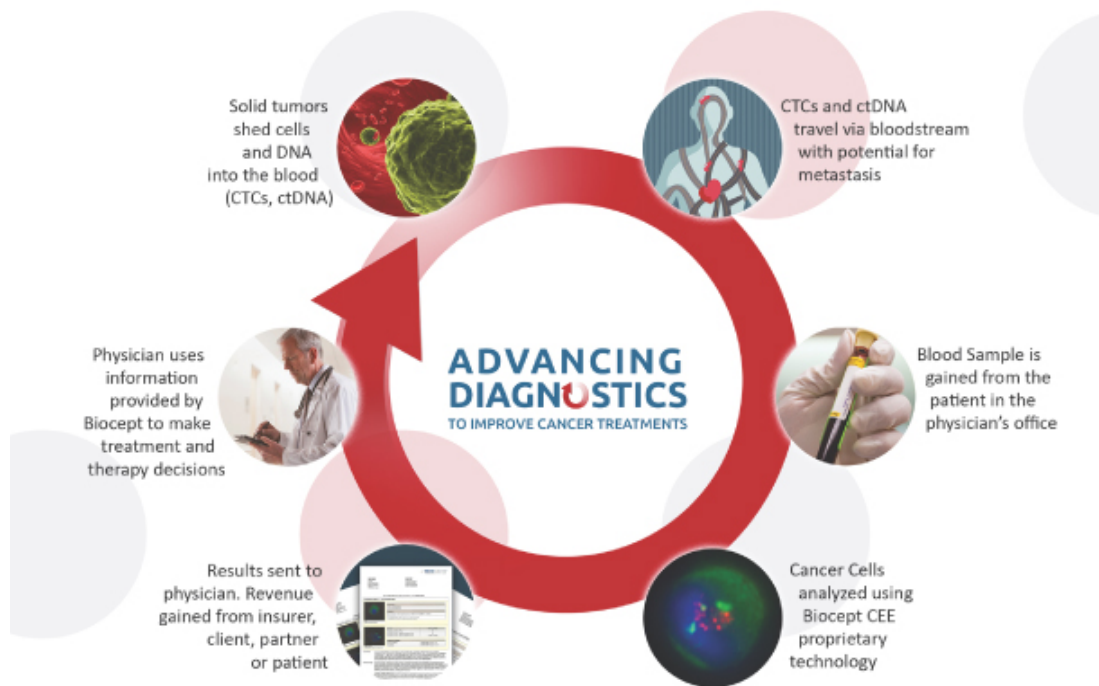
(1) See "Underwriting" beginning on page 127 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase up to 272,727 additional shares of common stock to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers in this offering on or about , 2014.

## Aegis Capital Corp

The date of this prospectus is , 2014.



**The CEE Solution**  
**Personalized Medicine from a Liquid Biopsy**

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Neither we nor the underwriters have authorized anyone to provide you with information that is different from that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus or in any free writing prospectus that we may authorize to be delivered or made available to you. Neither the delivery of this prospectus nor the sale of our common stock means that the information contained in this prospectus or any free writing prospectus is correct after the date of this prospectus or such free writing prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy the shares of common stock in any circumstances under which the offer or solicitation is unlawful.

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Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Special Note Regarding Forward-Looking Statements."

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We use in this prospectus our BIOCEPT LABORATORIES logo, for which we hold a registered United States trademark, our mark CEE, which is a registered United States trademark, and our marks OncoCEE-BR, OncoCEE-LU, CEE-Selector, CEE-Cap, CEE-Enhanced, CEE-Sure, OncoCEE-GA, OncoCEE-PR, OncoCEE-ME, OncoCEE-CR and OncoCEE, which in the United States are unregistered trademarks. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear (after the first usage) without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

## SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the “Risk Factors” section of this prospectus and the financial statements and related notes appearing at the end of this prospectus before making an investment decision.*

*Unless the context provides otherwise, all references in this prospectus to “Biocept,” “we,” “us,” “our,” the “Company,” or similar terms, refer to Biocept, Inc. We reincorporated from California to Delaware in July 2013. Except where otherwise expressly stated, no distinction is made in this prospectus between historic activities and results of the California and Delaware corporations.*

### Our Company

We are a cancer diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, tests utilizing a standard blood sample. Our first and currently only commercialized test is OncoCEE-BR™ for breast cancer CTC enumeration and analysis. OncoCEE-BR and our tests in development are designed to provide information to oncologists to enable them to select appropriate treatment for their patients due to better, timelier and more-detailed data on the characteristics of tumors. Our marketed test and our tests in development for the enumeration and analysis of CTCs utilize our Cell Enrichment and Extraction, or CEE®, technology, and our tests in development for the detection and analysis of ctDNA utilize our CEE-Selector™ technology, each performed on a standard blood sample. CEE is an internally developed, microfluidics-based CTC capture and analysis platform, with enabling features that change how CTC testing can be used by clinicians by providing real-time biomarker monitoring with only a standard blood sample. The CEE-Selector technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood plasma for ctDNA. From August 2011, when we launched OncoCEE-BR, to September 30, 2013, our revenues from OncoCEE-BR have totaled approximately \$211,000. To achieve profitability, we would need to increase our revenue, from OncoCEE-BR and any tests we introduce in the future, many-fold from such historic level. We are an emerging company.

From August 2011 to May 2013, we and our commercialization partner Clariant Diagnostic Services, Inc., or Clariant, were the exclusive marketers of the OncoCEE-BR test and we performed, on average, approximately 10 tests per month under our commercialization agreement with Clariant beginning from the first test under our commercialization agreement with Clariant in March 2012. In May 2013, we amended our commercialization agreement with Clariant such that Clariant is no longer the exclusive marketing partner for the test. Because we do not yet have an in-house sales force, this resulted in a reduction in the commercial testing rate. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013 Clariant was responsible for all billing associated with our tests. We do not have data for Clariant’s billing and collection experience with regard to our test, because Clariant paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013 we performed an average of 1-3 physician-ordered tests per month (in addition to the 20-30 tests per month which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute). Billing for physician-ordered tests is now handled for us by a non-Clariant billing service provider. In November and December 2013 we invoiced, through this service provider, for 13 physician-ordered tests. Of these tests, 8 were billed to private third-party payors and 5 were billed to Medicare. We have not yet had any response from the payors as to the bills submitted in late 2013. Accordingly, we do not yet have any data regarding reimbursement history or collectability experience. In addition, we believe the sample size of 13 is too small to be the basis for any conclusion about our ongoing payor mix.

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We also manufacture our CEE microfluidic channels, related equipment and certain reagents to perform our tests at this facility.

OncoCEE-BR is a breast cancer CTC test that is performed on a standard blood sample. It detects CTCs, which are typically very rare, and determines the patient’s human epidermal growth factor receptor 2, or HER2, status by fluorescence *in situ* hybridization, or FISH.

We anticipate launching OncoCEE-LU™, a test performed on a standard blood sample for non-small cell lung cancer, or NSCLC, in the first half of 2014. The OncoCEE-LU test’s biomarker analysis would include FISH for echinoderm microtubule-associated protein-like 4/ anaplastic lymphoma kinase, or EML4/ALK, and c-ros oncogene 1, receptor tyrosine kinase, or ROS1, gene fusions, as well as mutation analysis for the epidermal growth factor receptor, or EGFR, gene, the K-ras gene and the B-raf gene. Life Technologies Corporation will be collaborating with us in the commercialization of the OncoCEE-LU test.

We could add biomarker analyses to OncoCEE-BR and our planned tests as their clinical relevance is demonstrated, for example, ret proto-oncogene gene fusions in NSCLC. In addition, we are developing a series of other CTC and ctDNA tests for different solid tumor types, including colorectal cancer, prostate cancer, gastric cancer and melanoma, each incorporating treatment-associated biomarker analyses specific to that cancer. We also have a research and development program focused on technology enhancements and novel platform development, and a translational research group evaluating clinical applications for our cancer diagnostic tests in different cancer types and clinical settings. We plan to launch 5 new OncoCEE™ cancer tests over the next 3 years.

We collaborate with physicians and researchers at The University of Texas MD Anderson Cancer Center and the Dana-Farber Cancer Institute and plan to expand our current collaborative relationships to include other key thought leaders for the types of cancer we are targeting with OncoCEE-BR and our planned CTC and ctDNA tests. Such relationships help us develop and validate the effectiveness and utility of our current test and our planned tests in specific clinical settings and provide us access to patient samples and data.

### **Market Overview**

Despite many advances in the treatment of cancer, cancer remains one of the greatest areas of unmet medical need. In 2008, the World Health Organization attributed 7.6 million deaths worldwide to cancer-related causes. The World Health Organization projects that by 2030 this number will rise to 13.1 million deaths per year. The incidence of, and deaths caused by, the major cancers are staggering.

Cancer constitutes a heterogeneous class of diseases, characterized by uncontrollable cell growth, that result 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, while other cells in the tumor may not have these markers. It has only been in recent years that technology has progressed far enough to enable researchers to understand many cancers at a molecular level and attribute specific cancers to associated genetic changes.

### ***Limitations of Traditional Cancer Diagnostic and Profiling Approaches***

Cancer is difficult to diagnose and manage due to its heterogeneity at visual, 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. The tissue sample must be used in combination with chemical staining techniques to enable analysis of the biopsy. Through visual inspection, the pathologist determines whether the biopsy contains normal or cancerous cells, with those cells that are deemed cancerous being graded on a level of aggressiveness. In recent years, molecular (or genetic) testing has become the standard of care and will also be performed in order to provide information about which drugs a patient is likely or unlikely to respond to. After the diagnosis, a clinical workup is performed according to established guidelines for the specific cancer type. From there, the physician determines the stage of progression of the cancer based on a series of clinical measures, such as size, grade, metastasis rates, symptoms and patient history, and decides on a treatment plan that may include surgery, watchful waiting, radiation, chemotherapy, or stem cell transplant.

Molecular analysis is dependent on the availability of a relevant 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***

Circulating tumor cells, or CTCs, are cancer cells that have detached from the tumor and invaded the patient's blood or other bodily fluids. These cells are representative of the tumor and its metastases, and can function as their surrogates. Testing CTCs can complement pathologic information drawn from a biopsy or resected tissue sample, helping to insure that the analysis is comprehensive and not biased by tumor heterogeneity and sampling issues. Testing CTCs 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 cancer for the patient, or in other words they are considered “prognostic.” Since CTCs are understood to be representative of the tumor, they can also be used for biomarker analysis, for example, to help guide therapy selection. In this way they 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 and analyzed to evaluate a therapy’s continuing effectiveness, as well as to detect other biomarkers, such as new genetic mutations that may arise as a result of selection pressure by a particular therapy or by chance. Physicians can use this information to determine which therapy is most likely to benefit their patients at particular times through the course of their disease. Treatment decisions based on patient-specific information are the foundation of personalized medicine, and tests, or assays, that guide a physician in the selection of individualized therapy for a patient are termed “predictive assays.”

Nucleic acid that is released into blood by dying tumor cells is called ctDNA. 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. As a consequence, ctDNA is common in cancer patients, and like CTCs, scientists believe that it may be more representative of a patient’s tumor than a few thin sections from a tissue biopsy, thus reducing the heterogeneity problem. ctDNA is found in the plasma component of blood, and is readily accessible in a standard blood sample. Analyzing ctDNA for mutations that are used as biomarkers for therapy selection shows great promise. One of its strengths, 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 negative side of this approach is that the cellular context is lost, as 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 which co-exist in blood as normal cells die and are replaced in the body. Our CEE-Selector technology provides the necessary sensitivity and specificity, creating an opportunity for ctDNA testing to complement CTC analysis or potentially to serve as stand-alone tests.

#### ***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. In theory, almost any analysis that can be performed on tumor tissue can also be performed on CTCs, while the number of currently available assays that can be performed on ctDNA is more limited. We have focused and will focus our analysis of CTCs and ctDNA on known biomarkers associated with specific therapies to support treatment decisions and therapy selection made by oncologists. To analyze proteins and genetic aberrations and mutations which are detected in CTCs or ctDNA, we can use molecular diagnostic tests, such as PCR and gene sequencing. Specific examples include (i) 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) 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) the presence of an EGFR activating mutation in Non-Small Cell Lung Cancer (NSCLC), 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, while ctDNA only provides information on mutations. The resulting information is then used to guide patient care, specifically treatment selection.

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

#### **Our Business Strategy**

We plan to provide oncologists 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 test 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 (quantitation of CTCs) but also the assessment of treatment-associated biomarkers identified within the CTCs or in ctDNA, will provide information to oncologists that improve patient treatment and management and will become a key component in the standard of care for personalized cancer treatment.

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

- Develop and commercialize a portfolio of proprietary CTC and ctDNA tests and services, to enable physicians to develop personalized treatment plans.
- Establish our internal sales and marketing capabilities in a scalable manner.
- Develop and expand our collaborations with leading university hospitals and research centers.
- Enhance our efforts in reaching and educating community oncologists about CTC and ctDNA tests and services.
- Increase our efforts to provide biopharmaceutical companies and clinical research organizations with our current and planned CTC and ctDNA tests and services.
- Support our current test and our planned tests with clinical utility studies to drive adoption and facilitate reimbursement.
- Continue to enhance our current and planned CTC and ctDNA tests and reduce the costs associated with providing them through internal research and development and partnering with leading technology developers and reagent suppliers.

### **Our Competitive Advantages**

We believe that our competitive advantages are as follows:

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

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

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

*OncoCEE-BR is, and we anticipate our planned CTC and ctDNA tests will be, flexible and readily configurable to accommodate new biomarkers with clinical relevance as they are identified.* In theory, our CEE platform permits almost any analysis that is currently performed on tumor tissue to be performed on CTCs. As new therapies are approved, we will be able to include them in our tests with minimal changes. This is attractive to pharmaceutical and biotechnology companies that are developing such therapies, or seeking ways to make their clinical trials more efficient, as this flexibility would enable them to focus on patients more likely to respond to a particular therapy and demonstrate a benefit from that therapy.

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

*Our planned CEE-Selector mutation tests would not be platform dependent.* These tests are being designed to be able to be performed on almost any molecular instrument, which will provide flexibility in laboratory operations. To the extent we elect to develop these tests as in vitro diagnostic kits, or 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 greatly simplifies their distribution and commercialization.

## **Our Tests and Services**

We are in the process of commercializing our first test, OncoCEE-BR for breast cancer, and plan to continue to launch a series of tests for CTCs in different tumor types, including NSCLC, gastric, colorectal and prostate cancers and melanoma, incorporating analyses for different biomarkers, over the next 3 years. OncoCEE-BR and the planned future tests are based on the CEE technology platform. The CEE system isolates CTCs from blood samples of cancer patients for enumeration (or count) and genetic analysis. A sample is shipped to us in our specialized blood collection tube called the CEE-Sure™ tube for recovery and analysis of CTCs. When performing the CTC assay, the sample is processed in our laboratory. The specimen of blood is separated into its parts (red blood cells, buffy coat and plasma). The buffy coat is incubated with the antibody solution and passed through a proprietary microfluidic channel containing 9,000 microscopic posts coated with reagents to capture antibody-labeled tumor cells. The captured cells are suitable for further testing of whole cells directly in the microfluidic channel or by releasing the cells from the microfluidic channel and performing CEE-Selector or similar techniques.

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

In addition to enhanced capture, we are also improving identification of CTCs. We have developed alternative methods of fluorescent cell staining that are uniquely possible within the CEE system to enhance detection of CTCs. This technology is called CEE-Enhanced. We believe that the combination of our assay with more sensitive fluorescent detection of CTCs through CEE-Enhanced staining will lead to major advances in the capture, enumeration and analysis of CTCs. CEE-Enhanced staining is expected to be included in our commercially available and planned tests by mid-2014.

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

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

OncoCEE-BR is a Laboratory Developed Test, and our planned CTC and ctDNA tests would be Laboratory Developed Tests. FDA clearance or approval is not currently required to offer these types of tests in our laboratory once they have been clinically and analytically validated. We seek licenses and approvals for our laboratory facility and for our LDTs from the appropriate regulatory authorities, such as the Centers for Medicare & Medicaid Services, or CMS, 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. As part of this process, the State of New York requires validation of our tests. We are currently in the process of addressing the requirements for licensure in New York, and we expect to have soon re-obtained all required licenses and approvals from all other states requiring licensure for out-of-state laboratories. (We were required to re-license in these other states as a result of our July 2013 reincorporation to Delaware.)

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests in the future will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clariant was responsible for all billing associated with our tests. We do not have data for Clariant's billing and collection experience with respect to our test, because Clariant paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month (in addition to the 20-30 tests per month which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute). Billing for physician-ordered tests is now handled for us by a non-Clariant billing service provider. In November and December 2013, we invoiced, through this service provider, for 13 physician-ordered tests. Of these, 8 were billed to private third-party payors and 5 were billed to Medicare. We have not yet had any response or adjudication from any payor as to the bills submitted in late 2013. Accordingly, we do not yet have any data regarding reimbursement history or collectability experience. In addition, we believe the sample size of 13 is too small to be the basis for any conclusion about our ongoing payor mix.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may bill Medicare or the beneficiary for the service. There is currently no national coverage policy regarding the CTC capture/enumeration portion of our testing. The previous regional Medicare Administrative Contractor for California, Palmetto GBA, LLC, adopted a negative coverage policy for CTC capture/enumeration (with the exception that Janssen Diagnostics, LLC's CellSearch® test has historically been covered for CTC capture/enumeration). The current Medicare Administrative Contractor for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore the capture/enumeration portion of our OncoCEE testing is not currently covered and we will receive no payment from Medicare for this service unless and until the coverage policy is changed. On November 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of the capture/enumeration testing in order to seek to persuade the Medicare Administrative Contractors to allow coverage for this portion of our testing. Palmetto GBA responded on November 27, 2013, denying our request for Medicare coverage for the CTC capture/enumeration portion of our OncoCEE testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The earliest date we could submit another dossier on this matter is May 27, 2014. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

FISH analysis is a covered benefit for Medicare beneficiaries and accordingly we expect that the FISH portion of OncoCEE-BR and our planned tests are and will be covered and that when and as we bill Medicare we will receive payment from Medicare under the Physician Fee Schedule for FISH analysis. Molecular testing for the mutations we currently plan to test for with CEE-Selector is also a covered benefit, so we believe that CEE-Selector testing would thereby be covered and that when and as we bill Medicare we would receive payment from Medicare under the Clinical Laboratory Fee Schedule for CEE-Selector testing. As discussed above, we have not yet received from Medicare any response or adjudication regarding any of our late-2013 billings, including for the FISH portion of OncoCEE-BR testing.

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

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 for the foreseeable future.

### ***Clinical Trial Services***

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a study by Princess Margaret Hospital in Toronto estimated that over a five-year study period 85% of the new therapies for solid tumors which were tested in early clinical trials in the United States, Europe and Japan failed, and that of those that survive through to Phase III trials only half will actually be approved. Given such a high failure rate of oncology drugs in clinical development, combined with constrained budgets for biopharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to decrease these failure rates. For specific molecular-targeted therapeutics, the identification of appropriate biomarkers potentially 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.

Although through 2012 we had essentially no clinical trial testing services revenues, we believe clinical trial testing services can be an important part of our business in the future. We believe our testing and analysis can help increase the efficiency and economic viability of clinical trials for biopharmaceutical companies and clinical research organizations. Our clinical trial services could include developing customizable tests and techniques utilizing our proprietary CTC and ctDNA technologies to provide sensitive, real-time characterization of individual patient's tumors using a standard blood sample. These tests may also be useful as, and ultimately developed into, companion diagnostics associated with a specific therapeutic. Additionally, through our services we would hope to gain further insights into disease progression and the latest drug development that we can incorporate into our tests and services.

In 2013 and 2014 we have been providing clinical trial testing services for the Dana-Farber Cancer Institute, and this project resulted in approximately 85% of our 2013 revenues.

### **Risks That We Face**

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. The risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include, but are not limited to, the following:

- we are an early-stage company with a history of substantial net losses. We have never been profitable and we have an accumulated deficit of approximately \$120 million (at September 30, 2013). 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 to incur net losses in the future, and we may never achieve sustained profitability;
- our business depends upon our ability to introduce additional tests and increase sales of our cancer diagnostic test;
- our current cash resources are insufficient to fund our operations beyond February 2014 without this offering;
- our business depends on executing on our sales and marketing strategy for our cancer diagnostic tests and gaining acceptance of our current test and future tests in the market;
- our business depends on our ability to continually develop new cancer diagnostic tests and enhance our current test and future tests;
- our business depends on being able to obtain adequate reimbursement from governmental and other third-party payors for tests and services;
- our business depends on satisfying any applicable United States (including FDA) and international regulatory requirements with respect to tests and services; and many of these requirements are new and still evolving;
- our business depends on our ability to effectively compete with other diagnostic tests, methods and services that now exist or may hereafter be developed;
- we depend on our senior management and in August 2013 we hired a new chief executive officer;
- we depend on our ability to attract and retain scientists, clinicians and sales personnel with extensive experience in oncology, who are in short supply; and
- we need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned tests and services, and we must avoid infringement of third-party intellectual property.

## 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](http://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 prospectus. We were incorporated in California on May 12, 1997 and reincorporated as a Delaware corporation on July 30, 2013.

## Implications of Being an Emerging Growth Company

As a company with less than \$1.0 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An “emerging growth company” may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which such fifth anniversary will occur in 2018. However, if certain events occur before the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company before the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies in which you hold equity interests.

## The Offering

Common stock offered by us	1,818,181 shares of our common stock.
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 272,727 additional shares of our common stock from us at the public offering price less underwriting discounts and commissions.
Common stock outstanding after this offering	4,306,634 shares.
Use of proceeds	<p>We estimate that the net proceeds from our sale of shares of our common stock in this offering will be approximately \$17.7 million, or approximately \$20.5 million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none"><li>• approximately \$5 million to hire sales and marketing personnel and support increased sales and marketing activities;</li></ul>

- approximately \$5 million to fund further research and development, clinical utility studies and future enhancements of our current test and our planned tests and services;
- approximately \$3 million to acquire equipment, implement automation and scale our capabilities to prepare for significant test volume;
- approximately \$1 million to satisfy deferred salary obligations; and
- the balance for general corporate purposes and to fund ongoing operations and expansion of our business.

For additional information please refer to the section entitled “Use of Proceeds” on page 40 of this prospectus.

Risk Factors

See the section entitled “Risk Factors” beginning on page 13 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

NASDAQ Capital Market symbol

BIOC.

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The number of shares of our common stock to be outstanding after this offering is based on 1,834,465 shares of our common stock outstanding as of September 30, 2013 (including 1,652,851 shares issued upon the automatic conversion of all outstanding shares of our Series A preferred stock in connection with this offering after September 30, 2013) and excludes as of such date:

- 344,565 shares of our common stock issuable upon the exercise of stock options as of September 30, 2013, with a weighted average exercise price of \$5.13 per share;
- 133,971 shares of our common stock issuable upon the settlement of outstanding restricted stock units currently expressed in shares of common stock;
- an estimated 350,974 shares of our common stock issuable upon the exercise of outstanding common stock warrants as of September 30, 2013, at an estimated weighted average exercise price of \$11.00 per share;
- 192,262 common stock equivalents issuable upon the exercise of our outstanding warrants to purchase preferred stock (the warrants overlying all but 1,587 of which will terminate upon the closing of our initial public offering in accordance with their terms);
- any shares of our common stock issuable upon exercise of the underwriters’ over-allotment option;
- any shares of common stock that will underlie the representative’s warrant; and
- other shares of our common stock reserved for future issuance under our 2013 and 2007 Equity Incentive Plans.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- the filing of our amended certificate of incorporation and the adoption of our amended and restated bylaws, which will occur in connection with this offering;
- a 1-for-14 reverse stock split of our common stock effected on November 1, 2013;
- the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of our common stock in connection with this offering;
- the automatic issuance of 68,546 shares of common stock immediately before or immediately after the closing of the offering pursuant to the terms of outstanding restricted stock units currently expressed in shares of preferred stock;
- the automatic conversion of all outstanding convertible notes, at a conversion price equal to the public offering price per share of this offering, into shares of common stock upon the closing of this offering;



- no exercise of the outstanding options or warrants described above;
- no exercise by the underwriters of their option to purchase additional shares of our common stock to cover over-allotments, if any;
- the issuance of the warrants to be issued to the representative of the underwriters in connection with this offering as described in the “Underwriting—Representative’s Warrants” section of this prospectus; and
- no exercise by the representative of the underwriters of such representative’s warrants.

## SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. We have derived the statement of operations data for the years ended December 31, 2011 and 2012 and the balance sheet data as of December 31, 2012 from our audited financial statements appearing elsewhere in this prospectus. We have derived the statements of operations data for the nine months ended September 30, 2012 and 2013 and balance sheet data as of September 30, 2013 from our unaudited financial statements appearing elsewhere in this prospectus. All “Weighted average shares outstanding” data and all “Net loss per common share” data, whether derived from our audited financial statements or from our unaudited financial statements, have been adjusted to reflect a 1-for-14 reverse stock split which we effected on November 1, 2013. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our financial position as of September 30, 2013 and results of operations for the nine months ended September 30, 2012 and 2013. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus entitled “Capitalization,” “Selected Historical Financial Data,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

	Year ended December 31,		For the nine months ended September 30,	
	2011	2012	2012	2013
			(unaudited)	(unaudited)
	(in thousands, except share and per share data)			
<b>Statement of Operations Data:</b>				
Revenues	\$ 1	\$ 109	\$ 88	\$ 115
Cost of revenues	17	1,201	756	1,759
Gross profit	(16)	(1,092)	(668)	(1,644)
Research and development expenses	8,853	6,562	5,304	2,376
General and administrative expenses	2,729	2,063	1,613	1,736
Sales and marketing expenses	673	786	604	130
Loss from operations	(12,271)	(10,503)	(8,189)	(5,886)
Total other income/(expense)	(1,357)	(1,756)	(1,122)	(874)
Loss Before Income Taxes	\$ (13,628)	\$ (12,259)	\$ (9,311)	\$ (6,760)
Income tax expense	1	1	1	1
Net loss & comprehensive loss	<u>\$ (13,629)</u>	<u>\$ (12,260)</u>	<u>\$ (9,312)</u>	<u>\$ (6,761)</u>
Weighted average shares outstanding used in computing net loss per common share:				
Basic	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Diluted	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Net loss per common share				
Basic	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>
Diluted	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>

	As of December 31, 2012	As of September 30, 2013	
	Actual	Actual (Unaudited)	Pro Forma <sup>(1)</sup> (Unaudited)
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 185	\$ 303	\$ 303
Total assets	\$ 1,470	\$ 1,083	\$ 1,083
Notes payable, net of debt discount	\$ 22,376	\$ 4,330	\$ —
Line of Credit	\$ —	\$ 1,491	\$ 1,491
Total liabilities	\$ 28,855	\$ 11,356	\$ 4,595
Convertible preferred stock	\$ 3	\$ 7	\$ —
Total shareholders' deficit	\$ (27,385)	\$ (10,273)	\$ (3,512)

- (1) Gives effect to (i) the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of common stock, (ii) the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of our common stock in connection with the closing of our initial public offering, (iii) the issuance of an estimated 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, (iv) the termination of certain warrants upon the closing of our initial public offering in accordance with their terms and (v) the reclassification to shareholders' deficit of the fair value of certain warrants the exercise price and/or exercisability period length of which will be fixed upon the closing of our initial public offering in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus. The pro forma information is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

The unaudited pro forma balance sheet information as of September 30, 2013 assumes that the completion of our initial public offering had occurred as of September 30, 2013 and excludes 1,818,181 shares of common stock issued in the initial public offering and any related net proceeds.

## RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should consider carefully the specific risk factors described below in addition to the other information contained in this prospectus, including our financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in the prospectus, before making your investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### **Risks Relating to Our Financial Condition and Capital Requirements**

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

We have historically incurred substantial net losses, including net losses of \$13.6 million in 2011, \$12.3 million in 2012 and \$6.8 million in the first nine months of 2013, and we have never been profitable. At September 30, 2013, our accumulated deficit was approximately \$120 million. Before 2008, we were pursuing a business plan relating to fetal genetic disorders and other fields, all of which were unrelated to cancer diagnostics. The portion of our accumulated deficit that relates to the period from inception through December 31, 2007 is approximately \$66.5 million.

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

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

As described in Note 2 of our accompanying audited financial statements, our auditors have included a "going concern" provision in their opinion on our financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot secure the financing needed to continue as a viable business, our stockholders may lose some or all of their investment in us.

***We will need to raise additional capital.***

As of December 31, 2013, our cash and cash equivalents totaled approximately \$60,000. To continue as a going concern through February 2014, it will be necessary for us to raise additional bridge financing in January 2014 from our major shareholder, members of our board of directors and their affiliates, other accredited current investors and/or accredited new investors. We believe (although no assurance can be given) that we will be able to raise such additional bridge financing, when and as needed; during 2013 we continuously were seeking and successfully raising such bridge financing, when and as needed, and the prospect of the impending receipt of proceeds from this offering is expected to facilitate our efforts to raise additional bridge financing in January 2014. In the fourth quarter of 2013 we raised \$675,000 of bridge financing and drew down approximately an additional \$500,000 under our revolving line of credit from UBS Bank USA. As a result of raising such bridge financing and bank borrowing in the fourth quarter of 2013, it was not necessary for us to curtail, and we did not curtail, our operations.

We will also need to raise additional capital to expand our business to meet our long-term business objectives. Additional financing, which is not in place at this time, may be from the sale of equity or convertible or other debt securities in a public or private offering, from an additional credit facility or strategic partnership coupled with an investment in us or a combination of both. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Failure to raise additional capital in sufficient amounts would significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

## **Risks Relating to Our Business and Strategy**

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

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

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

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

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

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

- conducting clinical utility studies of such tests in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our non-exclusive partners, Life Technologies Corporation and Clariant, vigorously support our offerings;
- the success of the sales force which we intend to hire with some of the proceeds of this offering;
- whether healthcare providers believe such diagnostic tests provide clinical utility;
- whether the medical community accepts that such diagnostic tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
- whether health insurers, government health programs and other third-party payors will cover and pay for such cancer diagnostic tests and, if so, whether they will adequately reimburse us.

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

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

In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. Several new cancer drugs have been approved, and a number of new drugs in clinical development may increase patient survival time. There have also been advances in methods used to identify patients likely to benefit from these drugs based on analysis of biomarkers. We must continuously develop new cancer diagnostic tests and enhance any existing tests to keep pace with evolving standards of care. Our current test and our planned tests could become obsolete unless we continually

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innovate and expand them to demonstrate benefit in the diagnosis, monitoring or prognosis of patients with cancer. New cancer therapies typically have only a few years of clinical data associated with them, which limits our ability to develop cancer diagnostic tests based on, for example, biomarker analysis related to the appearance or development of resistance to those therapies. If we cannot adequately demonstrate the applicability of our current test and our planned tests to new treatments, by incorporating important biomarker analysis, sales of our tests could decline, which would have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In recent years, we have incurred significant costs in connection with the development of cancer diagnostic tests. For the year ended December 31, 2011, our research and development expenses were \$8.9 million and our sales and marketing expenses were \$0.7 million. For the year ended December 31, 2012, our research and development expenses were \$6.6 million and our sales and marketing expenses were \$0.8 million. We expect our expenses to continue to increase for the

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foreseeable future as we conduct studies of our current test and our planned cancer diagnostic tests, establish a sales and marketing organization, drive adoption of and reimbursement for our diagnostic tests and develop new tests. As a result, we need to generate significant revenues in order to achieve sustained profitability.

***If oncologists decide not to order OncoCEE-BR breast cancer diagnostic tests or our future cancer diagnostic tests, we may be unable to generate sufficient revenue to sustain our business.***

To generate demand for our current test and our planned cancer diagnostic tests, we will need to educate oncologists, pathologists, and other health care professionals on the clinical utility, benefits and value of the tests we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we need to assure oncologists of our ability to obtain and maintain adequate reimbursement coverage from third-party payors. We need to hire additional commercial, scientific, technical and other personnel to support this process. If we cannot convince medical practitioners to order our current test and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

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

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

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

***We are undergoing a management transition.***

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

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

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Michael W. Nall, our Chief Executive Officer and President, David F. Hale, our Executive Chairman, Lyle J. Arnold, Ph.D., our Senior Vice-President of Research & Development/Chief Scientific Officer, and Farideh Z. Bischoff, Ph.D., our Vice-President of Translational Research and Clinical Development. The collective efforts of each of these persons and others working with them as a team are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive



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management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our Chief Executive Officer and President, Executive Chairman, Chief Financial Officer and Chief Scientific Officer have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We do not maintain “key person” life insurance on any of our employees.

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

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

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

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

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

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

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

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

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

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

***We depend on third parties for the supply of blood samples and other biological materials that we use in our research and development efforts. If the costs of such samples and materials increase after we complete our initial public offering 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 test and our planned future tests. If one or more suppliers terminate their relationship with us or are unable to meet our requirements for samples, we will need to identify other third parties to provide us with blood samples and biological materials, which could result in a delay in our research and development activities and negatively affect our business. In addition, as we grow, our research and academic institution collaborators may seek additional financial contributions from us, which may negatively affect our results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current test and our planned future tests in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our current test and our planned future diagnostic tests cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; 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.

***Declining general economic or business conditions may have a negative impact on our business.***

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

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

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

There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Investment Act 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. The HIPAA amendments also impose 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. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to 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 state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

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

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

## Regulatory Risks Relating to Our Business

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

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

- Mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule annual Consumer Price Index update of 1.75% for the years 2011 through 2015. In addition, a permanent productivity adjustment is made to the fee schedule payment amount, which could range from 1.1% to 1.4% each year over the next 10 years. These changes in payments may apply to some or all of the tests we furnish to Medicare beneficiaries.
- Establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020.
- Requires each medical device manufacturer to pay an excise tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. 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 test and our planned future cancer diagnostic tests. The mandatory purchase of insurance has been strenuously opposed by a number of state governors, resulting in lawsuits challenging the constitutionality of certain provisions of the ACA. In 2012, the Supreme Court upheld the constitutionality of the ACA, with the exception of certain provisions dealing with the expansion of Medicaid coverage under the law. Therefore, most of the law's provisions will go into effect in 2013 and 2014. Congress has also proposed a number of legislative initiatives, including possible repeal of the ACA. At this time, it remains unclear whether there will be any changes made to the ACA, whether in part or in its entirety.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. 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 a 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. The full impact on our business of the ACA and the sequester law is uncertain. In addition, the Middle Class Tax Relief and Job Creation Act of 2012, or MCTRJCA, mandated an additional change in Medicare reimbursement for clinical laboratory tests. This legislation requires a rebasing of the Medicare Clinical Laboratory Fee Schedule to effect a 2% reduction in payment rates otherwise determined for 2013. This will serve as a base for 2014 and subsequent years. In January 2013, as a result of the changes mandated by the ACA and MCTRJCA, the Centers for Medicare & Medicaid Services, or CMS, reduced its reimbursement for laboratory tests for 2013 by approximately 3%.

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. On November 1, 2013, CMS issued its 2014 Physician Fee Schedule Final Rule, or the 2014 Final Rule. In the 2014 Final Rule, CMS called for a reduction of approximately 23.7% in the 2014 conversion factor that is used to calculate physician reimbursement. If in future years Congress does not adopt interim legislation to block or offset, and/or CMS does not moderate, any substantial CMS-proposed reimbursement reductions, the resulting decrease in payments from Medicare could adversely impact our revenues and results of operations.

In addition, many of the Current Procedure Terminology, or CPT, codes that we use to bill for cancer diagnostic tests were revised by the American Medical Association, effective January 1, 2013. In the 2013 Final Rule, CMS announced that it has decided to keep the new molecular codes on the Clinical Laboratory Fee Schedule rather than move

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them to the Physician Fee Schedule as some stakeholders had urged. Our reimbursement could be adversely affected by CMS' actions. If it reduces reimbursement for the new test codes or does not pay for our codes, then our revenues would be adversely affected. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

On July 9, 2013, CMS issued a proposed Physician Fee Schedule revision that would, in the aggregate, impose a 25% reduction for payments for pathology codes when services are provided by independent laboratories, to take effect beginning with calendar year 2014. The proposed cuts for certain services were drastic. For example, reimbursement for the technical component of FISH analysis would have been cut by 68%. We cannot predict the outcome of this initiative. However, the 2014 Physician Fee Schedule Final Rule issued by CMS in November 2013 left FISH reimbursement rates for independent laboratories and physicians essentially unchanged from 2013 reimbursement levels.

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

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

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

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

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

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

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



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

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clariant was responsible for all billing associated with our tests. We do not have data for Clariant's billing and collection experience with respect to our test, because Clariant paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month (in addition to the 20-30 tests per month which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute). Billing for physician-ordered tests is now handled for us by a non-Clariant billing service provider. In November and December 2013 we invoiced, through this service provider, for 13 physician-ordered tests. Of these, 8 tests were billed to private third-party payors and 5 were billed to Medicare. We have not yet had any response or adjudication from any payor as to the bills submitted in late 2013. Accordingly, we do not yet have any data regarding reimbursement history or collectability experience. In addition, we believe the sample size of 13 is too small to be the basis for any conclusion about our ongoing payor mix.

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

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

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

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may bill Medicare or the beneficiary for the service. There is currently no national coverage policy regarding the CTC capture/enumeration portion of our testing. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto GBA, LLC, adopted a negative coverage policy for CTC capture/enumeration (with the exception that Janssen Diagnostics, LLC's CellSearch® test has historically been covered for CTC capture/enumeration). The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore the capture/enumeration portion of our OncoCEE testing is not currently covered and we will receive no payment from Medicare for this service unless and until the coverage policy is changed. On November 4, 2013, we submitted a comprehensive dossier explaining to Palmetto GBA and Noridian the benefits of the capture/enumeration testing in order to seek to persuade the MACs to allow coverage for this portion of our testing. Palmetto GBA responded on November 27, 2013, denying our request for Medicare coverage for the CTC capture/enumeration portion of our OncoCEE testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The earliest date we could submit another dossier on this matter is May 27, 2014. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

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



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

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

Medicare and Medicaid have complex billing and documentation requirements that we must satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We must also comply with numerous other laws applicable to billing and payment for healthcare services, including privacy laws. Failure to comply with these requirements may result in 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.

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, Florida, Maryland, New York and Rhode Island require that we hold licenses to test specimens from patients in those states or received from ordering physicians in those states; Pennsylvania licensure or registration may be required as well, depending on the circumstances. 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. We currently do not have the Florida, Maryland and Rhode Island licenses, but we believe they will soon be re-issued to us. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions if we seek to expand international distribution of our tests outside the United States.

If we were to lose our CLIA certification or California laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenues and harm our business. If we were to lose our 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 test and our planned future tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our tests.***

Although the FDA maintains that it has authority to regulate the development and use of laboratory developed tests, or LDTs, such as ours, as medical devices, it has not exercised its authority with respect to most LDTs as a matter of enforcement discretion. The FDA could, at any time, change its policy with regard to this matter.

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We believe that our cancer diagnostic tests, as utilized in our clinical laboratory, are and would be LDTs. As a result, we believe that pursuant to the FDA's current policies and guidance, the FDA does not require that we obtain regulatory clearances or approvals for our LDTs. 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.

Moreover, FDA policy pertaining to diagnostic testing is continuing to evolve and is subject to ongoing review and revision. A significant change in any of the laws, regulations or policies may require us to achieve regulatory compliance. At various times since 2006, the FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our current test and our planned future tests. For example, in June 2010, the FDA announced a public meeting to discuss the agency's oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision-making and disease management, particularly in the context of personalized medicine. The FDA indicated that it was considering a risk-based application of oversight to LDTs and that, following public input and discussion, it might issue separate draft guidance on the regulation of LDTs, which ultimately could require that we seek and obtain either pre-market clearance or approval of LDTs, depending upon the risk-based approach the FDA adopts. The public meeting was held in July 2010 and further public comments were submitted to the FDA through September 2010. The FDA has stated it is continuing to develop draft guidance in this area. Section 1143 of the Food and Drug Administration Safety and Innovation Act of 2012 requires the FDA to notify U.S. Congress at least 60 days before issuing a draft or final guidance regulating LDTs and to provide details of the anticipated action.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our current test and our planned future tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. We believe it is possible that legislation will be enacted into law or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our breast cancer test or to develop and introduce new tests. Given the attention Congress continues to give to these issues, legislation affecting this area may be enacted into law and may result in increased regulatory burdens on us as we continue to offer our test and to develop and introduce new tests.

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any 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;

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- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established federal crimes for 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;
- federal false claims 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; 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.

The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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, because of amendments enacted in 2009 as part of the Fraud Enforcement and Recovery Act, 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 civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, 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 health care providers 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 health care provider, 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 integrity and availability of Protected Health Information in electronic form. These standards apply to covered health care providers and also to “business associates” or third parties providing services involving the use or disclosure of Protected Health Information. The HIPAA privacy and security regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing Protected Health Information. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws.

Moreover, the Health Information Technology for Economic and Clinical Health Act, or HITECH, among other things, established certain health information security breach notification requirements. 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 are publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected.

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

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

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

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

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

## **Intellectual Property Risks Related to Our Business**

***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 (including the MD Anderson Cancer Center, Columbia University and the University of California, San Diego), 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.

***If we are unable to maintain intellectual property protection, our competitive position could be harmed.***

Our ability to protect our discoveries and technologies affects our ability to compete and to achieve sustained profitability. Currently, we rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks and trademark applications, confidentiality or non-disclosure agreements, material transfer agreements, licenses, consulting agreements, work-for-hire agreements and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know-how, trade secrets and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets. Currently, we own 3 issued U.S. patents, 6 pending U.S. patent applications and their corresponding foreign patents and patent applications, relevant to our cancer diagnostics business, as well as 2 pending U.S. patent applications and their corresponding foreign patent applications we jointly own with Aegea Biotechnologies, Inc. (for which we have the exclusive rights for specified fields of use). While we intend to pursue additional patent applications, it is possible that our pending patent applications and any future applications may not result in issued patents. Even if patents are issued, third parties may

independently develop similar or competing technology that avoids our patents. Further, we cannot be certain that the steps we have taken will prevent the misappropriation of our trade secrets and other confidential information as well as the misuse of our patents and other intellectual property, particularly in foreign countries where we have not filed for patent protection. In addition, if Aegea Biotechnologies, Inc. were to challenge the scope of our rights under or attempt to terminate its Assignment and Exclusive Cross-License Agreement with us, our ability to use the technologies we in-license from Aegea, or to prevent others from using them in the fields of use for which we have an exclusive license, could be compromised.

From time to time the U.S. Supreme Court, other federal courts, the U.S. Congress or the U.S. Patent and Trademark Office, or USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, in 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court later reversed that decision in *Bilski v. Kappos*, finding that the “machine-or-transformation” test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. In 2012, in the case *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the U.S. Supreme Court reversed the Federal Circuit’s application of *Bilski* and invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. It is unclear at this time whether the USPTO will amend its patent prosecution guidelines for determining patentability of diagnostic or other processes, and how lower courts will implement the decision. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards.

In 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously ruled that, “A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated,” invalidating Myriad Genetics’ patents on the BRCA1 and BRCA2 genes. However, the Supreme Court also held that manipulation of a gene to create something not found in nature, such as a strand of synthetically-produced complementary DNA, could still be eligible for patent protection. The Supreme Court noted that method patents, which concern technical procedures for carrying out a certain process, are not affected by the ruling.

It should also be noted that in 2010, the Secretary’s Advisory Committee on Genetics, Health and Society voted to approve a report entitled “Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests.” That report defines “patent claims on genes” broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that HHS should explore, identify and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote nonexclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether HHS will act upon these recommendations, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

***We may face intellectual property infringement claims that could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.***

From time to time we may face intellectual property infringement or misappropriation claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third-party to succeed on an infringement claim against us, we may be required to pay substantial damages, including treble damages if such infringement were found to be willful. In addition, we could face an injunction, barring us from conducting the allegedly infringing activity. The outcome of the litigation could require us to enter into a license agreement which may not be pursuant to acceptable or commercially reasonable or practical terms or which may not be available at all.

It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non-infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non-infringing technologies which would require us to re-validate the test. Any such re-validation, in addition to being costly and time consuming, may be unsuccessful.

Finally, we may initiate claims to assert or defend our own intellectual property against third parties. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert our management's attention from our business and negatively affect our operating results or financial condition.

### **Risks Relating to Our Common Stock and This Offering**

***The price of our common stock may be volatile, and the market price of our common stock after this offering may drop below the price you pay.***

The initial public offering price per share may vary from the market price of our common stock after the offering. If an active market for our stock develops and continues, our stock price nevertheless may be volatile. Market prices for securities of early-stage life sciences companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price per share. 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 breast cancer test and our planned future cancer diagnostic tests;
- favorable or unfavorable decisions about our tests from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- termination of the lock-up agreements or other restrictions on the ability of our existing stockholders to sell shares after this offering;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled "Risk Factors"; and
- general market and economic conditions.

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

***The NASDAQ Capital Market may not list our securities, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.***

We anticipate that our securities will be listed on The NASDAQ Capital Market, a national securities exchange, upon consummation of this offering. Although, after giving effect to this offering, we expect to meet, on a pro forma basis, The NASDAQ Capital Market's minimum initial listing standards, which generally mandate that we meet certain requirements relating to stockholders' equity, market capitalization, aggregate market value of publicly held shares and distribution requirements, we cannot assure you that we will be able to meet those initial listing requirements. If The NASDAQ Capital Market does not list our securities for trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;



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- reduced liquidity with respect to our securities;
- a determination that our shares of common stock are “penny stock” which will require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as “covered securities.” Assuming our common stock will be listed on The NASDAQ Capital Market, our common stock will be covered securities. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on The NASDAQ Capital Market, our common stock would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

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

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

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

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

### ***Our quarterly operating results may fluctuate significantly.***

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

- the rate of adoption and/or continued use of our current breast cancer test and our planned future tests by healthcare practitioners;
- variations in the level of expenses related to our development programs;
- addition or reduction of resources for sales and marketing;
- addition or termination of clinical utility studies;



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- any intellectual property infringement lawsuit in which we may become involved;
- third party payor determinations affecting our tests; and
- regulatory developments affecting our tests.

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

***The shares you purchase in this offering will experience immediate and substantial dilution and may also be diluted by exercises of outstanding options and warrants.***

The initial public offering price per share of our common stock will be substantially higher than the net tangible book value per share of our common stock immediately after the offering. At the assumed initial public offering price of \$11.00 per share, purchasers of our common stock will effectively incur dilution of \$7.68 per share in the net tangible book value of their purchased shares. Conversely, the shares of our common stock that our existing stockholders currently own will receive a material increase in net tangible book value per share. As of September 30, 2013, we had outstanding options to purchase an aggregate of 344,565 shares of our common stock at a weighted average exercise price of \$5.13 per share and warrants to purchase an estimated aggregate of 350,974 shares of our common stock at an estimated weighted average exercise price of \$11.00 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. In addition, you may experience additional dilution if we issue common stock in the future. As a result of this dilution, you may receive significantly less than the full purchase price you paid for the shares in the event of liquidation.

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

Sales of substantial amounts of our common stock after this offering, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. The shares of common stock sold in this offering will be freely tradable, without restriction, in the public market, except for any shares sold to our affiliates.

In connection with this offering, we have agreed, subject to limited exceptions, not to issue, sell or transfer any shares of common stock for 180 days after the date of this prospectus without the consent of Aegis Capital Corp. Our officers, directors and certain stockholders have agreed before the commencement of this offering, subject to limited exceptions, not to sell or transfer any shares of common stock for 180 days after the date of this prospectus without the consent of Aegis Capital Corp. However, Aegis Capital Corp. may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any stockholder or the availability of shares for future sale will have on the market price of our common stock.

Approximately 1,834,465 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after the date of this prospectus, subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our common stock in the public market after the completion of this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock. See the section entitled “Shares Eligible for Future Sale” for a more detailed description of the restrictions on selling shares of our common stock after this offering.

In addition, as of September 30, 2013, we had outstanding options to purchase 344,565 shares of our common stock and outstanding warrants to purchase shares of our common and Series A preferred stock overlying an estimated aggregate of 822,372 common stock equivalents. We plan to register for offer and sale the shares of common stock that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options 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.

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In addition, we are registering the 90,909 shares of our common stock underlying the warrants to be issued to the representative of the underwriters in connection with this offering as described in the “Underwriting – Representative’s Warrants” section of this prospectus.

We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Underwriting” section of this prospectus.

***An active trading market may not develop for our common stock, and you may not be able to sell your stock at or above the initial public offering price per share.***

There is no established trading market for our common stock, the market for our common stock will likely be highly volatile, and the market price of our common stock may decline regardless of our operating performance. Before this offering, you could not buy or sell our securities publicly. Although we anticipate that our common stock will be approved for listing on The NASDAQ Capital Market, an active public market for our common stock may not develop or be sustained after this offering. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our common stock or how liquid that market might become. If a market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at the time you wish to sell them, at a price that is attractive to you, or at all.

The initial public offering price per share has been determined through negotiation between us and representatives of the underwriters, and may not be indicative of the market price for our common stock after this offering. You may not be able to sell your shares at or above the initial public offering price per share.

***If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

***Our largest stockholder will continue to have substantial influence over us after this offering and could delay or prevent a change in corporate control.***

Claire K. T. Reiss beneficially owns approximately 78% of our common stock and, upon the closing of this offering, assuming we sell 1,818,181 shares of common stock in this offering and there is no exercise of the underwriters’ option to purchase additional shares, will beneficially own approximately 44% of our common stock. Mrs. Reiss has significant influence over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership might harm the market price of our common stock by:

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

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

As a private company, we were not subject to the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. After completion of this offering, we will be required to document and test our internal control over financial reporting. If

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we fail to remediate any significant deficiencies or material weaknesses in internal controls that may be identified in the future, we may be unable to conclude that our internal control over financial reporting is effective. Under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, issuers that qualify as “emerging growth companies” under the JOBS Act will not be required to provide an auditor’s attestation report on internal controls for so long as the issuer qualifies as an emerging growth company. We currently qualify as an emerging growth company under the JOBS Act and we may choose not to provide an auditor’s attestation report on internal controls. However, if we cannot favorably assess the effectiveness of our internal control over financial reporting, or if we require an attestation report from our independent registered public accounting firm in the future and that firm is unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence and, in turn, our stock price could be materially adversely affected.

***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 this prospectus and 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 for up to five years, 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 this prospectus and our periodic reports and proxy statements. We cannot predict if investors will 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, will be 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The NASDAQ Stock Market to implement provisions of the Sarbanes-Oxley Act, imposes significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, there are significant corporate governance and executive compensation related provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted in 2010, that require the SEC to adopt additional rules and regulations

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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 and up to five years from the pricing of this offering. We intend to take 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.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our consolidated net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***Our management will have broad discretion over the use of the proceeds we receive in this offering, and may not apply the proceeds in ways that increase the value of your investment.***

We estimate that net proceeds of the sale of the common stock that we are offering will be approximately \$17.7 million, or \$20.5 million, if the underwriters exercise their option to purchase additional shares in this offering in full. We currently intend to use the net proceeds of the offering to hire sales and marketing personnel and support increased sales and marketing activities, to fund further research and development, clinical utility studies and future enhancements of our tests, to acquire equipment, implement automation and scale our capabilities to prepare for significant test volume, to satisfy deferred salary obligations, and for general corporate purposes and to fund ongoing operations and expansion of our business. We will have broad discretion in the application of the net proceeds in the category of “for general corporate purposes and to fund ongoing operations and expansion of our business,” and investors will be relying on our judgment regarding the application of the proceeds of this offering. The actual amounts and timing of our actual expenditures depend on numerous factors, including the success of our efforts to market OncoCEE-BR, the timing and progress of our discovery, research and development activities for the tests in our pipeline, our ability to reduce operating costs through the implementation of automation and economies of scale, changes in regulatory requirements for LDTs, and other unforeseen regulatory or compliance costs. The costs and timing of development activities, particularly conducting clinical utility studies and validation studies are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities and other unforeseen events, our plans and priorities may change and we may apply the net proceeds of this offering in different proportions than we currently anticipate. Moreover, you will not have the opportunity to influence our decision on how to use the proceeds from this offering. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment. See the Section entitled “Use of Proceeds.”

***Existing stockholders may view our initial public offering process unfavorably.***

The process of effecting an initial public offering has taken considerable time and is associated with several personnel and other changes, including a reverse common stock split. Some of our current stockholders have invested in our securities at prices which are at or above the initial public offering price per share. No assurances can be given as to whether any stockholders will seek to take actions against our company or the board with respect to our initial public offering process.

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

- classify our board of directors into three classes of equal (or roughly equal) size, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are “staggered”;
- allow the authorized number of directors to be changed only by resolution of our board of directors;
- authorize our board of directors to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholders meeting.

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

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

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

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

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an “ownership change,” as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect “five percent shareholders” increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period, typically three years. 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, which may be outside of our control, may trigger an “ownership change” and, consequently, Section 382 and 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. As of December 31, 2012, we had federal and state net operating loss carryforwards of approximately \$104.4 million and \$95.7 million, respectively, and federal and California research and development credits of \$2.9 million and \$3.0 million, respectively, which could be limited if we experience an “ownership change.”

***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.

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

This prospectus also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

## USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately \$17.7 million, or approximately \$20.5 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$11.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$1.7 million, or approximately \$1.9 million if the underwriters exercise their over-allotment option in full, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds of the offering as follows:

- approximately \$5 million to hire sales and marketing personnel and support increased sales and marketing activities;
- approximately \$5 million to fund further research and development, clinical utility studies and future enhancements of our current test and our planned tests and services;
- approximately \$3 million to acquire equipment, implement automation and scale our capabilities to prepare for significant test volume;
- approximately \$1 million to satisfy deferred salary obligations; and
- the balance for general corporate purposes and to fund ongoing operations and expansion of our business.

The expected use of net proceeds of this offering represents our current intentions based upon our present plan and business conditions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. We will have broad discretion in the application of the net proceeds in the category of “for general corporate purposes and to fund ongoing operations and expansion of our business,” and investors will be relying on our judgment regarding the application of the proceeds of this offering. For example, if we identify opportunities that we believe are in the best interests of our stockholders, we may use a portion of the net proceeds from this offering to acquire, invest in or license complementary products, technologies or businesses although we have no current commitments, understandings or agreements to do so. The actual amounts and timing of our actual expenditures depend on numerous factors, including the success of our efforts to market OncoCEE-BR, the timing and progress of our discovery, research and development activities for the tests in our pipeline, the success of our efforts to increase sales of our laboratory services, the success of our efforts to expand our international sales, changes in regulatory requirements for LDTs, and other unforeseen regulatory or compliance costs. The costs and timing of test discovery and development activities, particularly conducting clinical validation studies and obtaining regulatory clearance or approval, if required, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities and other unforeseen events, our plans and priorities may change and we may apply the net proceeds of this offering in different proportions than we currently anticipate.

## 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.

**CAPITALIZATION**

The following table sets forth our capitalization as of September 30, 2013:

- on an actual basis; and
- on a pro forma basis as of September 30, 2013, to reflect the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of common stock, the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of our common stock in connection with the closing of our initial public offering, and the issuance of an estimated 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, the termination of certain warrants upon the closing of our initial public offering in accordance with their terms and the reclassification to shareholders' deficit of the fair value of certain warrants the exercise price and/or exercisability period length of which will be fixed upon the closing of our initial public offering in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus.

You should read this table together with the sections entitled "Use of Proceeds" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as our financial statements and the related notes, which appear elsewhere in this prospectus.

<i>(dollars in thousands)</i>	<b>As of September 30, 2013</b>	
	<b>(unaudited) Actual</b>	<b>(unaudited) Pro Forma</b>
Cash and cash equivalents	\$ 303	\$ 303
Long term debt (inclusive of current portion)	5,821	1,491
Series A convertible preferred stock, par value \$0.0001 per share, 100,000,000 shares authorized, 69,421,047 shares issued and outstanding, actual; 5,000,000 shares of preferred stock authorized, no shares issued and outstanding, pro forma	7	—
Common stock, par value \$0.0001 per share, 53,000,000 shares authorized, 181,614 shares issued and outstanding, actual; 40,000,000 shares authorized, 2,458,154 shares issued and outstanding, pro forma	—	—
Additional paid-in capital	109,669	116,437
Accumulated deficit	(119,949)	(119,949)
Total stockholders' equity/(deficit)	(10,273)	(3,512)
Total capitalization	(4,452)	(2,021)



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The number of shares of common stock to be outstanding after the offering is based on the pro forma number of shares outstanding as of September 30, 2013 after giving effect to (i) the sale of 1,818,181 shares of common stock in this offering, (ii) the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of common stock, (iii) the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of our common stock in connection with the closing of our initial public offering, (iv) the issuance of 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, (v) the termination of certain warrants upon the closing of our initial public offering in accordance with their terms and (vi) the reclassification to shareholders' deficit of the fair value of certain warrants the exercise price and/or exercisability period length of which will be fixed upon the closing of our initial public offering in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus. This number excludes:

- 344,565 shares of our common stock issuable upon the exercise of stock options as of September 30, 2013, with a weighted average exercise price of \$5.13 per share;
- 133,971 shares of our common stock issuable upon the exercise of outstanding restricted stock units (which are currently expressed in shares of common stock) as of September 30, 2013;
- an estimated 350,974 shares of our common stock issuable upon the exercise of outstanding common stock warrants as of September 30, 2013, at an estimated weighted average exercise price of \$11.00 per share;
- 192,262 common stock equivalents issuable upon the exercise of our outstanding warrants to purchase preferred stock (the warrants overlying all but 1,587 of which will terminate upon the closing of our initial public offering in accordance with their terms);
- any shares of our common stock issuable upon exercise of the underwriters' over-allotment option;
- any shares of common stock that will underlie the representative's warrants; and
- other shares of our common stock reserved for future issuance under our 2013 and 2007 Equity Incentive Plans.

## **DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock in this offering and our pro forma net tangible book value per share immediately after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities less debt discounts, by the number of outstanding shares of our common stock. Before considering the effects of the proceeds of this offering, but giving effect to the completion of our initial public offering of 1,818,181 shares of our common stock at \$11.00 per share, the automatic conversion of our outstanding shares of Series A preferred stock into 1,652,851 shares of our common stock in connection with our initial public offering, the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) at a conversion price of \$11.00 per share, into an aggregate of 555,143 shares of our common stock, the issuance of 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, and the reclassification of the warrant liability balance of \$2,039,577 to additional paid-in capital as a result of the terms of common stock warrants being fixed, our pro forma net tangible book value (deficit) as of September 30, 2013 was \$(3,512,030), or approximately \$(1.43) per share. Upon completion of this offering, our pro forma net tangible book value as of September 30, 2013 will be approximately \$14.2 million or approximately \$3.32 per share. This represents an immediate increase in pro forma net tangible book value of \$4.75 per share to our existing stockholders and an immediate dilution of \$7.68 per share to new investors purchasing our common stock in this offering. The following table illustrates the per share dilution (unaudited):

Assumed public offering price per share	\$11.00
Pro forma net tangible book value (deficit) per share as of September 30, 2013	\$(1.43)
Increase in pro forma net tangible book value (deficit) per share after this offering	<u>4.75</u>
Pro forma net tangible book value (deficit) per share after this offering	<u>3.32</u>
Dilution in pro forma net tangible book value (deficit) per share to new investors	<u>\$ 7.68</u>

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The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value will increase to \$3.73 per share, representing an immediate increase to existing stockholders of \$5.16 per share and an immediate dilution of \$7.27 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, new investors will experience further dilution.

The following table summarizes, on a pro forma basis as of September 30, 2013, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed public offering price of \$11.00 per share (unaudited).

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	%	Amount	%	
Existing stockholders	2,458,154	57	\$112,932,635	85	\$ 45.94
New investors	1,818,181	43	\$ 20,000,000	15	\$ 11.00
Total	4,276,335	100	\$132,932,635	100	

The number of shares purchased from us by existing stockholders is based on 181,614 shares of our common stock outstanding as of September 30, 2013 and gives effect to the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of common stock, the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of our common stock in connection with the closing of our initial public offering, and the issuance of an estimated 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus. This number excludes:

- 344,565 shares of our common stock issuable upon the exercise of stock options as of September 30, 2013, with a weighted average exercise price of \$5.13 per share;
- 133,971 shares of our common stock issuable upon the exercise of outstanding restricted stock units (which are currently expressed in shares of common stock) as of September 30, 2013;
- an estimated 350,974 shares of our common stock issuable upon the exercise of outstanding common stock warrants as of September 30, 2013, at an estimated weighted average exercise price of \$11.00 per share;
- 192,262 common stock equivalents issuable upon the exercise of our outstanding warrants to purchase preferred stock (the warrants overlying all but 1,587 of which will terminate upon the closing of our initial public offering in accordance with their terms);
- any shares of our common stock issuable upon exercise of the underwriters' over-allotment option;
- any shares of common stock that will underlie the representative's warrants; and
- other shares of our common stock reserved for future issuance under our 2013 and 2007 Equity Incentive Plans.

To the extent that the underwriters' over-allotment option is exercised or any warrants or options are exercised, there will be further dilution to investors.

## SELECTED HISTORICAL FINANCIAL DATA

The following table summarizes our selected financial data for the periods and as of the dates indicated. Our selected statements of operations data for each of the years in the periods ended December 31, 2011 and 2012, and our selected balance sheet data as of December 31, 2011 and 2012, have been derived from our audited financial statements and their related notes, which are included elsewhere in this prospectus. The unaudited selected statements of operations data for the nine months ended September 30, 2012 and 2013, and the unaudited balance sheet data as of September 30, 2013, are derived from our unaudited financial statements, which are included elsewhere in this prospectus. All “Weighted average shares outstanding” data and all “Net loss per common share” data, whether derived from our audited financial statements or from our unaudited financial statements, have been adjusted to reflect a 1-for-14 reverse stock split which we effected on November 1, 2013. Our unaudited financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, include all adjustments, consisting of normal recurring adjustments necessary for a fair presentation of our financial condition as of such dates and our results of operations for such periods. Our historical results are not necessarily indicative of the results to be expected for any future periods and our interim results are not necessarily indicative of the results to be expected for the full fiscal year. Our selected financial data should be read together with the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and with our financial statements and their related notes, which are included elsewhere in this prospectus.

	Year ended December 31,		For the nine months ended September 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
	(in thousands, except share and per share data)			
Revenues	\$ 1	\$ 109	\$ 88	\$ 115
Cost of revenues	17	1,201	756	1,759
Gross profit	(16)	(1,092)	(668)	(1,644)
Research and development expenses	8,853	6,562	5,304	2,376
General and administrative expenses	2,729	2,063	1,613	1,736
Sales and marketing expenses	673	786	604	130
Loss from operations	(12,271)	(10,503)	(8,189)	(5,886)
Total other income/(expense)	(1,357)	(1,756)	(1,122)	(874)
Loss Before Income Taxes	\$ (13,628)	\$ (12,259)	\$ (9,311)	\$ (6,760)
Income tax expense	1	1	1	1
Net loss & comprehensive loss	<u>\$ (13,629)</u>	<u>\$ (12,260)</u>	<u>\$ (9,312)</u>	<u>\$ (6,761)</u>
Weighted average shares outstanding				
Basic	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Diluted	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Net loss per common share				
Basic	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>
Diluted	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>
Weighted average shares outstanding used in computing pro forma net loss per share attributable to common shareholders, basic and diluted (unaudited)		<u>2,436,933</u>		<u>2,457,494</u>
Pro forma net loss per common share				
Basic		<u>\$ (5.03)</u>		<u>\$ (2.75)</u>
Diluted		<u>\$ (5.03)</u>		<u>\$ (2.75)</u>

	As of December 31, 2012	As of September 30, 2013	
	Actual	Actual (unaudited)	Pro Forma <sup>(1)</sup> (unaudited)
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 185	\$ 303	303
Total assets	1,470	1,083	1,083
Notes payable, net of debt discount	22,376	4,330	—
Line of Credit	—	1,491	1,491
Warrant liability	982	2,040	—
Total liabilities	28,855	11,356	4,595
Convertible preferred stock	3	7	—
Total shareholders' deficit	(27,385)	(10,273)	(3,512)

- (1) Gives effect to (i) the automatic conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of common stock, (ii) the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of our common stock in connection with the closing of our initial public offering, (iii) the issuance of an estimated 68,546 shares of common stock in connection with our initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, (iv) the termination of certain warrants upon the closing of our initial public offering in accordance with their terms and (v) the reclassification to shareholders' deficit of the fair value of certain warrants the exercise price and/or exercisability period length of which will be fixed upon the closing of our initial public offering in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus. The pro forma information is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

The unaudited pro forma balance sheet information as of September 30, 2013 assumes that the completion of our initial public offering had occurred as of September 30, 2013 and excludes 1,818,181 shares of common stock issued in the initial public offering and any related net proceeds.

## 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 prospectus. 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 prospectus. The share numbers in the following discussion reflect a 1-for-3 reverse common stock split that we effected on November 3, 2011 and a further 1-for-14 reverse common stock split that we effected on November 1, 2013.*

### Overview

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

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

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

We are in the process of commercializing our first test, OncoCEE-BR, for breast cancer, and anticipate launching an OncoCEE-LU test for non-small cell lung cancer, or NSCLC, in the first half of 2014. These tests utilize our CEE technology platform and provide CTC enumeration as well as biomarker analysis from a standard blood sample. In the case of the OncoCEE-BR test, 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. We plan to include immunocytochemical analysis of estrogen receptor and progesterone receptor proteins in the OncoCEE-BR test within the next year. The OncoCEE-LU test's biomarker analysis would include FISH for EML4/ALK and ROS1 gene fusions, as well as mutation analysis for the epidermal growth factor receptor, or EGFR, gene, the K-ras gene and the B-raf gene.

The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are linked to the drugs Tarceva® and Iressa® (AstraZeneca). The T790M mutation of the EGFR gene as a resistance marker for EGFR tyrosine kinase inhibitors is linked to drugs in clinical development that address this resistance such as Gilotrif® (Boehringer-Ingelheim) and dacomitinib (Pfizer). The codon 12 and 13 mutations of the K-ras gene are linked to non-responsiveness to the EGFR kinase inhibitors, and the codon 600 mutations of the B-raf gene are linked to Zelboraf® and Tafenlar®, which are both approved for melanoma and are in clinical trials for lung cancer. Our OncoCEE-LU test would be performed on a standard blood sample.

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

### **Key Factors Affecting our Results of Operations and Financial Condition**

Our overall long-term growth plan depends on our ability to develop and commercialize tests through our CLIA laboratory. We have the OncoCEE-BR test available as a commercial product and we plan to enhance revenue for this product through the efforts of a sales and marketing organization we plan to hire after the completion of this offering. We are developing additional OncoCEE tests for non-small cell lung, colorectal, gastric and prostate cancers and melanoma that we expect to make available to physicians over the next three years. To facilitate market adoption of our tests, we anticipate having to successfully complete additional clinical utility studies with clinical samples to generate clinical utility data and then publish our results in peer-reviewed scientific journals. Our ability to complete such clinical studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research, to conduct the appropriate clinical studies and to obtain favorable clinical data.

We 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**

Almost all of our revenue in 2012 was generated through limited commercialization of our OncoCEE-BR test. Over 75% of this revenue was generated through our arrangement with Clariant. 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.

In 2012, \$67,000, which represented the majority of our commercial revenue for that year, was billed to Clariant, which until May 2013 had responsibility for billing the third-party payors. Because Clariant paid us a contracted amount per test performed regardless of their billing and collections, we do not have data about the payor mix, reimbursement history and collectability experience for the tests performed under such arrangement. Clariant has paid us for all tests that we conducted under our arrangement in 2012. In the May 2013 revision of our arrangements with Clariant, we undertook responsibility for billing the payors and for reporting the results of the tests to the ordering physicians, and the exclusivity of Clariant's marketing partner rights for OncoCEE-BR ended. The May 2013 revision of our arrangements with Clariant will, in general, have the effect of delaying the timing of revenue recognition (see the "Revenue Recognition" paragraph of Note 3 of the notes to our audited financial statements) and adding uncertainty to the collectability of our accounts receivable.

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

Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clariant was responsible for all billing associated with our tests. We do not have data for Clariant's billing and collection experience with respect to our test, because Clariant paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month (in addition to 20-30 tests per month performed since January 2013 under our development collaboration program with the Dana-Farber Cancer Institute). Billing for physician-ordered tests is now handled for us by a non-Clariant billing service provider. In November and December 2013 we invoiced, through this service provider, for 13 physician-ordered tests. Of these tests, 8 were billed to private third-party payors and 5 were billed to Medicare. We have not yet had any response or adjudication from the payors as to these bills, and accordingly we do not yet have any data as to reimbursement history or collectability experience. In addition, we believe the sample size of 13 is too small to be the basis for any conclusion about our ongoing payor mix.

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

### **Cost of Revenues**

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

### ***Operating Expenses***

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

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

*Sales and Marketing Expenses.* Our sales and marketing expenses consist principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including sales collaterals and trade shows. We expect our sales and marketing expenses to increase significantly after we complete our initial public offering as we hire additional sales and marketing personnel and launch new tests.

*General and Administrative Expenses.* General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, occupancy costs, and other general expenses. We expect that our general and administrative expenses will increase as we expand our business operations. When we begin billing a significant number of tests, bad debt is expected to become a greater expense. We further expect that general and administrative expenses will increase significantly due to increased information technology, legal, insurance, accounting and financial reporting expenses associated with being a public company.

### ***Seasonality***

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

### **Critical Accounting Policies and Significant Judgments and Estimates**

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

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

- Revenue recognition;
- Accounts receivable and bad debts;
- Stock-based compensation;
- Common stock valuation; and
- Warrant liability.

### **Revenue Recognition**

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

Our primary source of revenue for the year ended December 31, 2012 was Clariant, a collaboration partner. This revenue was derived from clinical laboratory testing performed in our laboratories under our collaboration agreement. As there was a contractually agreed upon price under our collaboration agreement as in effect until May 2013, and collectability from our collaboration partner is reasonably assured, revenues for these tests under our collaboration agreement as in effect until May 2013 is earned at the time the test is completed and the results are delivered to the third party.

### **Accounts Receivable and Bad Debts**

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

### **Stock-Based Compensation Expense**

We account for stock-based compensation under the provisions of ASC Topic 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. We estimate the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model, or Black-Scholes valuation model. 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. At September 30, 2013, we had unrecognized compensation cost related to nonvested employee stock options of approximately \$834,000, which amount is expected to be recognized over the next 1.76 years.

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, the expected life of the stock option, stock price volatility, risk-free interest rate and forfeiture rates.

### **Common Stock Valuation**

In the absence of a public trading market, our board of directors determined a reasonable estimate of the then-current fair value of our common stock for purposes of granting stock-based compensation based on input from management and valuation reports prepared by an independent third-party valuation specialist. We determined the fair value of our common



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

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

### ***Warrant Liability***

Warrants for shares that are contingently redeemable and for which the exercise price is not fixed are classified as liabilities on the accompanying balance sheets and carried at their estimated fair value, determined through use of a probability-weighted Black-Scholes valuation model. At the end of each reporting period, any changes in fair value are recorded as a component of total other income/(expense). We will continue to adjust the carrying value of the warrants until the earlier of the exercise of the warrants, the warrants no longer meeting the criteria to be classified as liabilities or the completion of a liquidation event, including the completion of an initial public offering under the Securities Act, at which time the exercise price will be fixed for the surviving warrants, and the fair value of those warrants will be reclassified to shareholders’ deficit.

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## Results of Operations

### Nine Months Ended September 30, 2012 and 2013

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

	Nine Months Ended September 30,		Change	
	2012	2013	\$	%
	(unaudited)	(unaudited)		
<i>(dollars in thousands)</i>				
Revenue	\$ 88	\$ 115	\$ 27	31%
Cost of revenues	756	1,759	1,003	132%
Research and development expenses	5,304	2,376	(2,928)	(55%)
General and administrative expenses	1,613	1,736	123	8%
Sales and marketing expenses	604	130	(474)	(79%)
<b>Total Operating Loss</b>	(8,189)	(5,886)	(2,303)	(28%)
Interest income/(expense), net	(1,529)	(1,435)	(94)	(6%)
Change in fair value of warrant liability	422	593	171	41%
Other income/(expense)	(15)	(32)	17	113%
<b>Income/(loss) before income taxes</b>	(9,311)	(6,760)	(2,551)	(27%)
Income tax expense	1	1	0	0.0%
<b>Net income/(loss)</b>	<u>\$ (9,312)</u>	<u>\$ (6,761)</u>	<u>\$(2,551)</u>	(27%)

### Revenue

Revenues were \$115,000 for the nine months ended September 30, 2013, compared with \$88,000 for the nine months ended September 30, 2012, an increase of \$27,000, or 31%. The increase was primarily related to clinical trial testing services for our development collaboration program with the Dana-Farber Cancer Institute, partially offset by a decrease in revenues from Clariant. Approximately 74% of our 2013 revenue has been from clinical trial testing services for the Dana-Farber Cancer Institute; we had no clinical trial testing services revenue in the nine months ended September 30, 2012. The average price per test decreased from \$762 for the nine months ended September 30, 2012 to an average of \$455 for the nine months ended September 30, 2013. The decrease in price is due to the 2013 period including the testing under the Dana-Farber program, which by agreement carries significantly lower pricing than commercial tests.

### Cost of Revenues

Cost of revenues were \$1.8 million for the nine months ended September 30, 2013, compared with \$756,000 for the nine months ended September 30, 2012, an increase of \$1.0 million, or 132%. The increase was related to the volume of tests performed, which increased from 116 for the nine months ended September 30, 2012 to 254 for the nine months ended September 30, 2013, an increase of 119%. The volume increase was due to tests performed under our 2013 development collaboration program with the Dana-Farber Cancer Institute.

**Operating Expenses***Research and Development Expenses.*

Research and development expenses were \$2.4 million for the nine months ended September 30, 2013, compared with \$5.3 million for the nine months ended September 30, 2012, a decrease of \$2.9 million, or 55%. The decrease was primarily due to a \$1.2 million decrease in personnel expenses relating to a reduction in research and development headcount from an average of 19 for the nine months ended September 30, 2012 to an average of 9 for the same period in 2013, and a \$1.0 million decrease in research and development expenses due to the allocation of lab expenses to cost of revenues based on the number of samples processed.

*General and Administrative Expenses.*

General and administrative expenses were \$1.7 million for the nine months ended September 30, 2013, compared with \$1.6 million for the nine months ended September 30, 2012, an increase of \$123,000, or 8%. The increase was primarily due to an increase of \$166,000 in legal fees, particularly fees pertaining to our patent portfolio, partially offset by an \$83,000 decrease in personnel expenses relating to a reduction in general and administrative headcount from an average of 10 for the nine months ended September 30, 2012 to an average of 6 for the same period in 2013.

*Sales and Marketing Expenses.*

Sales and marketing expenses were \$130,000 for the nine months ended September 30, 2013, compared with \$604,000 for the nine months ended September 30, 2012, a decrease of \$474,000, or 79%. The decrease was primarily due to a \$357,000 decrease in personnel expenses relating to a reduction in sales and marketing headcount from an average of 3 for the nine months ended September 30, 2012 to an average of 1 for the same period in 2013.

**Interest Income and Expense**

Net interest expense was \$1.4 million for the nine months ended September 30, 2013, compared with \$1.5 million for the nine months ended September 30, 2012, a decrease of \$94,000, or 6%. The decrease was due to lower amortization of debt discount due to the completion of the amortization in prior periods.

**Change in Fair Value of Warrant Liability**

The change in the fair value of warrant liability was \$593,000 for the nine months ended September 30, 2013 compared with \$422,000 for the nine months ended September 30, 2012, a decrease of \$171,000, or 41%. The decrease is primarily due to the timing of the issuance of new warrants, as well as the 2012 period's 55% decline in the price of the shares underlying preferred stock warrants, as compared to the 2013 period's 44% decline in the price of the shares underlying preferred stock warrants and 2% decline in the price of the shares underlying common stock warrants.

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### **Years Ended December 31, 2012 and 2011**

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

	Year Ended December 31,		Change	
	2011	2012	\$	%
<i>(dollars in thousands)</i>				
<b>Revenue</b>	\$ 1	\$ 109	\$ 108	10800.0%
Cost of revenues	17	1,201	1,184	6964.7%
Research and development expenses	8,853	6,562	(2,291)	(25.9%)
General and administrative expenses	2,729	2,063	(666)	(24.4%)
Sales and marketing expenses	673	786	113	16.8%
<b>Total Operating Loss</b>	(12,271)	(10,503)	(1,768)	(14.4%)
Interest income/(expense), net	(1,700)	(2,187)	487	28.6%
Change in fair value of warrant liability	361	454	93	25.8%
Other income/(expense)	(18)	(23)	5	27.8%
<b>Income/(loss) before income taxes</b>	(13,628)	(12,259)	(1,369)	(10.0%)
Income tax expense	1	1	—	0.0%
<b>Net loss</b>	<u><u>\$ (13,629)</u></u>	<u><u>\$ (12,260)</u></u>	<u><u>\$ (1,369)</u></u>	(10.0%)

### **Revenue**

Revenues were \$109,000 for the year ended December 31, 2012, compared with \$1,000 for the year ended December 31, 2011, an increase of \$108,000. The increase was primarily due to commercial tests ordered through Clariant. The average price per test decreased from \$866 for the year ended December 31, 2011 to an average of \$694 for the year ended December 31, 2012.

### **Cost of Revenues**

Cost of revenues was \$1.2 million for the year ended December 31, 2012, compared with \$17,000 for the year ended December 31, 2011, an increase of \$1.2 million. The increase was related to the volume of commercial tests performed, which was only 1 in the year ended December 31, 2011 and which increased to 130 for the year ended December 31, 2012. The volume increase was primarily due to tests ordered through Clariant.

### **Operating Expenses**

*Research and Development Expenses.* Research and development expenses were \$6.6 million for the year ended December 31, 2012, compared with \$8.9 million for the year ended December 31, 2011, a decrease of \$2.3 million, or 25.9%. Research and development expenses decreased by \$1.2 million due to the allocation of lab expenses to cost of revenues based on the number of samples processed. \$639,000 of the decrease was attributable to reduced expenditures on clinical samples and \$342,000 of the reduction related to lower expenses for lab supplies as we approached commercialization.

*General and Administrative Expenses.* General and administrative expenses were \$2.1 million for the year ended December 31, 2012, compared with \$2.7 million for the year ended December 31, 2011, a decrease of \$0.7 million, or 24.4%. \$534,000 of this decrease was attributable to a reduced level of legal fees, particularly fees pertaining to our patent portfolio. \$72,000 of the decrease related to the use of employees for functions that previously had been performed by consultants.

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*Sales and Marketing Expenses.* Sales and marketing expenses were \$786,000 for the year ended December 31, 2012, compared with \$673,000 for the year ended December 31, 2011, an increase of \$113,000, or 16.8%. This increase was primarily attributable to personnel costs relating to the two sales personnel we employed in 2012.

### **Interest Income and Expense**

Interest expense was \$2.2 million for the year ended December 31, 2012, compared with \$1.7 million for the year ended December 31, 2011, with the \$500,000 increase primarily related to higher debt balances.

### **Income Taxes**

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

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

### **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 resolving our outstanding debt.

Pursuant to a note and warrant purchase agreement executed as of June 28, 2013 to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million, we have borrowed an aggregate of \$4.3 million through September 30, 2013 (including \$0.7 million borrowed under this arrangement during fiscal year 2012.) The maturity date of each note is May 31, 2014 and may be extended for two successive six month periods. Each note bears interest at 8.0% per annum, payable at maturity. The principal amount of and accrued interest on each note will automatically convert into shares of our common stock upon the closing of an underwritten initial public offering resulting in at least \$8.0 million of gross proceeds to us, at a conversion price equal to the price per share of our common stock sold in the initial public offering. The number of shares underlying the associated common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the note principal, by the exercise price, which will be set at the price per share of common stock sold in the initial public offering.

In June 2013, we arranged the conversion of all outstanding indebtedness under our May 2010 amended and restated loan agreement, our February 2011 note and warrant purchase agreement and our January 2012 note and warrant purchase agreement. In this series of transactions, promissory notes with outstanding principal totaling \$20,231,000 and accrued interest of approximately \$2,581,000 were converted into 42,245,834 shares of Series A preferred stock. The conversion included the issuance of 41,694,122 shares of Series A preferred stock to directors and their affiliates and other related parties. All of the converted notes and interest were in default and classified as current as of December 31, 2012.

In connection with the conversion of the debt outstanding under the May 2010 amended and restated loan agreement, we issued 33,333 common stock warrants to Goodman Co. Ltd., a 5% shareholder.

In July 2013, we amended a secured promissory note with a principal balance of \$1.4 million, held by a trust affiliated with Claire K. T. Reiss, a 5% shareholder and at the time a director, to provide that all principal of and accrued interest on the note would automatically convert into common stock upon the closing of an initial public offering, at the price per share at which common stock is sold in such initial public offering. This amendment was not related to Mrs. Reiss' later decision to resign from the board of directors.

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In July 2013, we entered into a revolving line of credit with UBS Bank USA in the initial amount of \$1.5 million. The maximum amount of this line of credit has subsequently been increased to approximately \$2.2 million. Interest accrues daily on the outstanding balance and is paid monthly at a variable rate which is currently 2.75% over the 30 day LIBOR rate or a current effective annual interest rate of 2.942%. UBS Bank USA has the right to terminate the revolving line of credit at any time, and if it does, all amounts drawn under the revolving line of credit would be immediately payable. An affiliate of our director David F. Hale, and an affiliate of Claire K. T. Reiss, a 5% shareholder and at the time a director, and an affiliate of our director Edward Neff guaranteed the loan and pledged financial assets to UBS Bank USA to secure their guaranties. In return, we issued common stock warrants to the guarantors. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to UBS Bank USA, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. We have entered into an agreement with the guarantors that provides for us to reimburse them for any amounts paid by them on such guaranties. This reimbursement obligation is secured by a security interest in our assets.

In September 2013, we entered into an amendment of the lease for our headquarters/laboratory building in San Diego, California, extending the term through July 31, 2020 and providing for five months of free base rent (August 2013 – December 2013). In return, we agreed, among other things, to forfeit our security deposit and to issue common stock warrants to the landlord. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount of \$502,605, which is 100% of the five months of base rent forgone, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering.

## **Cash Flows**

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

	<b>Year Ended</b>		<b>Nine Months Ended</b>	
	<b>December 31,</b>		<b>September 30,</b>	
	<b>2011</b>	<b>2012</b>	<b>2012</b>	<b>2013</b>
			<b>(unaudited)</b>	<b>(unaudited)</b>
<i>(dollars in thousands)</i>				
<b>Cash provided by (used in):</b>				
Operating activities	\$ (10,985)	\$ (8,607)	\$ (6,719)	\$ (4,877)
Investing activities	(295)	(8)	(8)	(1)
Financing activities	10,205	8,365	6,365	4,995
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ (1,075)</b>	<b>\$ (250)</b>	<b>\$ (362)</b>	<b>\$ 117</b>

**Cash Used in Operating Activities.** Net cash used in operating activities was \$8.6 million for the year ended December 31, 2012, compared to net cash used in operating activities of \$11.0 million for the year ended December 31, 2011. Net cash used in operating activities was \$4.9 million for the nine months ended September 30, 2013, compared to net cash used in operating activities of \$6.7 million for the nine months ended September 30, 2012. In all periods the primary use of cash was to fund our net loss.

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*Cash Used in Investing Activities.* Cash used in investing activities was \$8,000 for the year ended December 31, 2012, compared to \$295,000 for the year ended December 31, 2011. The cash used in investing activities in 2011 was primarily used to acquire laboratory equipment and software.

*Cash Provided by Financing Activities.* Net cash provided by financing activities was \$8.4 million for the year ended December 31, 2012, compared to net cash provided by financing activities of \$10.2 million for the year ended December 31, 2011. Net cash provided by financing activities was \$5.0 million for the nine months ended September 30, 2013, compared to net cash provided by financing activities of \$6.4 million for the nine months ended September 30, 2012. Our primary source of financing in all periods consisted of loans received from our major shareholder and members of our board of directors and their affiliates, in exchange for convertible promissory notes and warrants. Our ability to continue as a going concern relies on the continued availability of financing from these and other sources.

### **Capital Resources and Expenditure Requirements**

We expect to continue to incur substantial operating losses in the future. It may take several years to achieve positive operational cash flow or we may not ever achieve positive operational cash flow. We expect that we will use a portion of the net proceeds from this offering and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our tests, acquire equipment, implement automation and scale our capabilities to prepare for significant test volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with being a public company. We may also use a portion of the net proceeds of this offering 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, 2013, our cash and cash equivalents totaled approximately \$60,000. To continue as a going concern through February 2014, it will be necessary for us to raise additional bridge financing in January 2014 from our major shareholder, members of our board of directors and their affiliates, other accredited current investors and/or accredited new investors. We believe (although no assurance can be given) that we will be able to raise such additional bridge financing, when and as needed; during 2013 we continuously were seeking and successfully raising such bridge financing, when and as needed, and the prospect of the impending receipt of proceeds from this offering is expected to facilitate our efforts to raise additional bridge financing in January 2014. In the fourth quarter of 2013 we raised \$675,000 of bridge financing and drew down approximately an additional \$500,000 under our revolving line of credit from UBS Bank USA. As a result of raising such bridge financing and bank borrowing in the fourth quarter of 2013, it was not necessary for us to curtail, and we did not curtail, our operations. Without the net proceeds from this offering, we believe our current cash resources are insufficient to satisfy our liquidity requirements at our current level of operations. If we do not consummate this offering by February 2014, we expect that we will need to raise additional financing at that time, which might not be available on favorable terms, if at all. 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 tests;
- our ability to manage the costs for manufacturing our microfluidic channels;
- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;
- our ability to collect revenues; and
- other risks discussed in the section entitled “Risk Factors”.

As of September 30, 2013, we had approximately \$7.2 million of outstanding indebtedness, \$5.7 million of which will convert to equity upon completion of this offering. Following completion of this offering, we believe we will have approximately \$2.5 million in outstanding indebtedness, which will consist of borrowings under our revolving line of credit from UBS Bank USA which was initiated in July 2013.

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Our auditor's report on our financial statements includes an explanatory paragraph expressing substantial doubt that we can continue as a going concern for the next twelve months. With the net proceeds of this offering, we believe that we will have sufficient funds to continue our current level of operations for the next eighteen months. During 2012, 2013 and this year to date, we are experiencing net cash outflows at our current level of operations of approximately \$2 million per quarter. Assuming that we continue at our current level of operations after consummation of our initial public offering and add our planned sales and marketing resources, we would expect our net cash outflow to increase by at least \$1 million per quarter.

Furthermore, we may need to raise additional capital to expand our business to meet our long-term business objectives. We expect that our operating expenses and capital expenditures will increase in the future as we expand our business. We plan to increase our sales and marketing headcount to promote our current breast cancer test and our planned future cancer diagnostic tests and our research and development headcount to validate the tests currently in our pipeline. These headcount increases are aimed to expand our pipeline and to perform work associated with our research collaborations. Until we can generate a sufficient amount of revenues to finance our cash requirements, which we may never do, we may need to continue to raise additional capital to fund our operations.

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

### **Off-Balance Sheet Arrangements**

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

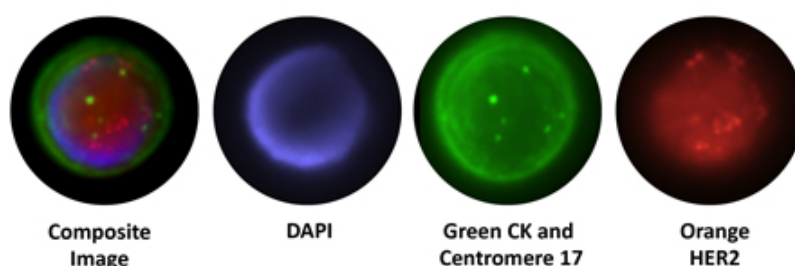
## **DESCRIPTION OF THE BUSINESS**

### **Company Overview**

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



## HER2<sup>+</sup> CTC in CK<sup>+</sup> Patient



At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP, and manufacture our CEE microfluidic channels, related equipment and certain reagents to perform our current breast cancer test and our planned future tests at this facility. CLIA certification and CAP accreditation are 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 OncoCEE-BR test and the tests we plan to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations.

OncoCEE-BR is a breast cancer CTC test that is performed on a standard blood sample. It detects CTCs, which are typically very rare compared to normal blood cells, and determines the patient's human epidermal growth factor receptor 2, or HER2, status by fluorescence *in situ* hybridization, or FISH. Pursuant to an agreement that we entered into with Clariant Diagnostic Services, Inc., a GE Healthcare Company, as revised in May 2013, Clariant is making OncoCEE-BR available to physicians through its sales force. (Clariant does not have the exclusive marketing rights for the test.)

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

We anticipate launching OncoCEE-LU, a test performed on a standard blood sample for non-small cell lung cancer, or NSCLC, in the first half of 2014. The biomarkers to be analyzed in the OncoCEE-LU test would include EML4/ALK and ROS1 gene fusions by FISH, and the epidermal growth factor receptor, or EGFR, gene, the K-ras gene and the B-raf gene by mutation analysis, in addition to CTC enumeration. Our OncoCEE-LU test would be run against a standard blood sample. We have entered into an agreement with Life Technologies Corporation, or Life Technologies, under which we are cooperating with Life Technologies to develop, promote and commercialize our OncoCEE-LU test. Under this agreement, we would perform OncoCEE-LU tests in our laboratory and transmit the results to Life Technologies for their interpretation and reporting to healthcare professionals.

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



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

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

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

Historically, our average price received per OncoCEE-BR test performed for commercial customers has been approximately \$695. This was heavily influenced by the fact that historically a high percentage of our sales were through our marketing partner, Clariant. We amended our arrangement with Clariant as of May 2013, and we do not expect a significant percentage of our future sales to come through Clariant. Our future average price for commercial customers

could increase from our historical figure, based on recognition of the medical value of our products, publication of clinical utility study results, possible improvement of the product, introduction of additional tests, increased demand generated by our future sales and marketing efforts, and similar commercial factors. Factors that could cause pricing for commercial customers to decrease include any perceived lack of clinical utility for CTC or ctDNA testing, or increased competition from other reference labs or IVD manufacturers. Third-party governmental and private payors have reimbursement policies and fee schedules which determine the amounts, if any, we would receive for performing tests for their covered patients. Such governmental and private third-party payors frequently make determinations about how much (if anything) they are willing to pay for tests such as ours, or for components of such tests; these determinations are important to our business and can have adverse or positive effects on the price we receive for our testing. For example, private payors often look to Medicare policies and rates when setting their reimbursement rates.

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

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

To date, we have engaged in only limited sales and marketing activities. Such activities have primarily related to our OncoCEE-BR test and have been conducted pursuant to an agreement with Clariant. This agreement was revised in May 2013 and Clariant no longer has exclusive marketing rights to this test. We expect that in the future the percentage of our revenue which is generated through our arrangement with Clariant will diminish. We also have established an agreement with Life Technologies for the commercialization of OncoCEE-LU tests when the development and validation of the OncoCEE-LU test are completed.

Using a portion of the proceeds from this offering, we plan to build an internal sales and marketing team to market and sell OncoCEE-BR and our planned future cancer diagnostic tests directly to oncologists. This team will also provide technical expertise and support for the sales representatives of our sales and marketing partners. Our plans call for starting with an initial group of 7 sales representatives, and, based on success and test volume, growing this number to 15-20 within two years.

We collaborate with physicians and researchers at MD Anderson Cancer Center and plan to expand our collaborative relationships to include other key thought leaders at other institutions for the cancer types we target with OncoCEE-BR and our planned future CTC and ctDNA tests. Such relationships help us develop and validate the effectiveness and utility of OncoCEE-BR and our planned future tests in specific clinical settings and provide us access to patient samples and data. We completed a study, recently published in *Cancer Medicine*, utilizing our OncoCEE-BR test, and a version of this test adapted for use with bone marrow samples, with a group at 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 oncologist that there is likely to be a survival benefit from treatment with Herceptin®, which has been demonstrated in a number of large clinical studies.

We are currently involved in a new clinical study following up on this finding in CTCs, employing OncoCEE-BR tests for patient selection and monitoring. This study, led by investigators at the Dana-Farber Cancer Institute, is currently enrolling patients, and is likely to produce initial results within a year. We believe that these results will provide clinical utility data to support the wide use of OncoCEE-BR tests as a routine diagnostic test for breast cancer patients. In the screening phase of this study, we are testing in our CLIA-certified laboratory blood samples from HER2 negative patients based on standard tumor tissue analysis, to identify those patients that have HER2 positive CTCs. These patients are then being randomized to chemotherapy plus/minus Herceptin®, and followed for a period of time, with additional CTC tests, including biomarker analysis for HER2 using FISH, performed at subsequent time points.

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

According to the National Cancer Institute, there will be approximately 230,000 new cases of breast cancer and approximately 230,000 new cases of lung cancer diagnosed in the United States in 2013, with over 3 million patients who have had a diagnosis of these cancers and either are living with these diseases and are undergoing treatment or are being monitored. For example, in breast cancer, many women have been deemed cancer-free, but continue to undergo periodic monitoring to assure there has been no disease recurrence. Our OncoCEE-BR test and our planned OncoCEE-LU test only require a readily accessible standard blood sample and thus may be used to help manage these patients, including supporting the selection of appropriate treatment, at multiple time points during the course of their disease. Because our tests require only a standard blood sample, they can be particularly useful when no, old or inadequate amounts of, biopsy or surgical material is available, as is often the case in lung cancer, even at the time of initial evaluation. For example, up to 25% of patients with lung cancer are not surgically treated for various reasons, including patient status (consensus statement from the American College of Chest Physicians and the Society of Thoracic Surgeons; *Chest*, Dec. 2012). This is also the case with breast and lung cancers once surgical resection of the tumor has taken place and treatment has been initiated. Patients with breast and lung cancer must often undergo surgical resection of their primary tumor as part of their treatment. Therefore, at the time of progression or recurrence there may be no ability to obtain a tissue biopsy. Additionally, many studies have shown that most tumors mutate during treatment and as the disease progresses, so information from the initial tumor tissue may not be relevant. Again, a significant benefit of our technology is that it allows physicians to assess the current status of the tumors on a real-time basis utilizing a standard blood sample.

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

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

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

Our sales strategy is focused on leveraging the sales forces of partners already selling to our target markets, as well as building an internal direct sales and marketing team that can also support our partners. In both cases we plan to engage oncologists in the United States at private and group practices, hospitals and cancer centers. In addition, our internal team will 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. In 2008, the World Health Organization attributed 7.6 million deaths worldwide to cancer-related causes. The World Health Organization projects that by 2030 this number will rise to 13.1 million deaths per year. 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 2013, and prevalence in 2010, in the United States for the major solid cancers types:

Cancer Type	Est. Incidence (New Cases/Year-2013)	Est. Mortality (Deaths/Year-2013)	Est. Prevalence (Diagnosed and Alive as of 2010)**
Bladder	72,570	15,210	563,640
Breast*	232,340	39,620	2,843,629
Cervical	12,340	4,030	249,496
Colorectal*	142,820	50,830	1,154,481
Endometrial	49,560	8,190	600,346
Gastric*	21,600	10,990	72,269
Kidney	65,150	13,680	341,505
Lung*	228,190	159,480	399,431
Melanoma*	76,690	9,480	921,780
Ovarian	22,240	14,030	186,138
Pancreatic	42,220	38,460	41,609
Prostate*	238,590	29,720	2,617,682
Thyroid	60,220	1,850	534,973

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

\*\* Includes active disease and disease-free.

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

### ***Cancer is a Heterogeneous Disease***

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

Cancer cells contain genetic alterations compared to normal human cells. Common genetic abnormalities correlated to cancer include gains or losses of genetic material on specific chromosomal regions, or loci, or changes in specific genes, or mutations, which ultimately result in detrimental cellular changes followed by cancerous or pre-cancerous conditions. For example, multiple gains or losses of or on various chromosomes, and the rearrangement of genetic material among chromosomes, or chromosomal translocations, have been observed in different cancer types, such as HER2 in breast cancer and EML4/ALK in NSCLC. In addition, mutations within gene sequences, or single nucleotide variations, can give rise to aberrant proteins that do not perform their functions correctly, leading to uncontrolled cell growth. Such genetic alterations can be a result of multiple factors, including genetic predisposition, environmental or lifestyle factors or viral infections. Importantly, these genetic changes can be used as biomarkers to help guide appropriate treatment. Detecting these biomarkers, particularly those representing drug targets, or those indicative of responsiveness or resistance of a tumor's cells to specific therapies, helps clinicians to select drugs, design treatment regimens and optimize patient care and management. Tests that provide such predictive information have the potential to dramatically improve treatment outcomes for patients suffering from cancer.

### ***Limitations of Traditional Cancer Diagnostic and Profiling Approaches***

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

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

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

### ***CTCs, ctDNA and Cancer***

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

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

Given the incidence of cancer in the United States, with an estimated 800,000 new cases in 2013 for the major solid tumors targeted by our planned test products, the markets for our current and planned cancer diagnostic tests are very large. Furthermore, these market opportunities are even greater due to the benefits of CTC and ctDNA testing, including not only the ability to offer physicians a simple way to augment an initial tumor biopsy analysis but also to provide a means for relatively frequent monitoring of the tumor's molecular status, utilizing a standard blood sample as a "liquid biopsy." The latter application enables the oncologist to determine if or how a tumor is changing over time or is responding to therapy and what the next treatment should be. For example, in the United States, the incidence of new cases of breast cancer alone is estimated to be over 230,000 in 2013, and the prevalence of this disease is over 2.8 million (the number of women with a history of breast cancer in the United States, including women being treated and women who have finished treatment), with an estimated 330,000 lumpectomies performed annually in the United States. Of these lumpectomies, 20% need to be repeated because on pathological examination it is shown the procedure did not result in "clean margins," thus suggesting not all the tumor was removed, according to a Johns Hopkins report. If a CTC test were performed at the time of initial diagnosis, at the time of surgery, or in lieu of, or as an adjunct to, a PET/CT scan (as a CTC test has the potential to identify a single tumor cell in a blood sample, while a scan requires a tumor mass of millions of cells to be detectable), to monitor disease progression or test for recurrence, thousands of tests, in breast cancer alone, could be performed per year with still relatively low market penetration.



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

CTCs and ctDNA are derived from, and are understood to be representative of, a solid tumor and its metastases and can be analyzed as adjuncts to or in place of the tumor, especially when a recent tumor biopsy is not available. 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 oncologists. The biomarkers we analyze and internal to analyze consist of proteins or protein modifications that can be identified by immunocytochemical means, cytogenetic or chromosomal aberrations, which are detected by FISH, and gene mutations which are detected in CTCs or ctDNA by molecular diagnostic tests, including CEE-Selector techniques and gene sequencing. Specific examples include (i) for immunocytochemistry, the detection of the estrogen receptor protein in breast cancer, indicative of the likely responsiveness to hormonal therapies like tamoxifen, often sold under the trade name Nolvadex®, (ii) for FISH, the presence of an amplified HER2 gene in breast cancer, indicative of the likely responsiveness to HER2-targeted agents like trastuzumab, often sold under the trade name Herceptin®, and (iii) for mutation detection, the presence of an EGFR activating mutation in NSCLC like L858R, indicative of the likely responsiveness to EGFR-targeted agents like Tarceva®. All of these biomarkers are currently tested on tumor tissue and can be tested on CTCs, and in the latter case on ctDNA. The resulting information could then be used to guide patient care, and specifically treatment selection.

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

### **Our Business Strategy**

We plan to provide oncologists 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 oncologists that improves patient treatment and management and will become a key component in the standard of care for personalized cancer treatment.

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

- *Develop and commercialize a portfolio of proprietary CTC and ctDNA tests and services, to enable physicians to develop personalized treatment plans.* We intend to continue the development of additional prognostic and predictive tests and services to provide information that is essential to personalized cancer treatment. By including predictive information on biomarkers linked to specific therapies in our analysis in addition to CTC enumeration, our tests are designed to provide a more complete profile of a patient's disease than existing CTC tests. The biomarker information will assist physicians in selecting appropriate therapies for individual patients. Our ctDNA tests are expected to offer enhanced sensitivity and specificity based on the CEE-Selector technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions. We have launched our first CTC test, OncoCEE-BR for breast cancer, performed in our CLIA-accredited testing facility. We are also developing a number of other CTC and ctDNA tests, including OncoCEE-LU for non-small cell lung cancer, OncoCEE-CR for colorectal cancer, OncoCEE-GA™ for gastric cancer, OncoCEE-PR™ for prostate cancer and OncoCEE-ME™ for melanoma. We plan to perform the necessary validation studies to allow us to commercialize these tests through our clinical laboratory.
- *Establish our internal sales and marketing capabilities in a scalable manner.* We are actively seeking additional partners to increase our market reach. We intend to build our own specialized sales force with experience in cancer diagnostic testing, focusing on key identified territories in order to provide geographic coverage



throughout the United States. We plan to start with 7 sales representatives, and depending on test volume, expect to increase this group to 15-20 within two years and potentially 40-50 within five years. This team will educate physicians directly on the benefits of our tests and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners such as Life Technologies.

- *Develop and expand our collaborations with leading university hospitals and research centers.* We collaborate with key thought leaders, physicians and clinical researchers, including those at the MD Anderson Cancer Center, Columbia University and the University of California, San Diego. Our collaborations enable us to test new technologies, validate the effectiveness and utility of our planned tests in a clinical setting and provide us access to clinically well-characterized and highly annotated patient data. These samples and data accelerate our validation process and facilitate the testing and refinement of our planned new tests.
- *Enhance our efforts in reaching and educating oncologists about CTC and ctDNA tests.* According to the American Society for Clinical Oncology, in 2011 there were approximately 10,000 oncologists in the United States, or 12,500 if gynecologic and pediatric oncologists are included. With the support of our key thought leader collaborators, we intend to focus on oncologists 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 so that they can better serve their cancer patients.
- *Increase our efforts to provide biopharmaceutical companies and clinical research organizations with our current and planned CTC and ctDNA tests and services.* Oncology drugs have the potential to be among the most personalized of therapeutics, yet oncology drugs have one of the worst approval rates, at 11% for leading indications and 2% for secondary indications of cancer drug compounds from first administration in humans to approval (2004-2011, Biotechnology Industry Organization). In an effort to improve the outcome of clinical trials for oncology drugs, and more rapidly advance targeted therapeutics, pharmaceutical and biopharmaceutical companies are increasingly looking to companies that have cancer diagnostic tests that specifically address their needs, including the ability to characterize and monitor a patient's tumor over time using CTC and ctDNA tests to analyze biomarkers of interest. There are over 5,000 active trials in the United States in breast, lung, colorectal, prostate and gastric cancers and melanoma according to clinicaltrials.gov. We expect to increase our sales and marketing focus in this business as well as seek additional collaborations and partnerships with pharmaceutical and biopharmaceutical companies.
- *Support our current and planned tests with clinical utility studies to drive adoption and facilitate reimbursement.* Through our agreement with the Dana-Farber Cancer Institute, we are currently conducting testing for a study that we expect to provide clinical utility data for our OncoCEE-BR test, demonstrating that patients who are treated with targeted therapies based on biomarkers identified on their CTCs, when those biomarkers are absent on their tumor tissue, have better outcomes. In this study, we are specifically identifying patients with metastatic breast cancer that are HER2 negative, by analysis of their tumor tissue, and who have HER2 positive CTCs utilizing our OncoCEE-BR test on a standard blood sample. These patients are being randomized for treatment with chemotherapy, the current standard of care, with or without Herceptin®, and then evaluated for progression-free survival and overall survival. We intend to conduct additional studies in breast cancer, and similar studies for our NSCLC test and other CTC and ctDNA tests we plan to introduce. Clinical utility and validation studies for our planned ctDNA tests may rely on archived plasma or blood samples from clinical trials in which patient outcomes are already available, in a retrospective-prospective design that significantly shortens the length of such studies.
- *Continue to enhance our current and planned CTC and ctDNA tests and reduce the costs associated with providing them through internal research and development and partnering with leading technology developers and reagent suppliers.* We intend to work closely with select key technology developers and suppliers to further automate the optical interpretation of our current breast cancer test and our planned additional CTC tests, including enumeration, immunocytochemical biomarker staining and FISH. We also intend to reduce the costs associated with key material components of these tests, including FISH probes. We have identified a technology group that, based on

initial studies, can provide an automation system that will significantly reduce the hands-on time of our cytotechnicians for microfluidic channel analysis while increasing the uniformity, and potentially the sensitivity and quality, of the data we generate. This system is also expected to provide the ability to evaluate multiple fluorescent signals of different wavelengths simultaneously for multiplexed analysis, again enhancing efficiency. Similarly, we have identified suppliers that can provide FISH probes at reduced cost and with a broader choice of available fluorors, enabling more extensive multiplexing of tests.

## **Our Competitive Advantages**

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

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

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

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

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

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

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

### **Our Tests and Services**

We have launched our first product, OncoCEE-BR for breast cancer, and plan to continue to launch a series of tests for CTCs in different tumor types, including NSCLC, gastric, colorectal and prostate cancers and melanoma, incorporating analyses for different biomarkers, over the next 3 years. OncoCEE-BR is and the planned tests will be based on the CEE technology platform. The CEE system isolates CTCs from blood samples of cancer patients for enumeration (or count) and genetic analysis. A sample is shipped to us in our specialized blood collection tube, called the CEE-Sure tube, for recovery and analysis of CTCs. When performing the CTC assay, the sample is processed in our laboratory. The specimen of blood is separated into its parts (red blood cells, buffy coat and plasma). The buffy coat is incubated with the antibody solution and passed through a proprietary microfluidic channel containing 9,000 microscopic posts coated with reagents to capture antibody-labeled tumor cells. The captured cells are suitable for further testing of whole cells directly in the microfluidic channel or by releasing the cells from the microfluidic channel and performing CEE-Selector or similar techniques.

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

In addition to enhanced capture, our technology also improves the detection of CTCs. As with EpCAM, tumor cells that have undergone EMT can down-regulate the synthesis of cytokeratin, leading to an underestimate or even an apparent absence of CTCs since their positive identification has traditionally relied on anti-cytokeratin staining. We have developed alternative methods of fluorescent cell staining that are uniquely possible within the CEE system to enhance or enable detection of CTCs with low or no cytokeratin signal. This technology is called CEE-Enhanced. We believe that the combination of specific cocktails of tumor-associated capture antibodies and more sensitive fluorescent detection of CTCs through CEE-Enhanced methodology will lead to major advances in the capture, enumeration and analysis of CTCs. CEE-Enhanced methodology is expected to be included in our commercially available tests by mid-2014.

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

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

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

The following outline indicates our current (OncoCEE-BR) and planned tests and indicates the stage the product is in and the targeted date of commercialization. As discussed in “Description of the Business—Test Development Process” below, prospective assays initially begin in research (stage 1) and progress through to development (stage 2), validation (stage 3) and finally availability for commercialization (stage 4). The OncoCEE-BR test has completed all stages as to CTC and HER2 test capabilities. Our remaining identified proposed tests have completed the research stage and are at the stages shown in the table below with their respective estimated timetables for completing stage 4. As with all scientific endeavors, such timetables are only estimates; unanticipated problems might result in delays. We consider these timetables to be fairly aggressive, given the likelihood of our experiencing such unanticipated problems and associated delays.

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

Our proposed tests have certain commonalities. For example, in each proposed test, biomarkers will be examined by one or both of FISH or CEE-Selector. Given the development, validation and commercialization of our first CTC/FISH test (OncoCEE-BR), all subsequent FISH- and Immunofluorescence-based assays have effectively been developed for the planned biomarker. Progression of these planned assays through stage 3 is largely dependent on the timing of our obtaining suitable validation specimens, although various scientific and other factors can also affect the pace of a particular proposed test’s progress through the validation stage. Thus, the OncoCEE-LU (i.e., CTC/FISH-based OncoCEE-LU), OncoCEE-GA and OncoCEE-DTC tests are targeted to be commercial in 2014. CTC-based OncoCEE-CR and OncoCEE-PR tests are targeted to be commercial in 2015 given our estimate of the timing to acquire appropriate positive and negative validation samples.

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

In “Use of Proceeds” above, we disclose that we currently intend to use approximately \$5 million of the net proceeds of this offering to fund further research and development and related activities. This includes all of the expenditures which we believe are needed to complete all four stages of development for the planned tests described below. Primarily these expenditures will be for existing and additional scientific personnel in the time periods reflected in the table below, and secondarily for obtaining a sufficient number of suitable validation specimens.

<b>Test Name</b>	<b>Solid Tumor Type and Biomarkers</b>	<b>Indication</b>	<b>Status of Test or Project</b>	<b>Targeted Year of Availability for Commercialization</b>
OncoCEE-BR™	Breast Cancer- Enumeration; HER2 by FISH, ER, PR	Prognosis, therapy selector, monitoring	CTC and HER2 already on the market; Validation – ER, PR	2012 for CTC and HER2; ER, PR 2014 Q1/Q2
OncoCEE-LU™	Lung Cancer- Enumeration; ALK and ROS1 by FISH,	Prognosis, therapy selector, monitoring	Validation – CTC and FISH portion of assay;	2014 Q2/Q3
	K-ras, B-raf and EGFR mutations by CEE-Selector™		Development – ctDNA portion of assay	2014 Q4
OncoCEE-GA™	Gastric Cancer- Enumeration; HER2 by FISH	Prognosis, therapy selector, monitoring	Validation of CTC and FISH assay	2014 Q2

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<u>Test Name</u>	<u>Solid Tumor Type and Biomarkers</u>	<u>Indication</u>	<u>Status of Test or Project</u>	<u>Targeted Year of Commercialization</u>
OncoCEE-CR™	Colorectal Cancer- Enumeration; EGFR by FISH	Prognosis, therapy selector, monitoring	Validation – CTC and FISH portion of assay	2015 Q1
	K-ras and B-raf by CEE-Selector™		Development – ctDNA portion of assay	2015 Q2
OncoCEE-PR™	Prostate Cancer- Enumeration; PTEN deletion and AR by FISH	Prognosis, therapy selector, monitoring	Validation – CTC and FISH assay	2015 Q3
OncoCEE-ME™	Melanoma- Enumeration and B-raf and N-ras mutations by CEE-Selector™	Prognosis, therapy selector, monitoring	Development of ctDNA assays	2015 Q2
OncoCEE-DTC™	Breast and Prostate Cancer- DTC analysis in bone marrow; HER2 and AR/PTEN by FISH, respectively	Prognosis, therapy selector, monitoring	Validation of DTC and FISH assays	2014 Q4 Breast 2015 Q3 Prostate
CEE-Selector™	Multiple cancer types- K-ras, B-raf, EGFR and other mutations detected in plasma	Therapy selector, monitoring	Development	2014 Q4

### ***Our Marketed OncoCEE CTC Test: OncoCEE-BR***

Our OncoCEE-BR breast cancer test is the first CTC test we developed and we are currently offering it to physicians through our CLIA laboratory. It is based on a standard blood sample and can be used at the time of diagnosis and for monitoring, including at the time of progression or recurrence. This allows the physician to characterize the tumor to help define treatment options, either augmenting tissue analysis or replacing it when a tumor biopsy is not available. The test currently includes CTC enumeration and determination of HER2 status by FISH on the captured CTCs, and then more broadly to any cell captured on our CEE microfluidic channels that is not a white blood cell. HER2 status is used by oncologists to determine suitability of a patient for treatment with HER2-targeted therapeutics, which include Herceptin®, as well as Kadcyla® and Perjeta®, monoclonal antibodies directed to HER2, and Tykerb®, a kinase inhibitor with activity against HER2. We plan to add immunocytochemistry analysis of CTCs for estrogen receptor and progesterone receptor to our OncoCEE-BR test, which will provide information on suitability of breast cancer patients for endocrine or hormonal therapies such as selective estrogen receptor modulators, including tamoxifen, aromatase inhibitors that block the synthesis of estrogen, including Femara® (Novartis) and Arimidex® (AstraZeneca) or other therapeutics that block estrogen production, including Zoladex® (AstraZeneca) and Lupron® (AbbVie).

### ***Other OncoCEE CTC Tests in Development***

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

#### ***OncoCEE-LU***

Up to 25% of lung cancer patients, especially those diagnosed at Stage IIIB or Stage IV, are not treated surgically for various reasons, including tumor accessibility and status of the patient. In these cases, CTC and ctDNA tests are alternatives for obtaining more detailed information about the molecular status of the tumor that helps the physician select appropriate therapy. This is even more important as the number of targeted therapies for lung cancer with associated biomarkers increases. Our OncoCEE-LU test would include several components: CTC enumeration, FISH analysis for EML4/ALK and ROS1, and potentially for ret proto-oncogene, all linked to the drug Xalkori® (Pfizer), mutation analysis for the EGFR gene,

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the K-ras gene and the B-raf gene. The L858R mutation of the EGFR gene and Exon 19 deletions are activators of EGFR kinase activity and are linked to the drugs Tarceva® (Astellas/Genentech/Roche) and Iressa® (AstraZeneca). The T790M mutation of the EGFR gene is a resistance marker for EGFR tyrosine kinase inhibitors and is linked to drugs in development that address this resistance, such as Gilotrif® (Boehringer-Ingelheim) and dacomitinib (Pfizer). The codon 12 and 13 mutations of the K-ras gene are linked to non-responsiveness to the EGFR kinase inhibitors such as Tarceva® and Iressa®, and the codon 600 mutations of the B-raf gene are linked to Zelboraf® and Tafinlar®, which are both approved for melanoma and are in clinical trials for lung cancer. Our OncoCEE-LU test would be performed on a standard blood sample.

In parallel, we plan to offer ctDNA tests for mutation analysis of, for example, EGFR, K-ras and B-raf genes, to provide information in situations where CTCs are not identified. In our development of this technology platform we have generated data showing detection of the T790M mutation in ctDNA from the blood plasma of lung cancer patients progressing on tyrosine kinase inhibitors in which no CTCs were detected.

### ***OncoCEE-GA***

We are developing our OncoCEE-GA test for gastric cancer based on the identification of HER2 as a biomarker for this disease. We plan to employ our CTC HER2 FISH test, which we had previously developed for breast cancer, for the analysis of gastric cancer CTCs. The presence of HER2 positive cells is an indication for likely benefit from the use of Herceptin®, which has been approved for the treatment of metastatic gastric cancer. 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 test would circumvent this need for tissue, as well as providing straightforward monitoring of HER2 status from a standard blood sample, on a real-time basis during treatment. Our OncoCEE-GA test would include CTC enumeration and HER2 analysis of CTCs by FISH.

### ***OncoCEE-CR***

Our current plan for our OncoCEE-CR test for colorectal cancer is to offer mutation testing analogous to that performed on lung cancer CTCs, namely detection of key mutations in the EGFR, K-ras and B-raf genes, along with CTC enumeration. Testing of the EGFR gene would focus on the L858R mutation and Exon 19 deletions as activators of EGFR kinase activity, and the T790M mutation as a resistance marker for certain EGFR tyrosine kinase inhibitors. Testing on the K-ras gene would focus on codons 12 and 13 mutations. Testing on the B-raf gene would focus on V600 mutations. Our OncoCEE-CR test would be run against a standard blood sample.

This testing is important because certain targeted therapies for colorectal cancer, including the monoclonal antibodies targeting EGFR, Erbitux® (Lilly/Bristol-Myers Squibb/Merck Serono) and Vectibix® (Amgen), and the kinase inhibitor Stivarga® (Onyx/Bayer) targeting vascular endothelial growth factor receptor kinases, but also ret proto-oncogene, KIT, platelet-derived growth factor receptor, or PDGF-R, and fibroblast growth factor receptor kinases, have been shown to be ineffective in patients who have a K-ras mutation, which is found in up to 40% of cases according to the National Comprehensive Cancer Network. While for each of codons 12 and 13 in K-ras, up to 15-20 mutations have been reported, there are reports in the scientific literature that patients with one particular mutation, G13D, do respond well to Erbitux®, and that there may be variability in response to different chemotherapies based on the specific K-ras mutation, suggesting that detailed information on mutation status is clinically relevant.

### ***OncoCEE-PR***

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

The androgen receptor normally binds the hormones testosterone and dihydrotestosterone, and is the target for several drug molecules, including those acting directly as antagonists for the receptor, such as Casodex® (AstraZeneca), and those acting indirectly through inhibition of androgen synthesis, such as Zytiga® (Janssen).

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

### **OncoCEE-ME**

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

### **Disseminated Tumor Cell (DTC) Assays Performed on Bone Marrow**

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

### **ctDNA Tests**

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

### **Laboratory Testing**

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

### **Clinical Trials Services**

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a study by Princess Margaret Hospital in Toronto estimated that over a five-year study period 85% of the new therapies for solid tumors which were tested in early clinical trials in the United States, Europe and Japan failed, and that of those that survive through to Phase III trials only half will actually be approved. Given such a high failure rate of oncology drugs in clinical development, combined with constrained budgets for pharmaceutical and biopharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to help decrease these failure rates. For



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

### Test Development Process

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

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

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

As part of our long-term strategy, we may seek FDA clearance or approval to expand the commercial use of tests to other laboratories and testing sites in the United States. We will also need to complete additional activities to submit each of these tests for regulatory clearance or approval before commercialization in each of the international markets where we would plan to introduce them.

Although the FDA maintains that it has authority to regulate the development and use of LDTs as medical devices, as a matter of enforcement discretion it has not exercised such authority with respect to most LDTs. If the FDA exercises this authority as to our current test or as to a planned test, our process would also need to allow for obtaining FDA review, clearance or approval, as applicable, which would add delay, expense and risk to our current test development process. Such an exercise of authority could arise as a result of changes in discretion on a general or particular basis, changes in applicable regulations, or changes in applicable statutes.



## Research and Development

We incurred research and development expenses of \$8.9 million, which represents 8416% of our net revenue, for the year ended December 31, 2011 and \$6.6 million, which represents 6010% of our net revenue, for the year ended December 31, 2012. Research and development expenses represented 72% of our total operating expenses for the year ended December 31, 2011 and 62% of our total operating expenses for the year ended December 31, 2012. Major components of the research and development expenses were direct personnel costs, laboratory equipment and consumables and overhead expenses.

### *Technology Development*

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

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

specificity of the CEE-Selector technology and leverage interest in the clinical research community for detecting any actionable biomarker in a particular tumor, as opposed to only those that are known to occur at relatively higher frequencies in that type of tumor. Such multiplexed mutation tests, relying on our CEE-Selector technology, could provide a more global evaluation of a tumor through analysis of either CTCs or ctDNA. This would offer a broader range of potential treatment options as well as enable the monitoring of the effectiveness of those treatments over time.

- **Development of Single Cell CTC Isolation Techniques for Molecular Analysis**

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

### ***Translational/Clinical Research***

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

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

The CEE system has the added advantage of post-capture immunocytochemical, cytogenetic and molecular genomic analyses of the CTCs. The CEE system captured cells can be analyzed directly within the microfluidic channel, thereby removing the need to re-deposit cells on a slide, which could result in cell loss or damage. Furthermore, given the transparency of the microfluidic channel, it can be immediately analyzed on a microscope. Together these two important features allow for a very efficient process that is well suited for a LDT performed in a CLIA laboratory. The post-capture analyses, which focus on the evaluation of biomarkers, are particularly important and valuable to physicians and patients, as they focus on actionable information related to therapy selection. We have performed a number of clinical research studies in collaboration with 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 MD Anderson Cancer Center, we evaluated matched samples of tumor tissue, blood for CTCs and bone marrow for DTCs in early stage breast cancer patients for evidence of HER2 amplification, which would indicate eligibility for HER2-targeted therapies like Herceptin®, a potentially life-saving treatment. These results were also presented at both the 2011 and 2012 annual meetings of the American Society of Clinical Oncology. In a study published in *Cancer Medicine* (2013, 2(2) 226-233) and involving 96 patients, HER2 positive CTCs and/or DTCs were identified in 18.8% of cases in which the primary tumor was HER2 negative. In the same cohort of patients, only 12.5% were HER2 positive in their primary tumor. In other words, beyond the 12 (of the 96) which traditional tumor tissue analysis had indicated could benefit from Herceptin-based therapy, the OncoCEE-BR test detected 18 (of the 96) patients who (despite the fact they were identified as being HER2 negative by primary-tumor testing) could benefit from Herceptin-based therapy. Patients classified as HER2 negative

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based on tumor tissue and found to have HER2 positive CTCs and/or DTCs will continue to be followed by our collaborators at MD Anderson Cancer Center to assess their overall and progression-free survival. Tumor heterogeneity is one likely cause of the discordance for HER2 status between tumor tissue and our test performed on blood and bone marrow samples. Tumor heterogeneity indicates an important clinical application for the OncoCEE-BR test, confirmation and crosschecking of the tissue analysis performed by the pathologist at the time of biopsy or surgery, especially if HER2 negative, with a CTC analysis derived from a standard blood sample.

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

### **Sales and Marketing**

Our sales and marketing efforts consist of working with our partners such as Life Technologies and establishing our own direct sales force in the United States focused on selling directly to community oncologists in hospitals, cancer centers and offices, and supporting our partners as technical specialists and medical science liaisons.

To date, we have engaged in only limited sales and marketing activities, primarily through an agreement with Clariant for the OncoCEE-BR test. Under a May 2013 revision of our arrangement with Clariant, its marketing rights for OncoCEE-BR are no longer exclusive. We also have an agreement with Life Technologies Corporation for the commercialization of the OncoCEE-LU test. With the proceeds of this offering we plan to build an internal sales and marketing team that will sell directly to community oncologists and serve as technical experts and clinical specialists to support the sales representatives of our partners. Under the arrangement with Clariant, as recently renegotiated, Clariant's sales force sells the test on a nonexclusive basis, and we are responsible for performing the test, reporting the results, billing, and obtaining reimbursement for the test. Under the agreement with Life Technologies, when our OncoCEE-LU test is commercially launched, Life Technologies' Medical Science Division sales force would sell the tests and Life Technologies' pathologists would perform the interpretation, otherwise called the professional component of the pathology service, in Life Technologies' laboratory. We would perform the technical component of the pathology service in our laboratory. Life Technologies would bill payors for the entire test, pay us for the technical component at an agreed upon rate and keep any amounts received for the professional component. Reimbursement would be based on Current Procedural Terminology, or CPT, codes. Under the Life Technologies agreement, the parties would share the payment and reimbursement risk, as we would be paid an agreed upon fee for the technical component of tests performed, and there would be a quarterly adjustment based on amounts actually received from payors. We will look to identify and engage additional groups with appropriately targeted sales efforts as partners for these and future tests and have initiated discussions with other companies.

Our plan for our sales organization calls for an initial group of 7 sales representatives placed in strategic locations around the country that have high concentrations of cancer patients, and potentially growing this number to 15-20 sales representatives within two years, and to 40-50 within five years. We have defined the initial sales territories and are targeting sales professionals with an average of 5-10 years of successful experience in clinical oncology sales or oncology diagnostic testing sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We plan on growing this specialized, oncology-focused sales force and supporting it with clinical specialists who bring significant technical knowledge in the use of CTC and ctDNA tests.

We will also be investing in sales headcount to focus on biopharma clinical trial opportunities. We plan to hire one additional representative for this initiative in the Northeast US and eventually add coverage in other areas with a large concentration of biotech and pharmaceutical companies.

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Finally, we plan to invest in managed care sales and marketing in order to ensure adequate payment and coverage for our testing. The key value proposition for these customers will be focused on cost savings by offering alternatives to expensive surgeries when tumor biopsy tissue is not available.

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

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

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

### ***Outside the United States***

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

While the initial focus of our agreement with Life Technologies for OncoCEE-LU tests is on customers in the United States, the parties plan to cooperate on accessing markets internationally. We plan for this to be accomplished either through partnerships with local groups and distributors or the development of IVDs and/or test systems, including instrumentation.

### **Competition**

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

- our ability to utilize standard blood samples, enabling testing of patients frequently through the course of their disease without a biopsy, thereby reducing cost and trauma, saving time, and providing real-time information on the current status of the tumor;
- our ability to include biomarker information in our analysis, in addition to CTC enumeration, thereby providing a more complete profile of a patient's disease than existing CTC tests can. This is actionable information that can assist physicians in selecting more personalized treatment plans for individual patients;
- our current and planned CTC tests' ability to capture and detect a broader range of CTC phenotypes than existing tests, and potentially at earlier stages of disease, resulting in fewer non-informative cases and more information for physicians. For example, our antibody capture cocktail targets not only EpCAM but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis;

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- our ability to rapidly integrate new biomarkers, either validated in academic laboratories or of interest to pharmaceutical and biopharmaceutical companies in the context of their new therapies, into our current and planned tests, facilitating the expansion of actionable information for oncologists;
- our research and clinical collaborations with key academic and clinical study groups, which enhance our research and development resources and, by enhancing our standing in the oncology community, support our marketing efforts; and
- our planned ctDNA tests based on the CEE-Selector technology are expected to offer enhanced sensitivity and specificity in detecting mutation targets or resistance markers, again supporting treatment decisions.

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

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

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

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA testing in various cancers. In particular, Janssen Diagnostics, LLC markets its CellSearch® test and Atossa Genetics markets its ArgusCYTE® test, which are competitive to our OncoCEE-BR test for CTC enumeration, and HER2 analysis, respectively. However, the ArgusCYTE® test measures HER2 mRNA, which is not typically used for HER2 analysis, while we employ FISH for this analysis. FISH is generally considered to be the gold standard. CTC and ctDNA testing is a new area of science and we cannot predict what tests others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the tests we develop. In addition to Janssen Diagnostics and Atossa Genetics, our competitors include public companies such as Alere (Adnagen) and Illumina as well as many

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private companies, including Apocell, EPIC Sciences, Clearbridge Biomedics, Cynvenio Biosystems, Fluxion Biosciences, RareCells, ScreenCell and Silicon Biosystems. Many of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents.

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

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

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

### **Third-Party Suppliers and Manufacturers**

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

### **Patents and Technology**

Our business is dependent upon our ability to develop and perform CTC and ctDNA tests that enable oncologists at hospitals, cancer centers and physician offices to receive information on properly characterized samples from individual cancer patients to select the most appropriate therapy for those patients. We rely on a combination of patents, patent applications, trademarks, trademark applications, trade secrets and industry know-how, in order to protect the proprietary aspects of our technology and assure that we can perform our tests.

Our patent portfolio consists of 3 issued U.S. patents, 6 pending U.S. patent applications and corresponding foreign patents and foreign patent applications. These patents and patent applications are related to various aspects of our current and planned CTC and ctDNA tests, including our CEE microfluidic channels, our CEE-Sure blood collection tubes, CEE-Cap antibody capture cocktail, CEE-Enhanced staining methodology, and CEE-Selector technology for mutation detection.

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*CEE Microfluidic Channels.* We have three issued U.S. patents related to our current business (U.S. Patent Nos. 7,439,062, 7,695,956 and 8,158,410), and a number of additional U.S. and foreign patent applications, which cover our microfluidic channel technology. Our microfluidic channels are differentiated from other microfluidic channels used for CTC capture based on their unique geometry, particularly the arrangement of posts within the flow channel. The posts are chemically derivatized to enable capture of antibody-tagged CTCs, and are positioned to disrupt streamline or laminar flow of cells through the microfluidic channel to assure they come in contact with the posts for capture. Because the capture area of the microfluidic channel is sealed on one side with a glass cover slip, immunocytochemical and cytogenetic staining and analysis can occur within the microfluidic channel.

*CEE-Sure Blood Collection Tubes.* We have a U.S. patent application (13/243,432) in prosecution for our CEE-Sure blood collection tubes, which contain reagents designed to prevent clumping of blood cells and CTCs that could clog the microfluidic channels and disrupt our assays. These reagents also provide stability to the sample for shipping and transport, enabling blood samples to be shipped at ambient temperature from a collection site anywhere in the United States, and even outside the United States, to our laboratory in San Diego, California, and perform well in our assays for up to 96 hours after collection. DNA has been shown to be stable and accessible in cells under these conditions, and preliminary work suggests the same may be true for ctDNA, with more research required.

*CEE-Cap Antibody Capture Cocktail.* We have two pending U.S. patent applications (12/730,738 and 13/269,532) as well as their corresponding foreign patent applications directed to our antibody capture cocktail technology, which includes using antibodies to a number of tumor-associated antigens from cancer cells of both epithelial and mesenchymal phenotype, as well as cancer stem cells. Such technology relies on the binding of the antibodies to the target CTCs in solution, which we have shown greatly improves the capture efficiency because of superior binding kinetics and the lack of spatial constraints imposed by attachment of the antibodies to a solid surface.

*CEE-Enhanced Staining.* We have one U.S. pending patent application (13/241,083) as well as its corresponding foreign patent applications directed to this technology. This technology was developed to enable detection of CTCs that do not express sufficient amounts of cytokeratin, an epithelial marker that, in conjunction with DAPI and CD45 staining, is used to identify CTCs. It has made it possible to detect non-traditional CTCs, including mesenchymal types such as result from EMT, which, in conjunction with the antibody capture cocktail, has significantly increased the sensitivity of our CTC assays, and the informative rate for clinical samples.

*CEE-Selector Mutation Detection Technology.* This technology was developed to perform mutation analysis on CTCs, ctDNA or other sample types. It addresses the challenge of a sample in which copies of the normal gene locus vastly exceed the copies of the mutant gene locus. The technology has been demonstrated to have utility for more-sensitive mutation detection in ctDNA as well as CTC analysis. It is co-owned with Aegea Biotechnologies, Inc., with Biocept having exclusive commercial rights for clinical oncology applications, including LDTs and IVDs, where tissue, blood, bone marrow and cerebrospinal fluid are the sample types. There are two pending U.S. patent applications (13/841,842 and 61/784,101), with Aegea responsible for the prosecution of U.S. provisional application 61/784,101 and Biocept responsible for the prosecution of the other U.S. patent application. Biocept has also filed an international PCT application related to U.S. patent application 13/841,842. Lyle J. Arnold, Ph.D., our Senior Vice-President of Research & Development and Chief Scientific Officer, is the controlling person of Aegea.

In 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court unanimously ruled that a “naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated,” invalidating Myriad Genetics’ patents on the BRCA1 and BRCA2 genes. This case removed some of the risk associated with testing laboratories like ours using isolated nucleic acid fragments for molecular analysis. Testing laboratories have been uncertain as to whether analysis of gene mutations covered by third party patents would violate such patents. We will continue to monitor developments in this area.

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

Through our clinical laboratory, we provide diagnostic testing and clinical services that utilize our proprietary trade secrets. In particular, we maintain trade secrets with respect to specimen accessioning, sample preparation and certain aspects of cytogenetic analysis. All of our trade secrets are kept in confidence and we take steps to ensure that our confidential information is not disseminated, including the use of non-disclosure agreements and confidentiality agreements.



## **Operations and Production Facilities**

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

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

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

In all cases, we provide the technical analysis, and in the case of our OncoCEE-BR test under our 2013 agreement with Clariant, we also provide the professional analysis. For our OncoCEE-LU test, while we would perform all of the technical analysis, the pathologists at our partner Life Technologies' CLIA laboratory would provide the professional evaluation of the laboratory data. For OncoCEE-BR tests, we will send the results to the ordering oncologist and bill the payor through an arrangement we have with Xifin, Inc. For OncoCEE-LU tests, Life Technologies would send out the report and bill the appropriate parties, then pay us a predetermined fee for the technical analysis with a subsequent quarterly adjustment of that fee based on payments actually received by Life Technologies from payors.

## **Quality Management Program**

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

We have established a Quality Management Program for our laboratory designed to help ensure accurate and timely test results, a consistent high quality of our testing services. The Quality Management Program documents the quality assurance and performance improvement plans and policies, the laboratory quality assurance and quality control procedures that are necessary to ensure that we offer the highest quality of diagnostic testing services. This program is designed to satisfy all the requirements necessary for local and state licensures and accreditation for clinical diagnostic laboratories by



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CAP. We follow the policies and procedures for patient and employee safety, hazardous waste disposal and fire codes stated in the general laboratory procedure manual. We believe that all pertinent regulations of CLIA, the Occupational Safety and Health Administration, the Environmental Protection Agency and the FDA are satisfied by following the established guidelines and procedures of our Quality Management Program.

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

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

### **Third-Party Payor Reimbursement**

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

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

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

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

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

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

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, a provider may not bill Medicare or the beneficiary for the service. There is currently no national coverage policy regarding the CTC capture/enumeration portion of our testing. The previous regional Medicare Administrative Contractor (MAC) for California, Palmetto GBA, LLC, adopted a negative coverage policy for CTC capture/enumeration (with the exception that Janssen Diagnostics, LLC's CellSearch® test has historically been covered for CTC capture/enumeration). The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore the capture/enumeration portion of our OncoCEE testing is not covered and we will receive no payment from Medicare for this service unless and until the coverage policy is changed. On November 4, 2013, we submitted a comprehensive dossier to Palmetto GBA and Noridian explaining the benefits of the capture/enumeration testing in order to seek to persuade the MACs to allow coverage for this portion of our testing. Palmetto GBA responded on November 27, 2013, denying our request for Medicare coverage for the enumeration/detection portion of our OncoCEE testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The earliest date we could submit another dossier on this matter is May 27, 2014. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration. On the other hand, FISH analysis is a covered benefit for Medicare beneficiaries and accordingly we expect that the FISH portion of OncoCEE-BR and our planned tests are and will be covered and that when and as we bill Medicare we will receive payment from Medicare under the Physician Fee Schedule for FISH analysis. Molecular testing for the mutations we currently plan to test for with CEE-Selector is also a covered benefit, so we believe that CEE-Selector testing would thereby be covered and that when and as we bill Medicare we would receive payment from Medicare under the Clinical Laboratory Fee Schedule for CEE-Selector testing. As discussed above, we have not yet received from Medicare any response or adjudication regarding any of our late-2013 billings, including for the FISH portion of OncoCEE-BR testing.

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

### **Billing and Billing Codes for Third-Party Payor Reimbursement**

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

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

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

#### **Coverage and Reimbursement for our Current Breast Cancer Test and our Planned Future Tests**

OncoCEE-BR is a new test, and because of our previous relationship with Clariant, under which Clariant had responsibility for billing and reimbursement until mid-2013, we do not have established coverage and reimbursement policies set with all third-party payors. Our Medicare Administrative Contractor has issued a negative coverage determination for the capture/enumeration component of all CTC tests (with the exception that Janssen Diagnostics, LLC’s CellSearch® test has historically been covered for CTC capture/enumeration). We have received reimbursement for the capture/enumeration component of our tests from some payors, including major private third-party payors, based on submission of standard CPT codes. FISH, ICC and Molecular Testing CPT codes are the subject of positive coverage national or local Medicare determinations. We believe these codes can be used to bill for the analysis components of our current and anticipated CTC tests.

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

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner Clariant was responsible for all billing associated with our tests. We do not have data for Clariant’s billing and collection experience with respect to our test, because Clariant paid us a contracted amount per test performed regardless of their billing and collections. From May to December 2013, we performed an average of 1-3 physician-ordered tests per month (in addition to the 20-30 tests per month which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute). Billing for these physician-ordered tests is now handled for us by a non-Clariant billing service provider. In November and December 2013, we invoiced, through this service provider, for 13 physician-ordered tests. Of these, 8 tests were billed to private third-party payors and 5 were billed to Medicare. We have not yet had any response or adjudication from any payor as to the bills submitted in late 2013. Accordingly, we do not yet have any data regarding reimbursement history or collectability experience. In addition, we believe the sample size of 13 is too small to be the basis for any conclusion about our ongoing payor mix. We cannot assure you that, even if OncoCEE-BR and our planned tests are otherwise successful, reimbursement for the currently Medicare-covered portions of OncoCEE-BR and our planned tests would, without Medicare reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

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

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

### **Legislative and Regulatory Changes Impacting Clinical Laboratory Tests**

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

Under the statutory formula for Medicare Clinical Laboratory Fee Schedule amounts, increases are made annually based on the Consumer Price Index for All Urban Consumers as of June 30 for the previous twelve-month period. From 2004-2008, Congress eliminated the Consumer Price Index for All Urban Consumers update in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. In addition, for years 2009 through 2013, the Medicare Improvements for Patients and Providers Act of 2008 mandated an approximately 0.5% cut to the Consumer Price Index for All Urban Consumers update. Accordingly, the update for 2009 was reduced to 4.5% and negative 1.9% for 2010. The ACA has, among other things, imposed additional cuts to the Medicare reimbursement for clinical laboratories. The ACA replaced the 0.5% cut enacted by the Medicare Improvements for Patients and Providers Act with a “productivity adjustment” that will reduce the Consumer Price Index update in payments for clinical laboratory tests. In 2011, the productivity adjustment was -1.2%. In addition, the ACA includes a separate 1.75% reduction in the CPI update for clinical laboratories for the years 2011 through 2015. The MCTRJCA, enacted in 2012, mandated an additional change in reimbursement for clinical laboratory service programs. This legislation requires CMS to reduce the Medicare Clinical Laboratory Fee Schedule by 2% in 2013, which in turn will serve as a base for 2014 and subsequent years. CMS has projected that because of the changes required by ACA and MCTRJCA, payment for clinical laboratory services will go down by approximately 3% by 2013.

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

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

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.

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Some of our Medicare claims may be subject to policies issued by Palmetto GBA and Noridian Healthcare Solutions, our former and current Medicare Administrative Contractor for California, respectively. Palmetto GBA, acting on behalf of many MACs, recently issued a Local Coverage Decision that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, Palmetto GBA will not cover any molecular diagnostic tests, such as the capture/enumeration component of our current breast cancer test and our planned future tests, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto GBA. Currently, laboratories may submit coverage determination requests to Palmetto GBA for consideration and apply for a unique billing code for each test (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. In addition, effective January 1, 2013, Palmetto GBA implemented its new Molecular Diagnostic Services Program, under which, among other things, laboratories must use the newly-assigned billing codes specific to the test (as implemented by the American Medical Association), in order to receive the indicated reimbursement amounts. Reimbursement amounts under these new single molecular diagnostics billing codes were in some cases lower, and in some cases higher, than amounts allowed by Medicare before January 1, 2013, but most were significantly lower. Palmetto GBA currently has a negative coverage determination for the capture/enumeration component of CTC tests such as our current and anticipated CTC tests, but there is no such negative coverage determination for the analysis component of such CTC tests. Denial (or continuation of denial) of coverage for the capture/enumeration component of our current and anticipated CTC tests by Palmetto GBA or its successor MAC, Noridian Healthcare Solutions, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our current breast cancer test and our planned future tests. Noridian Healthcare Solutions intends to follow, for CTC tests, the positive or negative coverage determinations which from time to time Palmetto GBA makes. Because Palmetto GBA denied on November 27, 2013 our request for coverage for the enumeration/detection portion of our OncoCEE testing, the earliest date we could submit another request on this matter is May 27, 2014. We intend to continue our efforts to obtain Medicare coverage for capture/enumeration.

## **Governmental Regulations**

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

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

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

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

### ***Federal, State and Foreign Fraud and Abuse Laws***

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

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

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

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act’s “whistleblower” or “qui tam” provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government and permit such individuals to share in any



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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, 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. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

### ***Corporate Practice of Medicine***

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

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

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

### ***Physician Licensing***

A number of the states where specimens originate require that the physician interpreting those specimens be licensed by that particular state. Physicians who fail to comply with these licensure requirements could face fines or other penalties for practicing medicine without a license and we could be required to pay those fines on behalf of our pathologists or subject to liability under the federal False Claims Act and similar state laws if we bill for services furnished by unlicensed pathologists. We do not believe that the services our pathologist performs constitute the practice of medicine in any state that requires out-of-state physician licensure. 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 are currently in the process of addressing the requirements for licensure in New York, and we expect to have soon re-obtained all required licenses and approvals from all other states requiring licensure for out-of-state laboratories. (We were required to re-license in these other states as a result of our July 2013 reincorporation to Delaware.)

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

### ***Other Regulatory Requirements***

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

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

### **Segment and Geographical Information**

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

### **Employees**

As of December 31, 2013, we had a total of 27 full-time and one part time employee, five of whom hold doctorate degrees and seven of whom are engaged in full-time research and development activities. We plan to expand production, sales and marketing and our research and development programs, and we plan to hire additional staff as these initiatives are implemented. None of our employees is represented by a labor union.

### **Properties**

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

In September 2013, we entered into an amendment of the lease, extending the term for 21 months so that it now ends on July 31, 2020 and providing for five months of free base rent (August 2013 – December 2013). In return, we agreed, among other things, to forfeit our security deposit and to issue common stock warrants to the landlord. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount of \$502,605, which is 100% of the five months of base rent forgone, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. The warrants will be exercisable for a five-year period beginning on the closing of our initial public offering.

Immediately following the execution of such amendment, we paid all amounts due under our lease. As of December 31, 2012 and September 30, 2013, we owed rent in arrears of approximately \$185,000 and \$0, respectively.



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In September 2012, in connection with an amendment of the lease, which included a rent deferral through November 30, 2012, we issued to our landlord warrants to purchase an aggregate of 66,666 shares of our Series A preferred stock at an exercise price of \$0.60 per share. These warrants are exercisable through September 2019 and, in connection with the closing of this offering, will become exercisable for 1,587 shares of our common stock at an exercise price of \$25.20 per share.

### **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.

Thomas Burns, our former Vice President of Operations, filed an administrative proceeding against us with the California Labor Commissioner in June 2013, seeking damages for alleged unpaid wages and penalties. After a hearing held on August 19, 2013, the California Labor Commissioner ruled that Mr. Burns was entitled to an award of approximately \$62,000 against us.

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the name, age and position of each of our directors and executive officers.

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Served as an Officer or Director Since</u>
David F. Hale	64	Executive Chairman of the Board of Directors	2011
Marsha A. Chandler <sup>(3)</sup>	68	Director	2013
Bruce E. Gerhardt, CPA <sup>(1)</sup>	62	Director	2010
Bruce A. Huebner	63	Director	2013
Michael W. Nall	51	Director, Chief Executive Officer and President	2013
Edward Neff <sup>(1)</sup>	61	Director	2006
Ivor Royston, M.D. <sup>(2)(3)</sup>	68	Director	2010
M. Faye Wilson <sup>(1)(2)(3)</sup>	75	Director	2009
Lyle J. Arnold, Ph. D.	67	Senior Vice-President of Research & Development, Chief Scientific Officer	2011
Farideh Z. Bischoff, Ph. D.	48	Vice-President Translational Research and Clinical Development	2007
William G. Kachioff	48	Senior Vice-President of Finance and Chief Financial Officer	2011

(1) Audit Committee

(2) Compensation Committee

(3) Nominating and Corporate Governance Committee

Our board of directors is classified into three classes of two or three directors each, 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.” The directors in Class I are Mr. Gerhardt and Mr. Neff. The next election of Class I directors by stockholders will be at our 2014 annual meeting of stockholders, with the elected candidates to then serve until our 2017 annual meeting of stockholders. The directors in Class II are Dr. Chandler, Mr. Huebner and Dr. Royston. The next election of Class II directors by stockholders will be at our 2015 annual meeting of stockholders, with the elected candidates to then serve until our 2018 annual meeting of stockholders. The directors in Class III are Mr. Hale, Mr. Nall and Ms. Wilson. The next election of Class III directors by stockholders will be at our 2016 annual meeting of stockholders, with the elected candidates to then serve until our 2019 annual meeting of stockholders.

Our executive officers are elected by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors and executive officers, except that Edward Neff is an uncle of Michael W. Nall. The business experience for the past five years (and, in some instances, for prior years) of each of our executive officers and directors is as follows:

#### **David F. Hale**

Mr. Hale was appointed as our Executive Chairman in March 2011. He is the Chairman and CEO of Hale BioPharma Ventures LLC, a private company focused on the formation and development of biotechnology, specialty pharma, diagnostic and medical device companies. He has also been the Chairman of Santarus, Inc., a specialty biopharmaceutical company, since 2004 and a member of Santarus’ board since 2000. He also serves as Chairman of Conatus Pharmaceuticals, Inc. He was previously President and CEO of CancerVax Corporation from October 1999 through its merger in May 2006 with Micromet, Inc., a biotechnology company focused on the development of novel biological products for the treatment of cancer, when he became Chairman of the combined companies. He is a co-founder and served as Chairman of Somaxon

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Pharmaceuticals, Inc. before its acquisition by Pernix Therapeutics Holdings, Inc., and as Chairman of SkinMedica, Inc., before its acquisition by Allergan, Inc. He also serves as Chairman of Neurelis, Inc., Coloresciences, Inc., CRISI Medical Systems, Inc. and other private companies. Mr. Hale is a serial entrepreneur who has been involved in the founding and/or development of a number of life sciences technology companies. In 1982, after joining Hybritech, Inc., the first monoclonal antibody company, he served as COO, President and then Chief Executive Officer, until Hybritech was acquired by Eli Lilly and Co. in 1986. From 1987 until 1997 he was Chairman, President and CEO of Gensia, Inc., which merged with SICOR to become Gensia Sicor, Inc., which was later acquired by Teva Pharmaceuticals. He was a co-founder and Chairman of Viagene, Inc. from 1987 to 1995, when Viagene was acquired by Chiron, Inc. He was President and CEO of Women First HealthCare, Inc. from late 1997 to June 2000, before joining CancerVax in October 1999. Before joining Hybritech, Mr. Hale was Vice President and General Manager of BBL Microbiology Systems, a diagnostics division of Becton, Dickinson & Co. and from 1971 to 1980, held various marketing and sales management positions with Ortho Pharmaceutical Corporation, a division of Johnson & Johnson, Inc.

We selected Mr. Hale to serve on and lead our board of directors due to his public and private company board experience as well as his extensive experience with and knowledge of health care issues and the operational activities of life sciences companies.

### ***Marsha A. Chandler***

Dr. Chandler has been the Executive Vice President/Chief Operating Officer of the Salk Institute for Biological Studies since 2007. She manages approximately 1,000 scientific and administrative personnel and oversees all institutional fiscal, administrative and fund-raising activities. From 1997 to 2007 she served as Senior Vice Chancellor for Academic Affairs at the University of California, San Diego, where she was the chief academic officer responsible for the policies and decisions relating to all academic programs and faculty appointments and performance. She served as Acting Chancellor from 2003-04 and holds an appointment as Professor of Political Science in the Graduate School of International Relations and Pacific Studies at UCSD.

Dr. Chandler is a Fellow of the Royal Society of Canada, the highest academic honor bestowed in that country. She received her Ph.D. from The University of North Carolina at Chapel Hill.

We selected Dr. Chandler to serve on our board of directors due to her experience in organizational management and her stature in the life sciences community. Dr. Chandler also serves as chair of our nominating and corporate governance committee.

### ***Bruce E. Gerhardt***

Mr. Gerhardt has been self-employed, practicing as a Certified Public Accountant, since 1986. He is also a tax and business advisor providing tax compliance for small businesses and upper income individuals. He earned his Bachelor of Arts Degree from the University of Southern California in 1973 and is a member of the American Institute of Certified Public Accountants.

We selected Mr. Gerhardt to serve on our board of directors due to his experience and expertise in financial accounting and auditing. Mr. Gerhardt also serves as a member of our audit committee.

### ***Bruce A. Huebner***

Mr. Huebner is currently and has been since 2004 a managing director of LynxCom Partners LLC, a healthcare consulting firm with a focus on cancer diagnostics and personalized medicine. Since March 2013 he has been Chairman of Vermillion, Inc., a publicly held molecular diagnostics company. He served as Interim Chief Executive Officer and President of Vermillion from November 2012 to March 2013. From October 2009 to June 2010, Mr. Huebner served as President and Chief Executive Officer of TrovaGene, Inc., a developer of molecular diagnostics products. From 2005 to 2008, Mr. Huebner served as President of Osmetech Molecular Diagnostics, obtaining FDA clearance for four molecular diagnostic microarray products and introducing them to the marketplace. From 2002 to 2004, Mr. Huebner was President and Chief Operating Officer of Nanogen, Inc., a publicly held nanotechnology/microarray company. From 1996 to 2002, Mr. Huebner was Executive Vice President and Chief Operating Officer of Gen-Probe Incorporated, a leader in the development of nucleic acid tests.

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Mr. Huebner received his Bachelor of Science degree in Chemistry from the University of Wisconsin-La Crosse and completed a graduate school senior executive program at Columbia University.

We selected Mr. Huebner to serve on our board of directors due to his strong background in cancer diagnostics sales, marketing, operations and reimbursement. Mr. Huebner also serves as a member of our compensation committee.

### ***Michael W. Nall***

Mr. Nall has over 25 years of healthcare sales and marketing experience, most recently serving at Clariant Diagnostic Services, Inc. in positions of increasing responsibility from 2002 through August 2013, with his last position being General Manager, North American Sales and Marketing. While at Clariant, Mr. Nall was also responsible for leading the team assimilating Clariant into GE Healthcare after Clariant was acquired in 2010.

From 1988 until joining Clariant, Mr. Nall served in the diagnostic and medical device industries in various commercial leadership roles for companies including Impath, American Cyanamid, Maquet Surgical, Strato Medical, Horizon Medical Products and Columbia Vital Systems.

Mr. Nall received a Bachelor of Science degree in Business Administration from Central Missouri State University (now known as the University of Central Missouri).

We selected Mr. Nall to serve on our board of directors due to his experience in the cancer diagnostics business, his expertise in the commercialization of products and services such as ours, his background in reimbursement and operations and his status as our chief executive officer and president.

Mr. Nall is a nephew of our director Edward Neff.

### ***Edward Neff***

Since 1990, Mr. Neff has been the Chief Executive Officer of Systems, Machines, Automation Components Corporation (also known as SMAC), a manufacturer of moving coil electric actuators.

Mr. Neff has received over 25 United States patents relating to robotics and precise automation. He is a graduate of the University of Michigan.

We selected Mr. Neff to serve on our board of directors due to his experience and expertise in business management and in automated systems. Mr. Neff also serves as a member of our audit committee.

Mr. Neff is an uncle of our Chief Executive Officer, President and director Michael W. Nall.

### ***Ivor Royston, M.D.***

Dr. Royston co-founded Forward Ventures and has served as its Managing Partner since 2000. From 1990 to 2000, he served as founding President and CEO of The Sidney Kimmel Cancer Center and from 1978 to 1990, he was a member of the oncology faculty of the University of California, San Diego. In addition to being a co-founder of Hybritech, Inc., in 1986 he co-founded IDEC Corporation, which later merged with Biogen to form BiogenIdec. Dr. Royston has been instrumental in the formation, financing and development of numerous biotechnology companies, including Applied Molecular Evolution (acquired by Eli Lilly), Corixa (acquired by GlaxoSmithKline), Dynavax, LigoCyte (acquired by Takeda), Morphotek (acquired by Eisai), Sequana Therapeutics (acquired by Celera), TargeGen (acquired by Sanofi-Aventis), and Triangle Pharmaceuticals (acquired by Gilead). He is currently a director of MMRGlobal, Inc., a publicly-traded health records management company. Dr. Royston received his B.A. and M.D. degrees from Johns Hopkins University and completed post-doctoral training in internal medicine and medical oncology at Stanford University. In 1997, President Clinton appointed Dr. Royston to a six-year term on the National Cancer Advisory Board.

We selected Dr. Royston to serve on our board of directors due to his extensive experience with emerging life sciences companies. Dr. Royston also serves as chair of our compensation committee and as a member of our nominating and governance committee.

***M. Faye Wilson***

Ms. Wilson has been a principal of Wilson Boyles & Co., LLC, a business management and strategic planning consulting firm, since 2003. Ms. Wilson is also a member of the board of directors of BioMed Realty Trust, Inc., a real estate investment trust. She served on the board of directors of Farmers Insurance Group of Companies from 1992 through 1998 and the board of directors of The Home Depot, Inc. from 1991 through 2001. Ms. Wilson was also a senior officer of Home Depot from 1998 through 2002. From 1992 until 1998, Ms. Wilson served in several senior management roles at Bank of America Corporation including Chairman of Security Pacific Financial Services and Executive Vice President and Chief Credit Officer for Bank of America's National Consumer Banking Group. She earned her Master's Degrees in International Relations and Business Administration from the University of Southern California and an undergraduate degree from Duke University.

We selected Ms. Wilson to serve on our board of directors due to her extensive experience as a director of public companies, her financial acumen and experience, and her expertise in business strategy. Ms. Wilson also serves as chair of our audit committee, as a member of our compensation committee and as a member of our nominating and governance committee.

***Lyle J. Arnold, Ph. D.***

Dr. Arnold joined us as Senior Vice President and Chief Scientific Officer in 2011. Before then, he consulted for us from May 2010 to April 2011. He is a biotechnology executive, entrepreneur, and developer of innovative technologies covering therapeutics, molecular diagnostics, and genomics. Dr. Arnold also serves as President of Aegea Biotechnologies, Inc., which he founded in 2010 to acquire, develop, and commercialize next generation nucleic acid technologies. Previously he was Vice President, Research at Gen-Probe Incorporated from September 2003 to October 2009. During the time between departing from Gen-Probe and joining us, Dr. Arnold worked as a consultant for various entities through Lyle Arnold Consulting LLC, and started Aegea Biotechnologies in February 2010. He has also held senior scientific and management positions at Molecular Biosystems (co-founder), Genta, Synteni, Incyte Genomics, and Oasis Biosciences (co-founder), where he was President and Chief Scientific Officer from October 2001 to September 2003. In addition, Dr. Arnold was a faculty member of the UCSD School of Medicine and a member of the UCSD Cancer Center. Dr. Arnold is an inventor or co-inventor on 39 issued U.S. patents and more than 140 issued and pending patents worldwide. He is the principal inventor of the chemiluminescent Hybridization Protection Assay (HPA) and associated technologies, core to Gen-Probe assays that have generated more than \$5 billion in product revenue. In addition, he has authored more than 50 scientific publications. Dr. Arnold serves on the board of directors of Asuragen, a rapidly emerging biotechnology company in Austin, Texas, as well as on the board of Aegea.

He received a B.S. in Chemistry from the University of California at Los Angeles and a Ph.D. in Chemistry/Biochemistry from the University of California at San Diego.

***Farideh Z. Bischoff, Ph. D.***

Dr. Bischoff joined us in 2007 as Director of Translational Research and Development and has been Vice President, Translational Research and Clinical Development since 2011. From 1994 to 2007, she was a full-time faculty member in the Department of Obstetrics/Gynecology at Baylor College of Medicine. An expert in clinical cytogenetics and molecular human genetics, she has conducted research and focused on clinical assays relevant to non-invasive (prenatal) genetic testing and more recently cancer screening and surveillance. Dr. Bischoff has been a key investigator in a multi-center NIH/NICHD funded study focused on establishment of protocols and investigations into the clinical utility of circulating rare fetal cells as well as cell-free DNA/RNA for noninvasive prenatal genetic diagnosis. She was also charged with establishment and supervision of the molecular cytogenetic pre-implantation genetic diagnostic (PGD) program at Baylor College of Medicine.

She holds a Ph.D. in Cancer Biology from University of Texas Graduate School for Biomedical Sciences, with postdoctoral training at the MD Anderson Cancer Center and Baylor College of Medicine. Her graduate thesis project directly contributed to the discovery of germline p53 mutations in Li-Fraumeni cancer patients. Dr. Bischoff has published numerous peer-reviewed papers and book chapters.

**William G. Kachioff**

Mr. Kachioff, who joined us as Senior Vice President and Chief Financial Officer in August 2011, is experienced in corporate finance, investor relations, corporate governance and manufacturing accounting and systems. He has over twenty years of experience in the life science industry, having most recently served as Vice President and Chief Financial Officer at Althea Technologies, Inc., a pharmaceutical contract manufacturer, from 2009 to 2011. From 2007 to 2009 he was a CFO Partner with Tatum LLC, a national Executive Services firm, where he served a variety of life science industry clients in senior financial management roles. From 2002 to 2005, Mr. Kachioff was Chief Financial Officer at MicroIslet, a publicly traded biotechnology company developing cell transplant therapies for insulin dependent diabetes. From 1999 to 2001, he was Director of Finance at Cutera where he helped prepare the company for the commercial launch of its first product and its initial public offering. Mr. Kachioff has also served in a variety of financial management roles at Coulter Pharmaceutical, Vivus and Abbott Laboratories. He began his professional career as an auditor with Deloitte LLP.

Mr. Kachioff has a B.S. in Management from the University at Buffalo, State University of New York with concentrations in Accounting and Information Systems. He is a member of the American Institute of Certified Public Accountants and the Association of Bioscience Financial Officers.

**Director Independence**

Upon the completion of this offering, we expect our common stock will be listed on The NASDAQ Capital Market. Under the rules of The NASDAQ Stock Market, independent directors must comprise a majority of a listed company's board of directors within 12 months after the completion of an initial public offering. In addition, the rules of The NASDAQ Stock Market require that, (i) on the date of the completion of this offering, at least one member of our audit, compensation and nominating and corporate governance committees be independent, (ii) within 90 days after the date of the completion of our initial public offering, a majority of the members of such committees be independent and (iii) within one year after the date of the completion of our initial public offering, all the members of such committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of The NASDAQ Stock Market, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that Dr. Chandler, Mr. Gerhardt, Mr. Huebner, Mr. Neff, Dr. Royston and Ms. Wilson, or six of our eight directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of The NASDAQ Stock Market.

Our board of directors also determined that (i) Messrs. Gerhardt and Neff and Ms. Wilson, who compose our audit committee, (ii) Mr. Huebner, Dr. Royston and Ms. Wilson, who compose our compensation committee, and (iii) Dr. Chandler, Dr. Royston and Ms. Wilson, who compose our nominating and corporate governance committee, each satisfy the independence standards for those committees established by the applicable rules and regulations of the SEC and The NASDAQ Stock Market. In making this determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. We intend to comply with all size and independence requirements for committees within the applicable time periods.

## EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table shows the compensation awarded to or earned in our last two fiscal years by our principal executive officer and our four most highly compensated executive officers who were serving as executive officers as of December 31, 2012. The persons listed in the following table are referred to herein as the “named executive officers.”

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)<sup>(1)</sup></u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$)<sup>(8)</sup></u>	<u>Other Compensation (\$)<sup>(9)</sup></u>	<u>Total</u>
David F. Hale	2012	342,632 <sup>(2)</sup>	—	—	—	\$323,406
<i>Executive Chairman</i>	2011	241,867 <sup>(2)</sup>	0 <sup>(7)</sup>	27,530	—	\$288,624
Michael J. Dunn	2012	266,065 <sup>(3)</sup>	—	—	—	\$263,844
<i>SVP, Corporate Development</i>	2011	214,139 <sup>(3)</sup>	—	19,350	—	\$235,710
William G. Kachioff	2012	224,937 <sup>(4)</sup>	—	—	—	\$222,843
<i>SVP Finance, Chief Financial Officer</i>	2011	87,250 <sup>(4)</sup>	—	15,600	—	\$104,943
Lyle J. Arnold, Ph. D.	2012	216,627 <sup>(5)</sup>	—	—	—	\$210,063
<i>SVP R&amp;D, Chief Scientific Officer</i>	2011	135,733 <sup>(5)</sup>	—	16,125	—	\$158,423
Farideh Z. Bischoff, Ph. D.	2012	168,091 <sup>(6)</sup>	—	—	76,337	\$244,428
<i>VP of Translational Research and Clinical Development</i>	2011	150,032 <sup>(6)</sup>	—	3,225	7,080	\$160,337

- (1) The “Salary” column includes both salary paid and salary amounts deferred under each named executive officer’s amended and restated Salary Reduction and Contingent Payment Agreement, 8% annual interest (compounded monthly) on such deferred salary amounts, and vacation earned but not taken (“accrued vacation”), in each year ended December 31. For information regarding the amended and restated Salary Reduction and Contingent Payment Agreement arrangements, see “Executive Compensation - Narrative Disclosure to Summary Compensation Table - Salary Deferrals.”
- (2) Mr. Hale commenced employment on March 10, 2011. 2012 salary amounts include deferred salary of \$276,979, interest on deferred salary of \$15,049, and accrued vacation of \$17,325. 2011 salary amounts include deferred salary of \$51,292 and accrued vacation of \$8,357.
- (3) Mr. Dunn commenced employment on February 15, 2011 and resigned effective on July 31, 2013. 2012 salary amounts include deferred salary of \$83,354, interest on accrued salary of \$1,628, and accrued vacation of \$14,437. 2011 salary amounts include accrued vacation of \$12,216.
- (4) Mr. Kachioff commenced employment on August 1, 2011. 2012 salary amounts include deferred salary of \$94,700, interest on accrued salary of \$3,331, and accrued vacation of \$6,605. 2011 salary amounts include deferred salary of \$6,615 and accrued vacation of \$4,512.
- (5) Dr. Arnold commenced employment on April 30, 2011. 2012 salary amounts include deferred salary of \$64,123, interest on accrued salary of \$1,252, and accrued vacation of \$15,374. 2011 salary amounts include accrued vacation of \$8,810.
- (6) 2012 salary amounts include deferred salary of \$68,606, interest on accrued salary of \$2,420, and accrued vacation of \$2,656. 2011 salary amounts include deferred salary of \$4,615 and interest on accrued salary of \$32.

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- (7) Mr. Hale received restricted stock units in 2011, as described in the “Narrative Disclosure to Summary Compensation Table” below. The aggregate compensation expense recorded for these restricted stock unit grants, computed in accordance with FASB ASC Topic 718, was zero. The assumptions we used in valuing the restricted stock unit grants are described in note 9 to our audited financial statements included in this prospectus. However, the aggregate value of the awards at the grant date, assuming that the highest level of performance conditions will be achieved, was \$540,477.
- (8) Represents the aggregate grant date fair value for grants made in 2012 and 2011 computed in accordance with FASB ASC Topic 718. The assumptions we used in valuing the options are described in note 9 to our audited financial statements included in this prospectus.
- (9) Includes car and telephone allowances to Dr. Bischoff in each of 2012 and 2011, and a \$46,832 commuting expenses reimbursement benefit we provided to Dr. Bischoff in 2012 plus \$22,425 of income taxes we paid for Dr. Bischoff in respect of such 2012 benefit.

### **Narrative Disclosure to Summary Compensation Table**

#### ***David F. Hale***

As of March 10, 2011, we entered into an employment agreement, effective retroactive to January 1, 2011 (“Executive Chairman Agreement”), with David F. Hale in connection with his appointment as our Executive Chairman of the Board of Directors. The Executive Chairman Agreement is effective through December 31, 2013. The Executive Chairman Agreement provides Mr. Hale the following: (i) a monthly fee of \$25,000 per month for each month before our board of directors appoints a chief executive officer and for each of the three months following the appointment of the new chief executive officer, with a reduction to \$12,500 per month commencing with the fourth month following the appointment of the new chief executive officer (i.e., commencing with December 2013), subject to normal employee payroll deductions and withholdings; and (ii) stock options under our 2007 Equity Incentive Plan to purchase 10,204 shares of common stock, vesting in equal monthly installments over a 4 year period, with full vesting upon a change of control or initial public offering. In addition, vesting would accelerate upon his termination by us or our shareholders without cause, as defined in the 2007 Equity Incentive Plan, provided that he gives us an effective waiver and release of claims. Also, upon an equity financing such as this initial public offering, Mr. Hale will be entitled to receive an additional stock option, on the same terms and conditions except for exercise price, to purchase a number of shares of common stock equal to the excess of (i) 1% of our fully-diluted equity capitalization as of immediately after the financing over (ii) the number of shares subject to the first stock option.

The Executive Chairman Agreement also entitled Mr. Hale to restricted stock units (“RSUs”). Mr. Hale received a time-based RSU award for 428,597 shares of our preferred stock, to fully vest and settle upon a change in control or initial public offering during the period of his continuous service. Mr. Hale would receive a prorated portion of such shares if the change in control or initial public offering occurs within 10 years after January 1, 2011 but after the involuntary termination of his continuous service. The proration would be based upon the number of months he provided continuous service to us divided by 48; but the RSUs would be deemed vested in full upon his involuntary termination without cause, provided that he gives us an effective waiver and release of claims. Upon the closing of this offering, Mr. Hale would receive 10,204 shares of common stock in settlement of the time-based RSUs.

The Executive Chairman Agreement also entitled Mr. Hale to a performance-based RSU award, which is divided into three equal tranches, each representing shares of our preferred stock equal to 0.5% of our fully-diluted equity capitalization, and each to fully vest (subject to satisfaction of milestones) and settle upon a change in control or initial public offering occurring within 10 years after January 1, 2011. The tranches were associated with achievement of a specified commercial milestone, a specified funding milestone, and specified leadership milestones. The Executive Chairman Agreement provides that if a change in control or initial public offering occurs during the time of his continuous service but before the performance requirements are achieved, he will be entitled to receive 0.5% of our fully-diluted equity capitalization as of immediately before such event for each of the three tranches. Upon the closing of this initial public offering, Mr. Hale would receive in settlement of the three tranches of the performance-based RSUs a number of shares of common stock equal to 1.5% of our fully-diluted equity capitalization as of immediately before the closing of this offering.

Our board of directors has asked Mr. Hale to continue to serve as our Executive Chairman of the Board of Directors from January 1, 2014 until the earlier of the completion of this offering or February 14, 2014, at a salary of \$12,500 per month. At such time, Mr. Hale would serve as our non-executive Chairman of the Board of Directors.



**Michael J. Dunn**

We entered into an employment agreement as of February 15, 2011 (“SVP Corporate Development Employment Agreement”) with Michael J. Dunn in connection with his appointment as our Senior Vice-President of Corporate Development. The SVP Corporate Development Employment Agreement provided Mr. Dunn the following: (i) a base salary of \$250,000 per year, provided that the salary will increase by \$25,000 per year upon the finalization of one or more corporate collaborations or other investments that provide at least \$15,000,000 in financing to us; (ii) stock options under our 2007 Equity Incentive Plan to purchase 5,952 shares of common stock, with 25% of all shares vesting on the one year anniversary of his employment start date and the remainder vesting in equal monthly installments over the following 3 year period; and (iii) an additional option to purchase 1,190 shares of common stock, vesting in equal monthly installments over a one year period, to be issued upon the completion of a corporate collaboration providing at least \$5,000,000 in financing to us.

Mr. Dunn resigned effective on July 31, 2013.

**William G. Kachioff**

We entered into an employment agreement as of August 1, 2011 (“CFO Employment Agreement”) with William G. Kachioff in connection with his appointment as our Senior Vice-President and Chief Financial Officer. The CFO Employment Agreement provides Mr. Kachioff the following: (i) a base salary of \$215,000 per year, provided that the salary will increase to \$240,000 per year upon our receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities, excluding the conversion of outstanding indebtedness; (ii) a one-time bonus of \$30,000 upon our receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities, excluding the conversion of outstanding indebtedness; (iii) stock options under our 2007 Equity Incentive Plan to purchase 5,952 shares of common stock, with 25% of all shares vesting on the one year anniversary of the grant and the remainder vesting in equal monthly installments over the following 3 year period; and (iv) an additional option to purchase 1,190 shares of common stock to be issued upon our receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities, excluding the conversion of outstanding indebtedness. This initial public offering would qualify as such a receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities.

**Lyle J. Arnold**

We entered into an employment agreement as of April 30, 2011 (“CSO Employment Agreement”) with Lyle J. Arnold in connection with his appointment as our Senior Vice-President of Research and Development and Chief Scientific Officer. The CSO Employment Agreement provides Dr. Arnold the following: (i) a base salary of \$200,000 per year, provided that the salary will increase to \$250,000 per year upon our receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities, excluding the conversion of outstanding indebtedness; (ii) stock options under our 2007 Equity Incentive Plan to purchase 5,952 shares of common stock, with 25% of all shares vesting on the one year anniversary of the grant and the remainder vesting in equal monthly installments over the following 3 year period; and (iii) an additional option to purchase 1,190 shares of common stock when, based upon a good faith determination by our board of directors, a second generation platform for the capture, detection and enumeration of CTCs has been finalized, with the shares vesting in equal monthly installments over the following 1 year period. This initial public offering would qualify as such a receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities.

**Salary Deferrals**

Pursuant to written agreements with 10 officers and senior employees, we deferred payment of portions of such individuals’ salaries in 2012. In exchange we agreed to pay 8% per annum interest (compounded monthly) on the deferred amounts and to award them each, based on their election, either 357 common stock options or 357 restricted stock unit awards. Additional deferrals have been made in 2013 only from the salary of David F. Hale and the salary of one other employee. As of December 31, 2013, the deferred salary amount owing to Mr. Hale was \$635,318 (inclusive of interest), the deferred salary amount owing to Dr. Arnold was \$70,505 (inclusive of interest), the deferred salary amount owing to Dr. Bischoff was \$81,530 (inclusive of interest), the deferred salary amount owing to Mr. Dunn was \$91,650 (inclusive of interest), the deferred salary amount owing to Mr. Kachioff was \$112,797 (inclusive of interest), and the aggregate deferred salary amount owing to the five other persons was \$322,105 (inclusive of interest). One of the uses of the proceeds of this offering is to satisfy these deferred salary amounts of approximately \$1 million.

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**Outstanding Equity Awards**

The following table sets forth certain information, on an award-by-award basis, concerning unexercised options to purchase common stock and common stock that has not yet vested for each named executive officer and outstanding as of December 31, 2012. These figures have been adjusted to reflect both our November 2011 1-for-3 reverse common stock split and the 1-for-14 reverse common stock split effected on November 1, 2013.

Name	Grant Date	Option Awards				Restricted Stock Units	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable <sup>(1)</sup>	Option Exercise Price (\$)	Option Expiration Date	Number of Unvested Securities Underlying (#)	Market Value of Units that are Unvested (\$)
David F. Hale	1/3/2011	—	—	—	—	10,204	112,244
	1/3/2011	—	—	—	—	59,261 <sup>(2)</sup>	651,871
Michael J. Dunn	3/25/11	2,728	3,224	4.62	3/25/2021	—	—
	3/25/11	1,190	—	4.62	3/25/2021	—	—
William G. Kachioff	8/1/2011	992	1,984	4.62	8/1/2021	—	—
	8/1/2011	992	1,984	4.62	8/1/2021	—	—
Lyle J. Arnold, Ph. D.	4/30/2011	2,356	3,596	4.62	4/30/2021	—	—
Farideh Z. Bischoff, Ph. D.	7/1/2009	2,211	315	5.04	7/1/2019	—	—
	8/11/2009	198	—	5.04	8/11/2019	—	—
	8/11/2009	198	—	5.04	8/11/2019	—	—
	8/11/2009	198	—	5.04	8/11/2019	—	—
	3/25/2011	520	669	4.62	3/25/2021	—	—

(1) The scheduled vesting dates, after December 31, 2012, of these options were as follows:

Mr. Dunn: 124 of the unvested option shares shall vest each month from January 2013, subject to continuing service, until 100% of the option shares are vested. (On July 31, 2013, our Board of Directors accelerated the vesting of the option.)

Mr. Kachioff: For each of the two option grants, 62 of the unvested option shares shall vest each month from January 2013, subject to continuing service, until 100% of the option shares are vested.

Mr. Arnold: 124 of the unvested option shares shall vest each month from January 2013, subject to continuing service, until 100% of the option shares are vested.

Dr. Bischoff: 77 of the unvested option shares shall vest each month from January 2013, subject to continuing service, until 100% of the option shares are vested.

(2) Estimated.

## Potential Payments upon Termination or Change-In-Control

Our employment agreement with Mr. Hale provided that his stock option for 10,204 shares of common stock will fully vest in the event of a change in control (or upon the completion of our initial public offering). Because Mr. Hale early-exercised the stock option in November 2011, the same vesting and acceleration provisions now apply to the lapsing of our right to repurchase the exercised shares. The Executive Chairman Agreement also provided that Mr. Hale's time-based RSU award for 428,597 shares of our preferred stock (equivalent to 10,204 shares of common stock) will fully vest and settle upon a change in control (or upon the completion of our initial public offering) during the period of his continuous service; he would receive a prorated portion of such shares if the change in control or initial public offering occurs within 10 years after January 1, 2011 but after the involuntary termination of his continuous service. The proration would be based upon the number of months he provided continuous service to us divided by 48; but the RSUs would be deemed vested in full upon his termination without cause, provided that he gives us an effective waiver and release of claims. The Executive Chairman Agreement also entitled Mr. Hale to a performance-based RSU award, which is divided into three equal tranches, each representing shares of our preferred stock equal to 0.5% of our fully-diluted equity capitalization, and each to settle upon a change in control (or upon the completion of our initial public offering) occurring within 10 years after January 1, 2011. The tranches were associated with achievement of a specified commercial milestone, a specified funding milestone, and specified leadership milestones. The Executive Chairman Agreement provides that if a change in control (or initial public offering) occurs during the time of his continuous service but before the performance requirements are achieved, he will be entitled to receive 0.5% of our fully-diluted equity capitalization as of immediately before such event for each of the three tranches. Because Mr. Hale's time-based and performance-based RSUs under the Executive Chairman Agreement will both vest and settle upon the closing of this offering, Mr. Hale would receive no additional payments thereunder if a change in control occurs after the closing of this offering.

Our employment agreement with Mr. Dunn provided that if his continuous service was terminated without cause or he resigned with good reason then, provided that he gives us an effective waiver and release of claims, he would be entitled to 6 months' salary plus up to 6 months of COBRA premiums. However, if he was terminated without cause or he resigned with good reason within 3 months before or 12 months after a change in control, then, provided that he gave us an effective waiver and release of claims, he would be entitled to 12 months' salary plus up to 12 months of COBRA premiums, plus all his then-outstanding stock options would fully vest. Effective on July 31, 2013, Mr. Dunn resigned, and there was no right to any such severance payments.

Our employment agreement with Mr. Kachioff provides that if his continuous service is terminated without cause or he resigns with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 6 months' salary plus up to 6 months of COBRA premiums. However, if he is terminated without cause or he resigns with good reason within 3 months before or 12 months after a change in control, then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months' salary plus up to 12 months of COBRA premiums. Additionally, all of his then-outstanding stock options will fully vest.

Our employment agreement with Dr. Arnold provides that if his continuous service is terminated without cause or he resigns with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 6 months' salary plus up to 6 months of COBRA premiums. However, if he is terminated without cause or he resigns with good reason within 3 months before or 12 months after a change in control, then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months' salary plus up to 12 months of COBRA premiums. Additionally, all of his then-outstanding stock options will fully vest.

The common stock RSUs granted to five of our non-employee directors under the 2007 Equity Incentive Plan provide for acceleration of vesting in the event of a change in control or the director's involuntary removal from the board of directors by our shareholders without cause.

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A total of 13,095 stock options granted to five of our non-employee directors under the 2007 Equity Incentive Plan were amended in February 2012 to provide for acceleration of vesting in the event of the director's involuntary removal from the board of directors by our shareholders without cause, provided that the director gives us an effective waiver and release of claims.

The 390,000 preferred stock RSUs (equivalent to 9,285 shares of common stock) granted to Dr. Royston vest only upon a change in control or the effectiveness of an underwriting agreement for an initial public offering within 10 years. If Dr. Royston is still serving on the board at that time, all of the preferred stock RSUs would vest. If Dr. Royston was not serving on the board at that time, his entitlement would be equal to the full award multiplied by a fraction (not to exceed 1), the numerator of which is the number of months he served on the board and the denominator of which is 48. This RSU award was amended in February 2012 to provide that in the event of his involuntary removal from the board of directors by our shareholders without cause before the change in control or the effectiveness of an underwriting agreement for an initial public offering, then (provided that the director gives us an effective waiver and release of claims) all the preferred stock RSUs would vest upon the change in control or the effectiveness of an underwriting agreement for an initial public offering.

The vesting of all stock options and RSUs awarded under our 2013 Equity Incentive Plan will accelerate fully in the event that the optionee's continuous service is terminated without cause, or the optionee resigns for good reason, within 10 days before or 12 months after a change in control. In addition, the vesting of all stock options and RSUs awarded in July 2013 to Mr. Hale, Mr. Kachioff, Dr. Arnold and Dr. Bischoff under our 2013 Equity Incentive Plan will, if the optionee's continuous service persists through the first anniversary of a change in control, accelerate fully upon such first anniversary.

### **Director Compensation**

In December 2010, our board of directors approved a resolution that each year on January 1, each non-employee director (with the exception of Mrs. Reiss and Mr. Neff) shall be automatically granted an annual RSU award under the 2007 Equity Incentive Plan covering a number of shares of common stock equal to 0.25% of our fully diluted outstanding capital stock as of the December 31 immediately preceding the applicable grant date of the RSUs. Such RSU awards were granted on January 1, 2011 and 2012, and vested in equal monthly installments over 12 months from the date of the grant. Additionally, in January 2012, each person who was serving as a non-employee director was granted a "true up grant" in addition to the annual RSU award covering a number of shares of common stock equal to 0.25% of our fully diluted outstanding capital stock as of December 31, 2011. These "true up grants" vested 100% on the date of the grant. In January 2012, five RSU awards, for a total of 20,930 shares of common stock, were granted in accordance with this resolution.

The RSU awards due to be granted on January 1, 2013 and January 1, 2014 were not in fact granted. Instead, on July 31, 2013, RSU awards for 8,735 shares of common stock were granted to each of Mr. Gerhardt, Mr. Neff and Dr. Royston and a RSU award for 14,285 shares of common stock was granted to Ms. Wilson. These awards vested in equal monthly installments over five months beginning August 1, 2013. The shares underlying the 2013 awards would be distributed no later than August 24, 2014.

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During 2012, the non-employee directors received compensation for their service as follows (we have listed the value of the RSU awards in the “Restricted Stock Awards (\$)” column):

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$) <sup>(1)</sup></u>	<u>Option Awards (\$) <sup>(2)</sup></u>	<u>Restricted Stock Awards (\$) <sup>(3)</sup></u>	<u>Total (\$)</u>
Edward A. Dennis, Ph. D. <sup>(4)</sup>	—	—	\$ 38,680	\$38,680
Bruce E. Gerhardt	—	—	\$ 38,680	\$38,680
Ivor Royston, M.D.	—	—	\$ 38,680	\$38,680
Daniel H. Petree <sup>(4)</sup>	—	—	\$ 38,680	\$38,680
M. Faye Wilson	—	—	\$ 38,680	\$38,680

- (1) During 2012, we did not pay any cash compensation to our non-employee directors.
- (2) During 2012, we did not issue stock option awards to our non-employee directors.
- (3) The amounts in the “Restricted Stock Awards” column reflect the aggregate grant date fair value of restricted stock units granted during the year computed in accordance with the provisions of FASB ASC Topic 718. For a description of these restricted stock units, see the first paragraph of this “Director Compensation” section.
- (4) Dr. Dennis and Mr. Petree resigned from our board of directors in January 2013.

In 2013 our board of directors adopted a resolution that, beginning at the closing of this offering, the previous non-employee directors automatic grant program shall be terminated and, instead, non-employee members of our board of directors shall be eligible to automatically receive annual cash and equity compensation, as follows:

- Annual Retainer. For service as a director: an annual cash retainer of \$15,000.
- Board Chair. For service as Board Chair: an annual cash retainer of \$85,000 (in addition to an annual cash retainer of \$15,000 as a director), plus an annual grant of an option to purchase 50,000 shares of common stock.
- Lead Independent Director. For service as Lead Independent Director: an annual cash retainer of \$20,000 (inclusive of the annual cash retainer of \$15,000 as a director), plus an annual grant of an option to purchase 20,000 shares of common stock.
- Audit Committee.
  - For service as Chair of the audit committee: an annual grant of an option to purchase 7,500 shares of common stock.
  - For service as member of the audit committee other than as its Chair: an annual grant of an option to purchase 3,000 shares of common stock.
- Compensation Committee.
  - For service as Chair of the compensation committee: an annual grant of an option to purchase 5,000 shares of common stock.
  - For service as member of the compensation committee other than as its Chair: an annual grant of an option to purchase 2,000 shares of common stock.
- Nominating and Corporate Governance Committee.
  - For service as Chair of the nominating and corporate governance committee: an annual grant of an option to purchase 3,000 shares of common stock.
  - For service as member of the nominating and corporate governance committee other than as its Chair: an annual grant of an option to purchase 1,500 shares of common stock.
- Initial Post-IPO Equity Award. For each non-employee director serving at the time of the closing of this offering: an annual grant of an option to purchase 20,000 shares of common stock.
- Initial Awards. For each non-employee director who is initially elected or appointed to the board after the closing of this offering: an annual grant of an option to purchase 20,000 shares of common stock.

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- **Subsequent Awards.**

- For each non-employee director who (i) has been serving on the board for at least six months as of the date of any annual meeting of our stockholders and (ii) will continue to serve as a non-employee director immediately following such meeting: an option to purchase 15,000 shares of common stock.
- For each non-employee director who (i) has been serving as Chair of the board for at least six months as of the date of any annual meeting of our stockholders and (ii) will continue to serve as Chair of the board immediately following such meeting: an additional option to purchase 50,000 shares of common stock.

The annual cash retainers shall be earned and paid on a calendar quarterly basis, subject to proration in the case of service during only a portion of a calendar quarter.

The per share exercise price of each option granted under this program shall equal the fair market value of a share of common stock on the date the option is granted. Each such stock option shall vest and become exercisable in substantially equal installments on each of the first three anniversaries of the date of grant, subject to continuing in service on the board through each such vesting date; provided, that each Subsequent Award shall vest and/or become exercisable on the first anniversary of the date of grant, subject to continuing in service on the board through such vesting date; and provided further, that all stock options under the program shall vest in full upon the occurrence of a change in control.

The term of each such stock option shall be 10 years from the date the option is granted. Upon a non-employee director's cessation of service on the board for any reason, his or her stock options granted under this program would, to the extent vested on the date of cessation of service, remain exercisable for 12 months following the cessation of his or her service on the board (or such longer period as the board may determine in its discretion on or after the date of such stock options).

## **Equity Compensation Plan Information**

The table below sets forth certain information as of December 31, 2012 regarding the shares of our common stock available for grant or granted under stock option plans and other compensation arrangements that (i) were adopted by our stockholders and (ii) were not adopted by our stockholders.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (\$)</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in 1<sup>st</sup> column)</u>
Equity compensation plans approved by security holders <sup>(1)</sup>	118,229	2.66	50,138
Equity compensation plans not approved by security holders <sup>(2)</sup>	68,546	—	—
Total	155,387	2.02	50,138

- (1) Represents shares of common stock that may be issued pursuant to options (and 54,615 restricted stock units) granted, or available for future grant, under the 2007 Equity Incentive Plan. See “Executive Compensation—Employee Stock Plans—2007 Equity Incentive Plan” for a description of this plan.
- (2) Under individual compensation arrangements, restricted stock units for an estimated aggregate of 68,546 common stock equivalents were outstanding in favor of David F. Hale and Ivor Royston as of December 31, 2012. See “Executive Compensation—Narrative Disclosure to Summary Compensation Table—David F. Hale” and “Executive Compensation—Potential Payments upon Termination or Change-In-Control” for a description of these individual compensation arrangements.

## **Employee Stock Plans**

We have two equity incentive plans: the 2007 Equity Incentive Plan, and the 2013 Equity Incentive Plan. Each plan is described separately below, followed by a description of certain federal income tax consequences with respect to plans of these types.

### ***2007 Equity Incentive Plan***

The following is a summary of the material terms of our 2007 Equity Incentive Plan, as amended to date. This description is not complete. For more information, we refer you to the full text of the 2007 Equity Incentive Plan, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

The purposes of the 2007 Equity Incentive Plan are: (i) to secure and retain the services of eligible employees, board members, consultants and other advisors to serve our company and its affiliates, (ii) to provide incentives for such persons to exert maximum efforts for the success of our company and its affiliates and (iii) to provide a means by which they can benefit from increases in the value of our common stock.

The 2007 Equity Incentive Plan authorizes the grant of the following types of awards: (i) nonstatutory stock options, or NSOs, (ii) incentive stock options, or ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards, or RSUs, (v) stock appreciation rights, or SARs, (vi) performance stock awards, and (vii) other stock awards. Awards may be granted to employees, directors, consultants and other service providers of our company and its affiliates. However, ISOs may not be granted to non-employees.

We have authorized a total of 178,571 shares of common stock for issuance pursuant to all awards granted under the 2007 Equity Incentive Plan. The number of shares issued or reserved pursuant to the 2007 Equity Incentive Plan (or pursuant to outstanding awards) is subject to adjustment as a result of mergers, consolidations, reorganizations, stock splits, reverse stock splits, stock dividends and other changes in our common stock. Shares subject to awards that have been terminated, expired unexercised, forfeited, settled in cash or cancelled in accordance with the cancellation and regrant procedures under the 2007 Equity Incentive Plan shall again become available for issuance under the 2007 Equity Incentive Plan. Shares of common stock used to pay the exercise price of awards shall also again become available for issuance under the 2007 Equity Incentive Plan.

However, shares in the following categories may not again be made available for issuance as awards under the 2007 Equity Incentive Plan: (i) shares of common stock not issued or delivered as a result of the net settlement of outstanding awards, (ii) shares of common stock used to pay the exercise price of NSOs or ISOs, and (iii) shares of common stock used to pay withholding taxes related to awards.

As of December 31, 2013, 36,156 shares had been issued under the 2007 Equity Incentive Plan, 68,931 shares underlay outstanding awards, and 73,484 other shares remained available to be subjected to further awards.

*Administration.* Our board of directors administers the 2007 Equity Incentive Plan, subject to the board’s authority to delegate some or all of such administration to the Compensation Committee.

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*Performance Criteria.* Vesting of any awards granted under the 2007 Equity Incentive Plan may be made subject to the satisfaction of one or more performance goals established by the board of directors, in addition to or instead of time-vesting. The performance goals may vary from participant to participant, group to group, and period to period. Performance goals may be weighted for different factors and measures.

*Transferability.* Unless otherwise determined by the board of directors, awards granted under the 2007 Equity Incentive Plan are generally not transferable other than by will or by the laws of descent and distribution.

*Corporate Transaction.* In the event we are acquired in a corporate transaction, as defined in the 2007 Equity Incentive Plan, unless otherwise provided in a written agreement between us and the holder of an outstanding 2007 Equity Incentive Plan award, the award will be assumed by the successor company or a similar award will be substituted by the successor company. If the successor company does not agree to assume or substitute the award, the vesting of the award will accelerate and the award will become exercisable in full.

*Effectiveness of the 2007 Equity Incentive Plan; Amendment and Termination.* The 2007 Equity Incentive Plan became effective on March 6, 2007. The 2007 Equity Incentive Plan will remain available for the grant of awards until the day before the tenth anniversary of the effective date. The board may amend, alter or discontinue the 2007 Equity Incentive Plan in any respect at any time, subject to certain exceptions, but no amendment may adversely affect the rights of a participant under any awards previously granted, without his or her consent, except that stockholder approval will be needed if required by applicable law.

The 2007 Equity Incentive Plan permits us to reprice any stock option granted under the plan without the approval of our stockholders.

### **2013 Equity Incentive Plan**

The following is a summary of the material terms of our 2013 Equity Incentive Plan. This description is not complete. For more information, we refer you to the full text of the 2013 Equity Incentive Plan, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

The purposes of the 2013 Equity Incentive Plan are: (i) to enable us to attract and retain the types of qualified employees, officers, directors, consultants and other service providers who will contribute to our long range success, (ii) to align the interests of employees, officers, directors, consultants and other service providers with those of our stockholders, and (iii) to promote the success of our business.

The 2013 Equity Incentive Plan authorizes the grant of the following types of awards: NSOs, ISOs, SARs, restricted stock, RSUs, and performance compensation awards. Awards may be granted to employees, officers, non-employee board members, consultants and other service providers of our Company and its affiliates. However, ISOs may be granted only to employees, including officers.

We have authorized a total of 403,571 shares of common stock for issuance pursuant to all awards granted under the 2013 Equity Incentive Plan, subject to an increase of 800,000 shares upon the completion of this offering and subject to additional increases every January 1 beginning January 1, 2015 equal to the lesser of (i) 5% of our outstanding common stock on such January 1, or (ii) a number of shares determined by our board in its discretion for use on such particular January 1. The number of shares issued or reserved pursuant to the 2013 Equity Incentive Plan, or pursuant to outstanding awards, is subject to adjustment as a result of mergers, consolidations, reorganizations, stock splits, reverse stock splits, stock dividends and other changes in our common stock. Shares subject to awards that have been cancelled, expired unexercised, or forfeited do not count as shares issued under the 2013 Equity Incentive Plan, and therefore shall again to that extent become available for issuance under the 2013 Equity Incentive Plan. However, shares in the following categories may not again be made available for issuance as awards under the 2013 Equity Incentive Plan: (i) shares of common stock not issued or delivered as a result of the net settlement of outstanding NSOs or ISOs, (ii) shares of common stock used to pay the exercise price of NSOs or ISOs, (iii) shares of common stock used to pay withholding taxes related to awards, or (iv) shares of common stock corresponding to the value of stock-designated SARs which are settled in cash.



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In no event shall any participant be granted under the 2013 Equity Incentive Plan in any one calendar year (i) NSOs, ISOs or SARs pursuant to which, in the case of NSOs or ISOs, the aggregate number of shares of common stock that may be acquired thereunder, or, in the case of SARs, the aggregate number of shares of common stock covered thereby, exceeds 357,142 shares, or (ii) any other types of awards covering in the aggregate over 35,714 shares of common stock. Also, the maximum number of shares of common stock subject to performance stock awards, other than NSOs, ISOs and SARs, payable to any one participant under the 2013 Equity Incentive Plan in any one performance period is 71,428 shares of common stock or, in the event such performance stock award is paid in cash, the equivalent cash value thereof on the first or last day of the performance period to which such award relates, as determined by the Compensation Committee. The maximum amount that can be paid in any calendar year to any participant pursuant to a performance cash bonus award under the 2013 Equity Incentive Plan shall be \$1,000,000. In addition, the maximum number of shares of common stock that may be issued during the life of the 2013 Equity Incentive Plan under ISOs is 392,857 shares. If an award is settled in cash, the number of shares of common stock on which the award is based shall count toward the applicable individual share limit.

As of December 31, 2013, no shares had been issued under the 2013 Equity Incentive Plan, no shares had otherwise become unavailable for issuance, 401,640 shares underlay outstanding awards, and 1,931 other shares remained available to be subjected to further awards.

*Administration.* The 2013 Equity Incentive Plan is administered by our Compensation Committee. The Compensation Committee has the discretion to determine the individuals to whom awards may be granted under the 2013 Equity Incentive Plan, the number of shares of our common stock subject to each award, the type of award, the manner in which such awards will vest and the other conditions applicable to awards. The Compensation Committee is authorized to interpret the 2013 Equity Incentive Plan, to establish, amend and rescind any rules and regulations relating to the 2013 Equity Incentive Plan and to make any other determinations that it deems necessary or desirable for the administration of the 2013 Equity Incentive Plan. All decisions, determinations and interpretations by the Compensation Committee, and any rules and regulations under the 2013 Equity Incentive Plan and the terms and conditions of or operation of any award, are final and binding on all participants. Notwithstanding the foregoing, the board of directors also has authority to take action expressly or implicitly in the capacity of the administrator of the 2013 Equity Incentive Plan, and the board also may delegate, to the extent allowed under Delaware law, its authority to one or more of our officers with respect to awards that do not involve covered employees within the meaning of Internal Revenue Code Section 162(m) or “insiders” within the meaning of Section 16 of the Exchange Act.

*Stock Options.* The Compensation Committee will determine the exercise price and other terms for each option and whether the options will be NSOs or ISOs. The exercise price per share of each option will not be less than 100% of the fair market value of our common stock on the date of grant (or 110% of fair market value in the case of an ISO granted to a 10% stockholder), which, unless otherwise determined by the Committee, will be deemed to be the closing price of a share of our common stock on its principal exchange on the grant date. ISOs may be granted only to employees and are subject to certain other restrictions. To the extent an option intended to be an ISO does not qualify as an ISO, it will be treated as an NSO. A participant may exercise an option by written notice and payment of the exercise price in cash, or in the discretion of the Compensation Committee, in the form of an irrevocable commitment by a broker to pay over the net proceeds from a sale of the shares issuable under an option, the delivery of previously owned shares and/or withholding of shares deliverable upon exercise, net-exercise, or any combination of these methods, or in any other form of legal consideration that may be acceptable to the Compensation Committee. The maximum term of any option granted under the 2013 Equity Incentive Plan is 10 years from the grant date (or five years in the case of an ISO granted to a 10% stockholder). The 2013 Equity Incentive Plan does not permit us to reprice any stock option granted under the plan without the approval of our stockholders. The 2013 Equity Incentive Plan authorizes us to, but does not require us to, withhold from participants shares of common stock having a fair market value equal to our withholding obligation with respect to exercised NSOs.

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*Stock Appreciation Rights.* The Compensation Committee may grant SARs independent of or in connection with an option. The Compensation Committee will determine the other terms applicable to SARs. The exercise price per share of each SAR will not be less than 100% of the fair market value of our common stock on the grant date, which, unless otherwise determined by the Committee, will be deemed to be the closing price of a share of our common stock on its principal exchange on the grant date. The price will be subject to adjustment for recapitalization or other changes in our common stock. The maximum term of any SAR granted under the 2013 Equity Incentive Plan will be 10 years from the grant date. Generally, each SAR will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value on the exercise date of one share of our common stock over the exercise price, multiplied by
- the number of shares of common stock covered by the SAR.

Payment may be made in shares of our common stock, in cash or partly in common stock and partly in cash, all as determined by the Compensation Committee.

*Restricted Stock and Restricted Stock Units.* The Compensation Committee will have the authority to award restricted common stock and/or RSUs under the 2013 Equity Incentive Plan. Restricted stock awards consist of shares of stock that are transferred to a participant subject to service and/or other restrictions that may result in forfeiture if specified conditions are not satisfied. Unless the Compensation Committee determines otherwise at the time the restricted stock award is granted, holders of restricted stock will have the right to vote the shares. RSUs confer the right to receive shares of our common stock, cash or a combination of shares and cash, at a future date upon or following the attainment of service and/or other conditions specified by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of restricted stock or RSUs, which may include performance-based conditions. The 2013 Equity Incentive Plan authorizes us to, but does not require us to, withhold from participants shares of common stock having a fair market value equal to our withholding obligation with respect to restricted stock and/or settled RSUs.

*Performance Compensation Awards.* The Compensation Committee may award performance stock awards under the 2013 Equity Incentive Plan. Performance stock awards are awards, denominated in shares of our common stock, cash or a combination thereof, which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each stock award.

*Performance Criteria.* Vesting of awards granted under the 2013 Equity Incentive Plan may be subject to a requirement of continuous service and/or the satisfaction of one or more performance goals established by the Compensation Committee. The performance goals may vary from participant to participant, group to group, and period to period. Performance goals may be weighted for different factors and measures.

*Transferability.* Unless otherwise determined by the Compensation Committee, awards granted under the 2013 Equity Incentive Plan will generally not be transferable other than by will or by the laws of descent and distribution.

*Change in Control.* Unless otherwise provided in an award agreement, in the event of a participant's termination of continuous service without cause or for good reason, but excluding termination as a result of resignation in the absence of good reason, during the 10-day period before a change in control or during the 12 month period following a change in control, all options and SARs shall become immediately exercisable with respect to 100% of the shares subject to such options or SARs, and/or the restricted period shall expire immediately with respect to 100% of the shares of restricted stock or RSUs as of the date of the participant's termination of continuous service.

With respect to performance compensation awards, in the event of a change in control, all incomplete performance periods in respect of such award in effect on the date the change in control occurs shall end on the date of such change and the Compensation Committee shall (i) determine the extent to which performance goals with respect to each such performance period have been met based upon such audited or unaudited financial information then available as it deems relevant and (ii) cause to be paid to the applicable participant partial or full awards with respect to performance goals for each such performance period based upon the Compensation Committee's determination of the degree of attainment of performance goals or, if not determinable, assuming that the applicable "target" levels of performance have been attained, or on such other basis determined by the Compensation Committee.

In addition, in the event of an anticipated change in control, the Compensation Committee may in its discretion and upon at least 10 days' advance notice to the affected persons, cancel upon or immediately before the change in control any outstanding awards and pay to the holders thereof, in cash or stock, or any combination thereof, the value of such awards based upon the value per share of common stock received or to be received or deemed received by our other stockholders in the event. In the case of any option or SAR with an exercise price that equals or exceeds the price paid for a share of common stock in connection with the change in control, the Compensation Committee may cancel the option or SAR without the payment of consideration therefor.

*Effectiveness of the 2013 Equity Incentive Plan; Amendment and Termination.* The 2013 Equity Incentive Plan was adopted and approved by our board of directors on July 31, 2013 and approved by our stockholders on August 6, 2013. The 2013 Equity Incentive Plan will remain available for the grant of awards until the tenth anniversary of the effective date. The board may amend, alter or discontinue the 2013 Equity Incentive Plan in any respect at any time, but no amendment may impair the rights of a participant under any awards previously granted, without his or her consent, except that stockholder approval will be needed for any amendment that would increase the maximum number of shares available for awards, other than the increase that occurs every January 1, reduce the exercise price of outstanding options or SARs, or if otherwise required by applicable law or stock market requirements.

### **Federal Income Tax Consequences**

Following is a summary of the federal income tax consequences of option and other awards under the 2007 Equity Incentive Plan and 2013 Equity Incentive Plan. Optionees and recipients of other rights and awards granted under the 2007 Equity Incentive Plan or the 2013 Equity Incentive Plan are advised to consult their personal tax advisors before exercising an option, stock appreciation right or award or disposing of any stock received pursuant to the exercise of an option, stock appreciation right or award. In addition, the following summary is based upon an analysis of the Code (the Internal Revenue Code of 1986, as amended and as currently in effect), existing laws, judicial decisions, administrative rulings, regulations and proposed regulations, all of which are subject to change and does not address state, local or other tax laws.

*Treatment of Options.* The Code treats ISOs and NSOs differently. However, as to both types of options, no income will be recognized to the optionee at the time of the grant of the options under the 2007 Equity Incentive Plan or the 2013 Equity Incentive Plan.

Generally, upon exercise of an NSO, including an option intended to be an ISO but which has not continued to so qualify at the time of exercise, an optionee will recognize ordinary income tax on the excess of the fair market value of the stock on the exercise date over the option price. In general, if an optionee, in exercising an NSO, tenders shares of our common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of an ISO and the tender is within two years after the date of grant or within one year after the date of exercise of the ISO, the tender will be a disqualifying disposition of the shares acquired upon exercise of the ISO.

For ISOs, there is no taxable income to an optionee at the time of exercise. However, the excess of the fair market value of the stock on the date of exercise over the exercise price will be taken into account in determining whether the alternative minimum tax will apply for the year of exercise. If the shares acquired upon exercise are held until at least two years from the date of grant and more than one year from the date of exercise, any gain or loss upon the sale of such shares, if held as capital assets, will be long-term capital gain or loss, measured by the difference between the sales price of the stock and the exercise price. Under current federal income tax law, a long-term capital gain will be taxed at a rate which is less than the maximum rate of tax on ordinary income. If the two-year and one-year holding period requirements are not met, an optionee will recognize ordinary income in the year of disposition in an amount equal to the lesser of (i) the fair market value of the stock on the date of exercise minus the exercise price or (ii) the amount realized on disposition minus the exercise price. The remainder of the gain will be treated as long-term capital gain, depending upon whether the stock has been held for more than a year. If an optionee makes such a disposition, he or she will be obligated to notify us.

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In general, if an optionee, in exercising an ISO, tenders shares of our common stock in partial or full payment of the option price, no gain or loss will be recognized on the tender. However, if the tendered shares were previously acquired upon the exercise of another ISO and the tender is within two years after the date of grant or within one year after the date of exercise of the other option, the tender will be a disqualifying disposition of the shares acquired upon exercise of the other option.

As noted above, the exercise of an ISO could subject an optionee to the alternative minimum tax. The application of the alternative minimum tax to any particular optionee depends upon the particular facts and circumstances which exist with respect to the optionee in the year of exercise. However, as a general rule, the amount by which the fair market value of the common stock on the date of exercise of an option exceeds the exercise price of the option will constitute an item of “adjustment” for purposes of determining the alternative minimum taxable income on which the alternative tax may be imposed. As such, this item will enter into the tax base on which the alternative minimum tax is computed and may therefore cause the alternative minimum tax to become applicable in any given year.

*Treatment of Stock Appreciation Rights.* Generally, the recipient of a stock appreciation right will not recognize any income upon grant of the stock appreciation right. Upon exercise of a stock appreciation right, the holder will recognize ordinary income equal to the fair market value of our common stock at that time.

*Treatment of Restricted Stock Awards.* Generally, absent an election to be taxed currently under Section 83(b) of the Code, or a Section 83(b) Election, there will be no federal income tax consequences to the recipient upon the grant of a restricted stock award. At the expiration of the restriction period and the satisfaction of any other restrictions applicable to the restricted shares, the recipient will recognize ordinary income equal to the fair market value of our common stock at that time. If a Section 83(b) Election is made within 30 days after the date the restricted stock award is granted, the recipient will recognize an amount of ordinary income at the time of the receipt of the restricted shares equal to the fair market value, determined without regard to applicable restrictions, of the shares of our common stock at such time. If a Section 83(b) Election is made, no additional income will be recognized by the recipient upon the lapse of restrictions on the shares, and before the sale of such shares, but, if the shares are subsequently forfeited, the recipient may not deduct the income that was recognized pursuant to the Section 83(b) Election at the time of the receipt of the shares.

The recipient of an unrestricted stock award will recognize ordinary income equal to the fair market value of our common stock that is the subject of the award when the award is made.

The recipient of an RSU will recognize ordinary income as and when the units vest. The amount of the income will be equal to the fair market value of the shares of our common stock issued at that time. The recipient of an RSU will not be permitted to make a Section 83(b) Election with respect to such award.

*Treatment of Performance Share Awards.* The federal income tax consequences of performance share awards, performance unit awards, other cash-based awards and other stock-based awards will depend on the terms and conditions of those awards.

*Tax Withholding.* We have the right to deduct or withhold, or require a participant to remit to us, the amount required to satisfy minimum statutory withholding requirements of federal, state and local tax laws and regulations, domestic or foreign, with respect to any taxable event arising as a result of the 2007 Equity Incentive Plan or the 2013 Equity Incentive Plan.

*Inapplicability of Code Sections and ERISA.* Sections 401(a) and 401(k) of the Code and the provisions of the Employee Retirement Income Security Act of 1974 are not applicable to the 2007 Equity Incentive Plan or the 2013 Equity Incentive Plan.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements for named executive officers and directors, we describe below each transaction and series of similar transactions, since January 1, 2011, to which we were a party or will be a party, in which the amount exceeds \$120,000 (or, if less, 1% of the average of our total assets amount at December 31, 2011 and December 31, 2012) and in which any related person had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in the section entitled “Executive Compensation.”

### **Michael W. Nall**

We entered into an employment agreement effective as of August 26, 2013 (“CEO Employment Agreement”) with Michael W. Nall in connection with his appointment as our Chief Executive Officer and President. The CEO Employment Agreement provides Mr. Nall the following: (i) a base salary of \$200,000 per year, provided that the salary will increase retroactively to \$350,000 per year upon completion of an initial public offering or an equity or debt financing of at least \$5,000,000; (ii) a target bonus of \$100,000 per year; (iii) a special one-time bonus of \$100,000 in January 2014 if an initial public offering or an equity or debt financing of at least \$5,000,000 has been completed by then; (iv) upon completion of an initial public offering or an equity or debt financing of at least \$5,000,000, a housing allowance of \$2,000 per month; (v) stock options under our 2013 Equity Incentive Plan to purchase a number of shares of common stock equal to at least 4% of our fully diluted stock outstanding as of August 26, 2013, vesting in equal monthly installments over 4 years beginning August 15, 2013; and (vi) performance-based restricted stock units under our 2013 Equity Incentive Plan for a number of shares of common stock equal to 1% of our common stock following completion of an initial public offering or an equity or debt financing of at least \$5,000,000, subject to the establishment of goals and objectives to be agreed with and approved by our board of directors. The CEO Employment Agreement calls for the vesting of such stock options to fully accelerate upon a change in control, and in the event Mr. Nall’s continuous service is terminated by us or our stockholders without cause or Mr. Nall resigns with good reason, for him to receive one year of additional vesting of such stock options.

The CEO Employment Agreement provides that in the event of termination of Mr. Nall’s employment by us without cause or his resignation for good reason, the vesting of any of his outstanding unvested stock options and RSUs which would have vested over the following 12 months will accelerate (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). Also, in the event of a change of control, the vesting of 50% of any of Mr. Nall’s outstanding unvested stock options and RSUs will accelerate on the date of the change of control and the remaining unvested stock options and RSUs will vest on the earliest of (i) the date of the termination of his employment by us without cause, (ii) the date of his resignation for good reason, or (iii) the first anniversary of the change of control (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). (For example, the foregoing would not apply to the initial stock options grant, which would fully accelerate upon a change in control.)

The CEO Employment Agreement provides that if Mr. Nall has a separation from service as a result of his discharge by us without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months’ salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage). However, the CEO Employment Agreement further provides that Mr. Nall will have no entitlement to any severance benefits before our completion of an initial public offering or an equity or debt financing of at least \$5,000,000.

### **Claire K. T. Reiss**

From time to time, Claire K. T. Reiss, who is our controlling stockholder and at all times described in this section was also a director of Biocept, individually and through entities affiliated with her has loaned us operating funds through various convertible and non-convertible debt instruments. These entities consist of Reisung Enterprises, Inc., of which Mrs. Reiss is the owner and president, and family trusts of which Mrs. Reiss is the trustee. Mrs. Reiss resigned from the board of directors on August 14, 2013.

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In February 2011, we executed a note and warrant purchase agreement with Mrs. Reiss's trusts. In exchange for a series of loans, we issued secured convertible promissory notes and warrants to purchase shares of our preferred stock to the trusts. The aggregate borrowing amount allowable under the February 2011 note and warrant purchase agreement was initially \$5.0 million and was subsequently raised to \$6.0 million, then \$12.0 million and then \$15.0 million, and the funding period was extended first to February 2012 and then to December 2012. The notes bore interest at 8%, payable at maturity. Under this note and warrant purchase agreement, we issued notes payable of \$1.25 million and \$10.0 million to Mrs. Reiss' family trusts and Reisung Enterprises, Inc. during 2012 and 2011, respectively. The notes matured during 2012, and all principal of these notes was unpaid at December 31, 2012. In June 2013, Mrs. Reiss' family trusts and Reisung Enterprises, Inc. converted the entire principal amount of \$11.25 million and accrued interest of \$1.7 million due on these notes into 24,002,689 shares of Series A preferred stock. The family trusts and Reisung Enterprises, Inc. retained the 4,166,667 preferred stock warrants they received under the 2011 note and warrant purchase agreement. Such warrants will terminate unexercised upon the closing of this offering. The exercise price of the warrants is \$0.54, subject to adjustment when any portion of the associated note has been converted.

In January 2012, we executed a note and warrant purchase agreement with several shareholders, including Mrs. Reiss' family trusts. The aggregate borrowing amount allowable under the January 2012 note and warrant purchase agreement was initially \$3.35 million and was subsequently raised to \$8.35 million, and the funding period was extended to December 2012. The notes bore interest at 10%, payable at maturity. Under this note and warrant purchase agreement, we issued notes payable to Mrs. Reiss' family trusts and Reisung Enterprises, Inc. for an aggregate principal amount of \$5.8 million during 2012. The notes matured during 2012, and all principal and accrued interest on these notes was unpaid at December 31, 2012. In June 2013, Mrs. Reiss' family trusts and Reisung Enterprises, Inc. converted the entire principal amount of \$5.8 million and accrued interest of \$627,000 due on these notes into 11,921,156 shares of Series A preferred stock. The family trusts and Reisung Enterprises, Inc. retained the 2,151,852 preferred stock warrants they received under the 2012 note and warrant purchase agreement; such warrants will terminate unexercised upon the closing of this offering. The number of warrants exercisable under this series of warrant agreements is determined by dividing the warrant coverage amount of 20% by the exercise price. The exercise price of the warrants is \$0.54.

As of June 2013, we executed a note and warrant purchase agreement with several shareholders, including a family trust affiliated with Mrs. Reiss and Reisung Enterprises, Inc., to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. We had borrowed \$0.72 million under this arrangement from Mrs. Reiss' family trust before December 31, 2012 and we borrowed another \$1.8 million under it from her family trust and Reisung Enterprises, Inc. in 2013. The maturity date of each note is May 31, 2014 and may be extended for two successive six month periods. Each note bears interest at 8.0% per annum, payable at maturity. The principal amount of and accrued interest on each note automatically convert into common stock upon the closing of an underwritten initial public offering resulting in at least \$8.0 million of gross proceeds to us, at a conversion price equal to the price per share of our common stock sold in our initial public offering. The number of shares underlying the associated common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the loan principal, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding for amounts we borrowed from Mrs. Reiss and entities affiliated with her under this arrangement was approximately \$2.7 million. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), the family trust and Reisung Enterprises, Inc. will together have 113,864 common stock warrants, with an exercise price of \$11.00 per share, in connection with these loans. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

In July 2013, we and one of Mrs. Reiss' family trusts amended a \$1.4 million promissory note which we had issued to the trust in 2008 to provide that the entire principal amount of and accrued interest on such note would automatically convert, upon the closing of an initial public offering, into shares of our common stock at a price per share equal to the offering price per share to the public in such offering. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding on such note was approximately \$1.6 million.

As compensation for guaranteeing, along with two other guarantors, our July 2013 revolving line of credit from UBS Bank USA, which had an initial credit availability of \$1.5 million, and which now has credit availability of approximately \$2.2 million, a family trust affiliated with Mrs. Reiss received common stock warrants from us. The number of shares underlying the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the family trust to secure the trust's guaranty obligations to UBS Bank USA, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. Assuming a public offering price of \$11.00 per share (the midpoint of the price

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range listed on the cover page of this prospectus), the family trust will have 42,091 common stock warrants, with an exercise price of \$11.00 per share, in connection with this guaranty. The warrants will be exercisable for a two-year period beginning on the closing of this offering.

### **Edward Neff**

Edward Neff, a member of our board of directors, is the chief executive officer and owner of Systems, Machines, Automation Components Corporation (SMAC), a company which has loaned us operating funds under convertible debt arrangements and provided financing for certain fixed asset purchases.

Under the note and warrant purchase agreement executed in February 2011, we borrowed \$125,000 and \$425,000 from SMAC in 2011 and 2012, respectively. See details of the February 2011 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. The principal and accrued interest on these notes was unpaid at December 31, 2012. In June 2013, SMAC converted the principal of \$550,000 and accrued interest of \$53,000 due on these notes into 1,116,498 shares of Series A preferred stock. SMAC retained 203,698 preferred stock warrants it received under the 2011 note and warrant purchase agreement. Such warrants will terminate unexercised upon the closing of this offering.

During 2011, we entered into two financing arrangements with SMAC, for the purchase of lab equipment from SMAC totaling \$256,000, of which \$138,000 and \$60,000 was outstanding as of December 31, 2011 and 2012, respectively. The stated interest rate on each financing agreement was 0.0%. Under the first financing arrangement, the maximum amount which could be borrowed was \$147,000, the largest amount of principal outstanding during the period from January 1, 2012 to date was \$72,000, the principal amount outstanding on September 30, 2013 was \$22,000, the amount of principal paid during the period from January 1, 2012 to date was \$50,000, and the amount of imputed interest (calculated using a 8.00% per annum imputed interest rate) during the period from January 1, 2012 to date was \$7,000. Under the second financing arrangement, the maximum amount which could be borrowed was \$109,000, the largest amount of principal outstanding during the period from January 1, 2012 to date was \$66,000, the principal amount outstanding on September 30, 2013 was \$39,000, the amount of principal paid during the period from January 1, 2012 to date was \$27,000, and the amount of imputed interest (calculated using a 8.00% per annum imputed interest rate) during the period from January 1, 2012 to date was \$5,000.

As of June 2013, we executed a note and warrant purchase agreement with several shareholders, including SMAC, to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. See details of the June 2013 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. We borrowed \$25,000 from SMAC under this arrangement in 2012 and an additional \$925,000 in 2013. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding for amounts we borrowed from SMAC under this arrangement was approximately \$1.0 million. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), SMAC will have 43,182 common stock warrants, with an exercise price of \$11.00 per share, in connection with these loans. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

As compensation for guaranteeing, along with two other guarantors, our July 2013 revolving line of credit from UBS Bank USA, which had an initial credit availability of \$1.5 million, and which now has credit availability of approximately \$2.2 million, Mr. Neff received common stock warrants from us. The number of shares underlying the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by Mr. Neff to secure his guaranty obligations to UBS Bank USA, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), Mr. Neff will have 26,181 common stock warrants, with an exercise price of \$11.00 per share, in connection with this guaranty. The warrants will be exercisable for a two-year period beginning on the closing of this offering.

### **David F. Hale**

Under the note and warrant purchase agreement executed in February 2011, we issued a note payable of \$50,000 during 2011 to Hale BioPharma Ventures LLC, which is controlled by our Executive Chairman David F. Hale. Under the note and warrant purchase agreement executed in January 2012, we issued notes payable of \$100,000 to Hale BioPharma Ventures LLC. See details of the February 2011 and January 2012 note and warrant purchase agreements in the description of transactions with Claire K. T. Reiss, above. The principal and interest on these notes was unpaid at December 31, 2012. In



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June 2013, Hale BioPharma Ventures LLC converted the entire \$150,000 principal balance of and accrued interest of \$18,000 due on these notes into 310,392 shares of our Series A preferred stock. Hale BioPharma Ventures LLC retained 55,555 preferred stock warrants it received under the 2011 and 2012 note and warrant purchase agreements. Such warrants will terminate unexercised upon the closing of this offering.

As of June 2013, we executed a note and warrant purchase agreement with several shareholders, including Hale BioPharma Ventures LLC, to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. See details of the June 2013 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. We borrowed \$443,500 under it from Hale BioPharma Ventures LLC in 2013. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding for amounts we borrowed from Hale BioPharma Ventures LLC under this arrangement was \$467,822. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), Hale BioPharma Ventures LLC will have 20,159 common stock warrants, with an exercise price of \$11.00 per share, in connection with these loans. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

As compensation for guaranteeing, along with two other guarantors, our July 2013 revolving line of credit from UBS Bank USA, which had an initial credit availability of \$1.5 million, and which now has credit availability of approximately \$2.2 million, Hale BioPharma Ventures LLC received common stock warrants from us. The number of shares underlying the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by Hale BioPharma Ventures LLC to secure its guaranty obligations to UBS Bank USA, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), Hale BioPharma Ventures LLC will have 30,728 common stock warrants, with an exercise price of \$11.00 per share, in connection with this guaranty. The warrants will be exercisable for a two-year period beginning on the closing of this offering.

### **M. Faye Wilson**

Under the note and warrant purchase agreement executed in February 2011, we issued notes payable of \$75,200 during 2011 to our director M. Faye Wilson and Wilson Boyles & Co., LLC, which is controlled by Ms. Wilson. Under the note and warrant purchase agreement executed in January 2012, we issued a note payable of \$20,000 to Ms. Wilson. See details of the February 2011 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. The principal and interest on these notes was unpaid at December 31, 2012. In June 2013, Ms. Wilson and Wilson Boyles & Co., LLC converted the entire \$95,200 principal balance of and accrued interest of \$10,000 due on these notes into 194,859 shares of our Series A preferred stock. Ms. Wilson retained 30,536 preferred stock warrants she received under the 2011 and 2012 note and warrant purchase agreements and Wilson Boyles & Co., LLC retained 4,722 preferred stock warrants it received under the 2011 and 2012 note and warrant purchase agreements. Such warrants will terminate unexercised upon the closing of this offering.

As of June 2013, we executed a note and warrant purchase agreement with several shareholders, including Ms. Wilson, to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. See details of the June 2013 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. We borrowed \$25,000 under it from Ms. Wilson in 2013. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding for amounts we borrowed from Ms. Wilson under this arrangement was \$26,271. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), Ms. Wilson will have 1,136 common stock warrants, with an exercise price of \$11.00 per share, in connection with these loans. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

### **Ivor Royston, M.D.**

Under the note and warrant purchase agreement executed in February 2011, we issued a note payable of \$100,000 during 2011 to the individual retirement account of our director Ivor Royston, M.D. See details of the February 2011 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. The principal and interest on this note was unpaid at December 31, 2012. In June 2013, Dr. Royston's IRA converted the entire \$100,000 principal balance of and accrued interest of \$10,000 due on this note into 204,059 shares of our Series A preferred stock. Dr. Royston's IRA retained 37,037 preferred stock warrants it received under the 2011 note and warrant purchase agreement. Such warrants will terminate unexercised upon the closing of this offering.



**Bruce E. Gerhardt**

Under the note and warrant purchase agreement executed in February 2011, we issued a note payable of \$25,000 during 2011 to our director Bruce E. Gerhardt. Under the note and warrant purchase agreement executed in January 2012, we issued notes payable of \$30,000 to Mr. Gerhardt. See details of the February 2011 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. The principal and interest on these notes was unpaid at December 31, 2012. In June 2013, Mr. Gerhardt converted the entire \$55,000 principal balance of and accrued interest of \$7,000 due on these notes into 115,084 shares of our Series A preferred stock. Mr. Gerhardt retained 20,370 preferred stock warrants he received under the 2011 and 2012 note and warrant purchase agreements. Such warrants will terminate unexercised upon the closing of this offering.

As of June 2013, we executed a note and warrant purchase agreement with several shareholders, including Mr. Gerhardt, to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. See details of the June 2013 note and warrant purchase agreement in the description of transactions with Claire K. T. Reiss, above. We borrowed \$10,000 under it from Mr. Gerhardt in 2013. As of December 31, 2013, the aggregate amount of principal and accrued interest outstanding for amounts we borrowed from Mr. Gerhardt under this arrangement was \$10,458. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), Mr. Gerhardt will have 455 common stock warrants, with an exercise price of \$11.00 per share, in connection with these loans. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

**Lyle J. Arnold**

Lyle J. Arnold, Ph.D., our Senior Vice-President of Research and Development and Chief Scientific Officer, is the controlling person of Aegea Biotechnologies, Inc. On June 2, 2012, we entered into an Assignment and Exclusive Cross-License Agreement with Aegea in regard to the CEE-Selector technology. Under the Agreement, each party has an undivided joint ownership interest in all of the patents and other intellectual property rights for such technology. We obtained an exclusive, worldwide, royalty-free, fully-paid, irrevocable, sublicensable license for all applications in the fields of oncology clinical testing and oncology diagnostics (including both laboratory developed tests and IVD tests as applied to the oncology field) and oncology basic and clinical research that is performed internally by us, as a service offered by us, or in a bona fide collaboration between us and one or more third parties (where the sample types tested are tissue, whole blood, bone marrow, cerebrospinal fluid or derivatives of any of such sample types); provided that any such collaboration must not be solely or primarily directed to providing research reagents or research technologies to such collaborator, and must not involve the sale or resale of patented research reagents or the licensing of technologies for patented research applications by such collaborator to third parties. Under the Agreement's license, we are free of any obligation to obtain further consent from Aegea or to account to Aegea. Aegea obtained an exclusive, worldwide, royalty-free, fully-paid, irrevocable sublicensable license for all applications in all other fields, without any obligation to obtain further consent from us or to account to us. We were given responsibility for prosecuting some of the relevant patent applications, and Aegea was given responsibility for prosecuting others, but the two parties will share all patent prosecution and maintenance costs equally.

**Goodman Co. Ltd.**

In June 2013, Goodman Co. Ltd., a beneficial owner of more than 5% of our common stock, converted the entire principal amount of \$1,935,000 and accrued interest of approximately \$105,000 due on a secured promissory note held by it into 3,777,324 shares of Series A preferred stock. In connection with this conversion, we issued to Goodman Co. Ltd. a warrant to purchase 23,809 shares of common stock at an exercise price equal which will be set at the price per share of our common stock sold in our initial public offering. The warrants will be exercisable for a two-year period beginning on the closing of this offering.

### **Indemnification Agreements**

We have entered into indemnification agreements with each of our current directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to us and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. We also intend to enter into indemnification agreements with our future directors and executive officers. In addition, our predecessor company Biocept, Inc., a California corporation, entered into indemnification agreements with certain of our current directors and executive officers and certain prior directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under California law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

### **Policies and Procedures for Related Party Transactions**

In anticipation of becoming a public company upon completion of this offering, we adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, collectively, related parties, are not permitted to enter into a transaction with us without the prior consent of our board of directors acting through the audit committee. Any request for us to enter into a transaction with a related party in which the amount involved exceeds \$120,000, and in which such related party would have a direct or indirect interest, must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related person's interest in the transaction.

## PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of December 31, 2013 by:

- each person, or group of affiliated persons, whom we know to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the column labeled “Percentage of Shares Beneficially Owned—Before Offering” is based upon 181,614 shares of common stock and 69,421,047 shares of Series A preferred stock outstanding, and treats the 69,421,047 outstanding shares of Series A preferred stock as if they had been converted into 1,652,851 shares of common stock as of December 31, 2013 (i.e., the percentage ownership information shown in the column is based on an assumption that there were 1,834,465 shares of common stock outstanding as of December 31, 2013). The percentage ownership information shown in the column labeled “Percentage of Shares Beneficially Owned—After Offering” is further based upon the sale of 1,818,181 shares of common stock in this offering, and upon an assumption that there is no exercise of the underwriters’ overallotment option.

All percentages shown treat each share of Series A preferred stock as being one-forty-second of one share of common stock, because all of our shares of Series A preferred stock will in fact be converted into common stock at a 1-for-42 rate given our November 2011 1-for-3 reverse common stock split and our November 2013 1-for-14 reverse common stock split. We are not presenting a separate table showing individual or percentage beneficial ownership of Series A preferred stock. Claire K. T. Reiss’ and her affiliates’ beneficial ownership percentage of our Series A preferred stock at December 31, 2013 was 81.5%.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before March 1, 2014, which is 60 days after December 31, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. We have, however, excluded warrants to purchase shares of Series A preferred stock which, although exercisable at December 31, 2013, will nonetheless not be exercised and will terminate unexercised upon the completion of this offering. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

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Except as otherwise noted below, the address for persons listed in the table is c/o Biocept, Inc., 5810 Nancy Ridge Drive, San Diego, California 92121.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before Offering</u>	<u>After Offering</u>
<b>5% Stockholders</b>			
Claire K. T. Reiss <sup>(1)</sup>	1,488,510	78.4%	43.8%
Goodman Co. Ltd. <sup>(2)</sup>	102,653	5.6%	2.9%
<b>Named Executive Officers, Executive Officers and Directors:</b>			
David F. Hale <sup>(3)</sup>	33,738	1.8%	5.1%
Marsha A. Chandler <sup>(4)</sup>	2,604	*	*
Bruce E. Gerhardt <sup>(5)</sup>	6,541	*	*
Bruce A. Huebner <sup>(6)</sup>	1,860	*	*
Michael W. Nall <sup>(7)</sup>	100,000	5.2%	2.3%
Edward Neff <sup>(8)</sup>	43,424	2.4%	4.6%
Ivor Royston, M.D. <sup>(9)</sup>	7,040	*	*
M. Faye Wilson <sup>(10)</sup>	8,834	*	*
Lyle J. Arnold, Ph. D. <sup>(11)</sup>	18,626	*	*
Farideh Z. Bischoff, Ph. D. <sup>(12)</sup>	17,351	*	*
Michael J. Dunn <sup>(13)</sup>	5,952	*	*
William G. Kachioff <sup>(14)</sup>	16,083	*	*
All Executive Officers and Directors as a Group (11 persons)	256,101	12.7%	14.9%

\* denotes less than 1%.

- (1) The number of shares currently beneficially owned includes 64,638 shares issuable upon conversion of a convertible note (including accrued interest on the note) held by a family trust controlled by Mrs. Reiss. Also includes outstanding shares held by various family trusts and a private corporation controlled by Mrs. Reiss. The calculation of the percentage of shares beneficially owned after this offering also includes approximately 329,000 additional shares into which notes held by various family trusts and Reisung Enterprises, Inc., a corporation controlled by Mrs. Reiss, will be converted upon the completion of this offering and 155,955 shares for which common stock warrants held by various family trusts and Reisung Enterprises, Inc., a corporation controlled by Mrs. Reiss, will become exercisable upon the completion of this offering (each assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus). The address of Mrs. Reiss is 9675 La Jolla Farms Road, La Jolla, California 92037.
- (2) The calculation of the percentage of shares beneficially owned after this offering also includes 23,809 shares of common stock underlying warrants which will become exercisable upon the completion of this offering. The address of Goodman Co. Ltd. is 108 Fujigaoka, Meito-ku, Nagoya 465-0032 Japan.
- (3) Includes 16,145 shares of common stock underlying stock options. Includes shares held by Hale BioPharma Ventures LLC, which is controlled by Mr. Hale, and shares held by the Hale Family Trust, which is controlled by Mr. Hale as co-trustee. The calculation of the percentage of shares beneficially owned after this offering also includes approximately 43,000 shares of common stock into which notes held by Hale BioPharma Ventures LLC will be converted upon the completion of this offering and 50,887 shares for which common stock warrants held by Hale BioPharma Ventures LLC will become exercisable upon the completion of this offering (each assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus), approximately 41,873 shares of common stock to underlie the “1% true-up” stock option to be issued to Mr. Hale immediately after the completion of the offering, and approximately 60,295 shares of common stock to be issued upon the settlement of

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restricted stock units, at or immediately after the time of the completion of the offering.

- (4) Includes 2,604 shares of common stock underlying stock options.
- (5) Includes 2,346 shares of common stock underlying stock options. The calculation of the percentage of shares beneficially owned after this offering also includes approximately 950 shares into which a note held by Mr. Gerhardt will be converted upon the completion of this offering and 455 shares for which common stock warrants held by Mr. Gerhardt will become exercisable upon the completion of this offering (each assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus).
- (6) Includes 1,860 shares of common stock underlying stock options.
- (7) Includes 100,000 shares of common stock underlying stock options.
- (8) Includes shares held by Systems, Machines, Automation Components Corporation, which is controlled by Mr. Neff. The calculation of the percentage of shares beneficially owned after this offering also includes approximately 91,000 shares into which notes held by Systems, Machines, Automation Components Corporation will be converted upon the completion of this offering and 69,363 shares for which common stock warrants held by Systems, Machines, Automation Components Corporation will become exercisable upon the completion of this offering (each assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus).
- (9) Includes 2,182 shares of common stock underlying stock options. Includes shares owned by Dr. Royston's individual retirement account. The calculation of the percentage of shares beneficially owned after this offering also includes 9,285 shares of common stock to be issued upon the settlement of restricted stock units, at or immediately after the time of the completion of the offering.
- (10) Includes 2,619 shares of common stock underlying stock options. Includes shares held by Wilson Boyles & Co., LLC, which is controlled by Ms. Wilson. The calculation of the percentage of shares beneficially owned after this offering also includes approximately 2,400 shares into which a note held by Ms. Wilson will be converted upon the completion of this offering and 1,136 shares for which common stock warrants held by Ms. Wilson will become exercisable upon the completion of this offering (each assuming an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of this prospectus).
- (11) Includes 18,626 shares of common stock underlying stock options.
- (12) Includes 17,351 shares of common stock underlying stock options.
- (13) Includes 5,952 shares of common stock underlying stock options. Mr. Dunn resigned from his positions as a Company officer and employee on July 31, 2013. The address of Mr. Dunn is 1829 El Camino del Teatro, La Jolla, California 92037.
- (14) Includes 16,083 shares of common stock underlying stock options.

## DESCRIPTION OF CAPITAL STOCK

### General

Our amended certificate of incorporation, which will be in effect upon the completion of this offering, authorizes us to issue up to 40,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.0001 per share. We effected a 1-for-3 reverse common stock split on November 3, 2011 and we effected a 1-for-14 reverse common stock split on November 1, 2013. All common stock share numbers in this prospectus give effect to these reverse common stock splits.

As of September 30, 2013, there were 181,614 shares of common stock outstanding, held of record by 172 stockholders. The number of shares of common stock outstanding as of September 30, 2013 does not include (i) 350,974 shares of common stock issuable upon the exercise of our outstanding warrants to purchase common stock as of September 30, 2013, (ii) 192,262 common stock equivalents issuable upon the exercise of our outstanding warrants to purchase preferred stock (the warrants overlying all but 1,587 of which will terminate upon the closing of our initial public offering in accordance with their terms), (iii) 344,565 shares of common stock issuable upon the exercise of outstanding options to purchase common stock, (iv) 133,971 shares of common stock issuable upon the settlement of outstanding restricted stock units expressed in common stock, (v) approximately 41,873 shares of common stock which would underlie a “1% true-up” stock option to be granted to David F. Hale upon the completion of this offering, (vi) an estimated 68,546 common stock equivalents issuable upon the settlement of outstanding restricted stock units expressed in preferred stock, (vii) the shares of common stock that will be issued in this offering, (viii) the shares of common stock underlying the underwriters’ over-allotment option, (ix) the shares of common stock that will underlie the representative’s warrant, and (x) other shares of our common stock reserved for future issuance under our 2013 and 2007 Equity Incentive Plans. The above figures assume that we will sell in this offering 1,818,181 shares of common stock (as stated on the cover page of this prospectus) at a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus).

As of September 30, 2013, there were 69,421,047 shares of our Series A preferred stock outstanding. Before the consummation of this offering, all of our outstanding Series A preferred stock will be converted into an aggregate of 1,652,851 shares of our common stock.

The following descriptions of our capital stock and provisions of our amended certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering, and applicable law. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect (i) changes to our capital structure that will occur in connection with this offering and (ii) Delaware law.

### Common Stock

The holders of our common stock are entitled to the following rights:

#### *Voting Rights*

Holders of our common stock are entitled to one vote per share in the election of directors and on all other matters on which stockholders are entitled or permitted to vote. Holders of our common stock are not entitled to cumulative voting rights.

#### *Dividend Rights*

Subject to the terms of any outstanding series of preferred stock, the holders of our common stock are entitled to dividends in the amounts and at times as may be declared by the board of directors out of funds legally available therefor.

### ***Liquidation Rights***

Upon liquidation or dissolution, holders of our common stock are entitled to share ratably in all net assets available for distribution to stockholders after we have paid, or provided for payment of, all of our debts and liabilities, and after payment of any liquidation preferences to holders of our preferred stock.

### ***Other Matters***

Holders of our common stock have no redemption, conversion or preemptive rights. There are no sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to the rights of the holders of shares of any series of preferred stock that we may issue in the future.

### **Preferred Stock**

Our board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders. Although we have no present plans to issue any other shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal. The preferred stock provides for an adjustment of the conversion price in the event of an issuance or deemed issuance at a price less than the applicable conversion price, subject to certain exceptions.

Our currently outstanding Series A preferred stock will all be converted before the effective date of this offering, and all references to the Series A preferred stock will be removed from the amended certificate of incorporation which will be in effect the completion of this offering.

### **Stock Options**

As of September 30, 2013, we had outstanding options to purchase an aggregate of 344,565 shares of our common stock with exercise prices ranging from \$4.62 to \$5.18 per share, with an approximate weighted average exercise price of 5.13 per share. The shares of our common stock underlying all such options will be registered for sale with the SEC as promptly as practicable following the completion of this offering.

### **Warrants**

We have outstanding warrants to purchase shares of our common stock as follows:

- Warrants to purchase 23,809 shares of our common stock at an exercise price to be determined in accordance with the warrant agreement, issued to Goodman Co. Ltd. in connection with the June 28, 2013 conversion of its secured promissory note into shares of our Series A preferred stock. The exercise price will be set at the price per share of our common stock sold in our initial public offering. The warrants will be exercisable for a two-year period beginning on the closing of this offering.
- Warrants exercisable for an indeterminate number of shares of our common stock issued to investors pursuant to our June 2013 note and warrant purchase agreement. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the investor's respective note principal amount, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. At December 31, 2013, the aggregate note principal amount under the June 2013 note and warrant purchase agreement was approximately \$5.0 million. Assuming the aggregate principal amount of the notes does not increase and assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), the investors will have an aggregate of 226,818 common stock warrants, with an exercise price of \$11.00 per share, in connection with our June 2013 note and warrant purchase agreement. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

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- Warrants exercisable for an indeterminate number of shares of our common stock issued to guarantors of our July 2013 revolving line of credit from UBS Bank USA. The number of shares underlying the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to UBS Bank USA, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. Assuming the aggregate fair market value of such collateral was approximately \$1.8 million and assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), the guarantors will have approximately 85,362 common stock warrants, with an exercise price of \$11.00 per share, in connection with this guaranty. The warrants will be exercisable for a two-year period beginning on the closing of this offering.
- Warrants exercisable for an indeterminate number of shares of our common stock issued to our landlord in connection with our September 2013 lease amendment which was effective as of August 1, 2013. The number of shares underlying the common stock warrants will be determined by dividing the warrant coverage amount of \$502,605, which is 100% of the five months of base rent forgone by the landlord pursuant to the lease amendment, by the exercise price, which will be set at the price per share of our common stock sold in our initial public offering. Assuming a public offering price of \$11.00 per share (the midpoint of the price range listed on the cover page of this prospectus), the landlord will have 45,691 common stock warrants, with an exercise price of \$11.00 per share, in connection with this lease amendment. The warrants will be exercisable for a five-year period beginning on the closing of this offering.

In addition, as of September 30, 2013, we have outstanding warrants to purchase an aggregate of 8,076,430 shares of our Series A preferred stock as follows (all but 66,666 of these warrants will terminate upon the closing of this offering):

- Warrants to purchase an aggregate of 233,333 shares of our Series A preferred stock at an exercise price of \$0.60 per share, issued to an investor in connection with our December 2008 note and warrant purchase agreement. These warrants will terminate upon the closing of this offering.
- Warrants to purchase an aggregate of 1,000,000 shares of our Series A preferred stock at an exercise price per share to be determined in accordance with the warrant agreement, issued to Goodman Co. Ltd. in connection with a January 2009 amended and restated loan agreement. These warrants will terminate upon the closing of this offering.
- Warrants to purchase an aggregate of 4,569,030 shares of our Series A preferred stock at an exercise price of \$0.54 per share, issued to investors in connection with our February 2011 note and warrant purchase agreement. These warrants will terminate upon the closing of this offering.
- Warrants to purchase an aggregate of 2,207,401 shares of our Series A preferred stock at an exercise price of \$0.54 per share, issued to investors in connection with our January 2012 note and warrant purchase agreement. These warrants will terminate upon the closing of this offering.
- Warrants to purchase an aggregate of 66,666 shares of our Series A preferred stock at an exercise price of \$0.60 per share, issued to our landlord in connection with our September 2012 lease amendment. These warrants are exercisable through September 2019 and, in connection with the closing of this offering, will become exercisable for 1,587 shares of our common stock at an exercise price of \$25.20 per share.

## **Convertible Promissory Notes**

We executed a note and warrant purchase agreement as of June 2013 with several affiliates to reflect certain prior and possible future borrowings under a series of notes, totaling up to \$7.0 million. We had borrowed \$0.7 million under this arrangement before December 31, 2012 and we borrowed another \$4.3 million under it in 2013. The principal amount of and accrued interest on each note automatically convert into common stock upon the closing of an underwritten initial public offering resulting in at least \$8.0 million of gross proceeds to us, at a conversion price equal to the price per share of our common stock sold in our initial public offering.

In December 2008, we issued a \$1.4 million secured convertible promissory note to an affiliated trust of Claire K. T. Reiss, our major shareholder and at the time a director. In July 2013 the note was amended to provide that the principal amount of and accrued interest on the note automatically convert into common stock upon the closing of an initial public offering, at a conversion price equal to the price per share of our common stock sold in the initial public offering.



## **Representative's Warrants**

We have agreed to issue to the representative of the underwriters in this offering warrants to purchase up to 90,909 shares of our common stock at a per share price of 125% of the public offering price. A complete description of the representative's warrants is included in the "Underwriting – Representative's Warrants" section of this prospectus.

## **Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws**

The provisions of Delaware law, our certificate of incorporation and our bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

### ***Section 203 of the Delaware General Corporation Law***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years before the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

### ***Certificate of Incorporation and Bylaws***

Our certificate of incorporation and/or bylaws provide that:

- our board of directors is classified 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";

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- the authorized number of directors can be changed only by resolution of our board of directors;
- our bylaws may be amended or repealed by our board of directors or our stockholders;
- no action can be taken by stockholders except at an annual or special meeting of the stockholders called in accordance with our bylaws, and stockholders may not act by written consent, unless the stockholders amend the certificate of incorporation to provide otherwise;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board;
- our board of directors will be authorized 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;
- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

### **Potential Effects of Authorized but Unissued Stock**

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

### **Limitations of Director Liability and Indemnification of Directors, Officers and Employees**

Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

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Our bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by law, and may indemnify employees and other agents. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding.

We have obtained a policy of directors' and officers' liability insurance.

We enter into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for any and all expenses (including reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by such directors or officers or on his or her behalf in connection with any action or proceeding arising out of their services as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request provided that such person follows the procedures for determining entitlement to indemnification and advancement of expenses set forth in the indemnification agreement. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

### **Transfer Agent**

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. Its address is 17 Battery Place, 8<sup>th</sup> Floor, New York, New York 10004 and its telephone number is (212) 509-4000.

### **Listing**

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol "BIOC."

### **SHARES ELIGIBLE FOR FUTURE SALE**

Immediately before this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we have applied to have our common stock listed on The NASDAQ Capital Market, we cannot assure you that there will be an active public market for our common stock.

Based on the number of shares of our common stock outstanding as of September 30, 2013 and assuming (1) the issuance of 1,818,181 shares in this offering, (2) the conversion of all outstanding shares of our Series A preferred stock into 1,652,851 shares of our common stock, which will occur in connection with this offering, (3) no exercise of the underwriters' option to purchase additional shares of common stock, and (4) no exercise of outstanding options or warrants, we will have outstanding an aggregate of approximately 4,306,634 shares of common stock.

Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

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The remaining shares of common stock will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, each of which is summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below.

In addition, of the 333,103 shares of our common stock that were subject to outstanding stock options as of December 31, 2013, options to purchase 137,011 of such shares of common stock were vested and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements described below and Rules 144 and 701 under the Securities Act. Also, the 397,993 shares of our common stock that will underlie outstanding warrants as of immediately after the closing of this offering would, upon exercise, be eligible for sale subject to the lock-up agreements described below and Rule 144 under the Securities Act.

### **Lock-Up Agreements**

We and each of our directors and executive officers and significant securityholders have agreed that we and they will not, subject to limited exceptions that are described in more detail in the section in this prospectus entitled “Underwriting,” during the period ending 180 days after the date of this prospectus:

- sell, offer, contract or grant any option to sell (including any short sale), pledge or transfer any shares of our common stock;
- otherwise dispose of any shares of our common stock, options or warrants to acquire shares of our common stock, or securities exchangeable or exercisable for or convertible into shares of our common stock, currently or hereafter owned either of record or beneficially; or
- publicly announce an intention to do any of the foregoing.

Aegis Capital Corp. may, in its sole discretion and at any time or from time to time before the termination of the 180-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares before the expiration of the restricted period.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### **Rule 144**

#### ***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 43,066 shares immediately after this offering; or
- the average weekly trading volume in our common stock on The NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and The NASDAQ Capital Market concurrently with either the placing of a sale order with the broker or the execution of a sale directly with a market maker.

### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity incentive plans and employee stock purchase plan. We expect to file the registration statement covering shares offered pursuant to our stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

### **Registration Rights**

We and two trusts affiliated with our major stockholder Claire K. T. Reiss are parties to an amended and restated investor rights agreement dated October 31, 2011. Under the agreement, the trusts are entitled to piggyback registration rights with respect to the shares of common stock issued or issuable upon conversion of their Series A preferred stock, which currently amounts to 1,346,838 shares of common stock. The piggyback registration rights expire on the third anniversary of the closing of an initial public offering. In addition, our landlord has the right to partake in such piggyback registration rights with respect to the shares of common stock issued or issuable upon conversion of the shares of Series A preferred stock for which its warrant is exercisable, which currently amounts to 1,587 shares of common stock. Registration of these shares under the Securities Act would result in these shares becoming (subject to the expiration of or release from the terms of any applicable lock-up agreement) fully tradable without restriction under the Securities Act immediately upon the effectiveness of the resale registration statement.

## UNDERWRITING

Aegis Capital Corp. is acting as the sole manager of the offering and as representative of the underwriters. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the representative of the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of shares of common stock listed next to its name in the following table.

<u>Underwriters</u>	<u>Number of Shares</u>
Aegis Capital Corp.	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of nondefaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters' over-allotment option described below. The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Discounts and Commissions

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise of the over-allotment option we granted to the representative of the underwriters.

	<u>Per Share</u>	<u>Total Without Over- Allotment Option</u>	<u>Total With Over- Allotment Option</u>
Public offering price	\$	\$	\$
Underwriting discounts and commissions			
Non-accountable expense allowance			
Proceeds, before expenses, to us			

We have agreed to pay a non-accountable expense allowance to the representative of the underwriters equal to 1% of the gross proceeds received in the offering; provided, however, that an allowance shall not be paid in connection with the over-allotment option if the over-allotment option is exercised. We have paid an expense deposit of \$50,000 to the representative of the underwriters, which will be applied against accountable expenses that will be paid by us to the representative in connection with this offering, which advance will be refunded to us to the extent not actually incurred by the representative in the event this offering is terminated.

We have also agreed to pay the representative's expenses relating to the offering, including (a) all actual filing fees incurred in connection with the review of this offering by the Financial Industry Regulatory Authority, or FINRA, and all fees and expenses relating to the listing of our shares of common stock on the NASDAQ Capital Market; (b) all fees, expenses and disbursements relating to background checks of our officers and directors in an amount not to exceed \$2,000 per individual, and not to exceed \$15,000 in the aggregate; (c) all actual fees, expenses and disbursements relating to the

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registration or qualification of securities offered under state securities laws, or “blue sky” laws, or under the securities laws of foreign jurisdictions designated by the representative; (d) all actual fees, expenses and disbursements relating to the registration, qualification or exemption of our shares of common stock under the securities laws of such foreign jurisdictions as the representative may reasonably designate; (e) the costs of all mailing and printing of the underwriting documents as the representative may reasonably deem necessary; (f) the costs associated with bound volumes of the public offering materials as well as commemorative mementos and Lucite tombstones, in an amount not to exceed \$1,000; (g) the fees and expenses of the representative’s legal counsel not to exceed \$50,000, (h) \$21,775 for the underwriters’ use of Ipreo’s book-building, prospectus tracking and compliance software for this offering; and (i) up to \$20,000 of the representative’s actual accountable road show expenses for the offering.

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$ million and are payable by us.

### **Over-Allotment Option**

We have granted to the underwriters an option to purchase up to 272,727 additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 45 days from the date of this prospectus solely to cover sales of shares of common stock by underwriters in excess of the total number of shares set forth in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

### **Representative’s Warrants**

We have agreed to issue to the representative of the underwriters warrants to purchase up to 90,909 shares of common stock, which is 5% of the shares sold in this offering, excluding the over-allotment option, as additional compensation. The shares issuable upon exercise of these warrants are identical to those offered by this prospectus. We are registering hereby the warrants and the shares of common stock issuable upon exercise of the warrants. The warrants are exercisable for cash or on a cashless basis at per share exercise price equal to 125% of the public offering price per share in this offering commencing on a date which is one year from the date of effectiveness and expiring on a date which is no more than five years from the date of effectiveness in compliance with FINRA Rule 5110(f)(2)(H)(i). The warrants and the shares of common stock underlying the warrants have been deemed compensation by FINRA and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The representative (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate these warrants or the securities underlying these warrants, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of these warrants or the underlying securities for a period of 180 days after the effective date. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the date of effectiveness in compliance with FINRA Rule 5110(f)(2)(H)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(H)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants, other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of common stock at a price below the warrant exercise price.

### **Determination of Offering Price**

Before this offering, there has been no public market for our common stock. The initial public offering price will be negotiated between us and the representative. Among the factors to be considered in these negotiations are:

- the prospects for our Company and the industry in which we operate;
- our past and present financial and operating performance;

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- financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;
- the prevailing conditions of U.S. securities markets at the time of this offering; and
- other factors deemed relevant.

### **Lock-Up Agreements**

We, our officers and directors and our significant securityholders have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock or securities convertible into, or exchangeable or exercisable for, common stock, during a period ending 180 days after the date of this prospectus, without first obtaining the written consent of representative of the underwriters.

Specifically, we and these other individuals have agreed not to:

- offer, pledge, sell or contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or other securities, in cash or otherwise;
- make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities convertible into or exchangeable or exercisable for shares of our common stock; or
- publicly announce an intention to do any of the foregoing.

The restrictions described above do not apply to:

- the sale of shares of common stock to the underwriters pursuant to the underwriting agreement;
- the issuance by us of shares of common stock upon the exercise of an option or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing or that is described in this prospectus;
- the grant by us of stock options or other stock-based awards, or the issuance of shares of common stock upon exercise thereof, to eligible participants pursuant to employee benefit or equity incentive plans described in this prospectus, provided that, before the grant of any such stock options or other stock-based awards that vest within the restricted period, each recipient of such grant shall sign and deliver a lock-up agreement agreeing to be subject to the restrictions on transfer described above;
- the establishment of a Rule 10b5-1 trading plan under the Exchange Act by a security holder for the sale of shares of common stock, provided that such plan does not provide for the transfer of common stock during the restricted period;
- transfers by security holders of shares of common stock or other securities as a bona fide gift or by will or intestacy;
- transfers by distribution by security holders of shares of common stock or other securities to partners, members, or shareholders of the security holder; or
- transfers by security holders of shares of common stock or other securities to any trust for the direct or indirect benefit of the security holder or the immediate family of the security holder;

provided that in the case of each of the preceding three types of transactions, the transfer does not involve a disposition for value and each transferee or distributee signs and delivers a lock-up agreement agreeing to be subject to the restrictions on transfer described above.



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The 180-day restricted period is subject to extension if (1) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (2) before the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the restricted period, in which case the restrictions imposed in the lock-up agreements will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

### **Right of First Refusal**

Subject to certain conditions, we granted the representative of the underwriters in this offering, for a period of 12 months after the date of effectiveness, a right of first refusal to act as sole book-running manager for each and every future public and private equity and public debt offering.

### **Indemnification**

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

### **NASDAQ Listing**

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol “BIOC.”

### **Price Stabilization, Short Positions and Penalty Bids**

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising the over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. “Naked” short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market before the completion of the offering.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the representative of the underwriters purchases common stock in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

## **Electronic Offer, Sale and Distribution of Shares**

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters and selling group members that may make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

## **Notice to Non-U.S. Investors**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, each of which we refer to as a relevant member state, with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state, or the relevant implementation date, an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than €43,000,000 and (iii) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of representative for any such offer; or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares of common stock in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the same may be varied in that member state by any measure implementing the Prospectus Directive in that member state and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

## **Other Relationships**

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with any of the underwriters for any further services.

## **Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

### **Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer for the offeree under this prospectus.

### **China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

### **European Economic Area—Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

(a) to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €€ 43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €€ 50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

(c) to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

### **France**

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in France.

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Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

### ***Ireland***

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the “Prospectus Regulations”). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

### ***Israel***

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

### ***Italy***

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, “CONSOB” pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 (“Decree No. 58”), other than:

- qualified investors, as defined in Article 100 of Decree no. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 (“Regulation no. 11971”) as amended (“Qualified Investors”); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

### ***Japan***

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the “FIEL”) pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

### ***Portugal***

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to be distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are “qualified investors” (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

### ***Sweden***

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are “qualified investors” (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

### ***Switzerland***

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

### ***United Arab Emirates***

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

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No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

### ***United Kingdom***

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to “qualified investors” (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA.

This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49 (2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together “relevant persons”). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

## **LEGAL MATTERS**

The validity of the shares offered hereby will be passed upon for us by Stradling Yocca Carlson & Rauth, P.C., San Diego, California. Certain legal matters in connection with this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

## **EXPERTS**

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our balance sheets as of December 31, 2011 and 2012, and the related statements of operations and comprehensive loss, changes in shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2012, as set forth in their report, which report expresses an unqualified opinion and includes an explanatory paragraph relating to our ability to continue as a going concern. We have included our financial statements in this prospectus and in this registration statement in reliance on the report of Mayer Hoffman McCann P.C. given on their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We will be subject to reporting requirements pursuant to the Exchange Act and we will file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov).

You may read and copy this information at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, on official business days during the hours of 10:00 a.m. to 3:00 p.m., at prescribed rates. You may obtain information regarding the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Our website address is [www.biocept.com](http://www.biocept.com). The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

## GLOSSARY OF SCIENTIFIC AND HEALTHCARE-RELATED ACRONYMS

<b>ACA</b>	Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act
<b>ALK</b>	Anaplastic lymphoma kinase
<b>CAP</b>	College of American Pathologists; the leading organization of board-certified pathologists, serving patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide
<b>CE</b>	Conformité Européenne; a conformity mark which is placed on all products including medical devices marketed in the European Economic Area
<b>CLIA</b>	Clinical Laboratory Improvement Amendments of 1988; federal regulatory standards that apply to all clinical laboratory testing performed on human samples in the United States
<b>CMS</b>	Centers for Medicare & Medicaid Services; a U.S. federal agency that administers Medicare, Medicaid and the Children’s Health Insurance Program
<b>CPT</b>	Current Procedure Terminology
<b>CTC</b>	Circulating tumor cell
<b>ctDNA</b>	Circulating tumor DNA
<b>DTC</b>	Disseminated tumor cell
<b>EGFR</b>	Epidermal growth factor receptor
<b>EML4</b>	Echinoderm microtubule-associated protein-like 4
<b>EMT</b>	Epithelial-to-mesenchymal transition
<b>EpCAM</b>	Epithelial cell adhesion molecule
<b>FDA</b>	United States Food and Drug Administration
<b>FISH</b>	Fluorescence in situ Hybridization; a molecular cytogenetic technique that is used to detect chromosomal aberrations that include deletions, amplifications and translocations; DNA FISH probes are fluorescently labeled segments of DNA that are complementary to specific sequences on a chromosome
<b>HER2</b>	Human epidermal growth factor receptor 2
<b>HHS</b>	United States Department of Health and Human Services
<b>HIPAA</b>	Health Insurance Portability and Accountability Act of 1996
<b>HITECH</b>	Health Information Technology for Economic and Clinical Health Act
<b>IHC</b>	Immunohistochemistry



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<b>IVD</b>	In vitro diagnostic
<b>LDTs</b>	Laboratory Developed Tests; assays developed in the laboratory for diagnostic or prognostic purposes
<b>MAC</b>	Medicare Administrative Contractor
<b>MCTRJCA</b>	Middle Class Tax Relief and Job Creation Act of 2012
<b>NSCLC</b>	Non-small cell lung cancer
<b>PCR</b>	Polymerase chain reaction
<b>ROS1</b>	c-ros oncogene 1, receptor tyrosine kinase

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**BIOCEPT, INC.**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of **Biocept, Inc.** as of December 31, 2012 and 2011, and the related statements of operations and comprehensive loss, shareholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of **Biocept, Inc.** as of December 31, 2012 and 2011, 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, as of December 31, 2012, has liabilities significantly in excess of assets. These conditions, among others as discussed in Note 2 to the financial statements, 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  
August 16, 2013, except as to Note 17, as to  
which the date is January 8, 2014

**Biocept, Inc.**

**Balance Sheets**

	<u>December 31,</u> <u>2011</u>	<u>December 31,</u> <u>2012</u>	<u>September 30,</u> <u>2013</u> <u>(unaudited)</u>	<u>Pro Forma</u> <u>September 30,</u> <u>2013</u> <u>(unaudited)</u>
Current assets:				
Cash & cash equivalents	\$ 435,292	\$ 185,256	\$ 302,908	\$ 302,908
Accounts receivable	5,251	18,885	60,484	60,484
Inventories	—	61,283	90,129	90,129
Prepaid expenses	<u>367,610</u>	<u>310,442</u>	<u>206,767</u>	<u>206,767</u>
Total current assets	808,153	575,866	660,288	660,288
Fixed assets, net	982,253	624,730	422,801	422,801
Other non-current assets	<u>269,083</u>	<u>269,083</u>	<u>—</u>	<u>—</u>
Total assets	<u>\$ 2,059,489</u>	<u>\$ 1,469,679</u>	<u>\$ 1,083,089</u>	<u>\$ 1,083,089</u>
Current liabilities:				
Accounts payable	\$ 1,033,124	\$ 1,387,677	\$ 1,266,896	\$ 1,266,896
Line of credit	—	—	1,490,996	1,490,996
Notes payable	12,039,694	21,631,427	4,329,618	—
Warrant liability	923,325	981,747	2,039,577	—
Supplier financings - current	314,445	251,146	60,343	60,343
Accrued liabilities	<u>1,201,279</u>	<u>3,346,806</u>	<u>2,001,208</u>	<u>1,609,593</u>
Total current liabilities	15,511,867	27,598,803	11,188,638	4,427,828
Notes payable, net of current portion	1,575,000	745,000	—	—
Supplier financings, net of current portion	81,191	—	—	—
Deferred rent	<u>268,934</u>	<u>510,771</u>	<u>167,291</u>	<u>167,291</u>
Total liabilities	17,436,992	28,854,574	11,355,929	4,595,119
Commitments and contingencies (see note 16)				
Shareholders' deficit:				
Series A convertible preferred stock, \$0.0001 par value, 36,460,000 authorized; 27,175,213 issued and outstanding at December 31, 2011 and 2012; 100,000,000 authorized and 69,421,047 issued and outstanding at September 30, 2013; liquidation preference of \$16,305,127 at December 31, 2011 and 2012 and \$41,652,628 at September 30, 2013 (see note 9); 5,000,000 shares authorized, no shares issued and outstanding on a pro forma basis at September 30, 2013 (see <i>Unaudited Pro Forma Information</i> paragraphs in note 3).	2,718	2,718	6,943	—
Common stock, \$0.0001 par value, 14,600,000 authorized; 160,393 issued and outstanding at December 31, 2011 and 2012. 53,000,000 authorized; 181,614 issued and outstanding at September 30, 2013 (see note 9); 40,000,000 authorized, 2,458,154 issued and outstanding on a pro forma basis at September 30, 2013 (see <i>Unaudited Pro Forma Information</i> paragraphs in note 3).	16	16	18	246
Additional paid-in capital	85,548,030	85,800,164	109,669,166	116,436,691
Accumulated deficit	<u>(100,928,267)</u>	<u>(113,187,793)</u>	<u>(119,948,967)</u>	<u>(119,948,967)</u>
Total shareholders' deficit	<u>(15,377,503)</u>	<u>(27,384,895)</u>	<u>(10,272,840)</u>	<u>(3,512,030)</u>
Total liabilities and shareholders' deficit	<u>\$ 2,059,489</u>	<u>\$ 1,469,679</u>	<u>\$ 1,083,089</u>	<u>\$ 1,083,089</u>

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

**Biocept, Inc.**

**Statements of Operations and Comprehensive Loss**

	<b>For the year ended December 31,</b>		<b>For the nine months ended September 30,</b>	
	<b>2011</b>	<b>2012</b>	<b>2012</b>	<b>2013</b>
	<b>(unaudited)</b>		<b>(unaudited)</b>	<b>(unaudited)</b>
Revenues	\$ 1,052	\$ 109,289	\$ 88,342	\$ 115,445
Cost of revenues	17,322	1,201,694	756,524	1,759,568
Gross profit/(loss)	(16,270)	(1,092,405)	(668,182)	(1,644,123)
Operating expenses				
Research and development expenses	8,853,350	6,562,152	5,304,444	2,375,892
General and administrative expenses	2,728,442	2,063,199	1,612,720	1,736,192
Sales and marketing expenses	672,934	785,319	603,546	129,678
Loss from operations	(12,270,996)	(10,503,075)	(8,188,892)	(5,885,885)
Other income/(expense)				
Interest expense, net	(1,699,607)	(2,187,499)	(1,528,707)	(1,435,087)
Change in fair value of warrant liability	361,186	454,389	421,808	593,365
Other income/(expense)	(19,069)	(22,541)	(15,810)	(32,767)
Total other income/(expense)	(1,357,490)	(1,755,651)	(1,122,709)	(874,489)
Loss before income taxes	(13,628,486)	(12,258,726)	(9,311,601)	(6,760,374)
Income tax expense	800	800	800	800
Net loss & comprehensive loss	<u><u>\$(13,629,286)</u></u>	<u><u>\$(12,259,526)</u></u>	<u><u>\$(9,312,401)</u></u>	<u><u>\$(6,761,174)</u></u>
Weighted average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Diluted	<u>113,754</u>	<u>160,393</u>	<u>160,393</u>	<u>180,954</u>
Net loss per common share:				
Basic	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>
Diluted	<u>\$ (119.81)</u>	<u>\$ (76.43)</u>	<u>\$ (58.06)</u>	<u>\$ (37.36)</u>
Weighted average shares outstanding used in computing pro forma net loss per share attributable to common shareholders (unaudited):				
Basic		<u>2,436,933</u>		<u>2,457,494</u>
Diluted		<u>2,436,933</u>		<u>2,457,494</u>
Pro forma net loss per share attributable to common shareholders:				
Basic		<u>\$ (5.03)</u>		<u>\$ (2.75)</u>
Diluted		<u>\$ (5.03)</u>		<u>\$ (2.75)</u>

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

**Biocept, Inc.**

**Statements of Shareholders' Deficit**

	Preferred Stock						Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Series A		Series AA		Series BB						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2010	—	\$ —	20,442,883	\$ 2,044	8,939,990	\$ 894	104,903	\$ 10	\$ 85,365,560	\$ (87,298,981)	\$ (1,930,473)
Shares surrendered as part of investor settlement	—	—	(143,140)	(14)	—	—	(1,193)	—	14	—	—
Conversion from Series AA preferred stock to common stock	—	—	(2,064,520)	(206)	—	—	49,155	5	201	—	—
Conversion from Series AA and Series BB preferred stock to Series A preferred stock	27,175,213	2,718	(18,235,223)	(1,824)	(8,939,990)	(894)	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	10,212	1	47,182	—	47,183
Retirement of common stock	—	—	—	—	—	—	(2,684)	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	135,073	—	135,073
Net loss	—	—	—	—	—	—	—	—	—	(13,629,286)	(13,629,286)
Balance at December 31, 2011	27,175,213	2,718	—	—	—	—	160,393	16	85,548,030	(100,928,267)	(15,377,503)
Stock-based compensation expense	—	—	—	—	—	—	—	—	252,134	—	252,134
Net loss	—	—	—	—	—	—	—	—	—	(12,259,526)	(12,259,526)
Balance at December 31, 2012	27,175,213	2,718	—	—	—	—	160,393	16	85,800,164	(113,187,793)	(27,384,895)
Stock-based compensation expense (unaudited)	—	—	—	—	—	—	—	—	683,396	—	683,396
Stock issuance for RSU (unaudited)	—	—	—	—	—	—	21,846	2	(2)	—	—
Exercise of stock options (unaudited)	—	—	—	—	—	—	85	—	395	—	395
Repurchase of common shares (unaudited)	—	—	—	—	—	—	(710)	—	(4,111)	—	(4,111)
Shares issued for conversion of notes payable and accrued interest of \$20.2 million and \$2.6 million, respectively (unaudited)	42,245,834	4,225	—	—	—	—	—	—	22,808,179	—	22,812,404
Reclassification of warrant liability derivative due to triggering event (unaudited)	—	—	—	—	—	—	—	—	381,145	—	381,145
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	(6,761,174)	(6,761,174)
Balance at September 30, 2013 (unaudited)	69,421,047	\$ 6,943	—	\$ —	—	\$ —	181,614	\$ 18	\$109,669,166	\$ (119,948,967)	\$ (10,272,840)

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

**Biocept, Inc.**

**Statements of Cash Flows**

	<u>For the year ended December 31,</u>		<u>For the nine months ended September 30,</u>	
	<u>2011</u>	<u>2012</u>	<u>2012</u>	<u>2013</u>
			<u>(unaudited)</u>	<u>(unaudited)</u>
<b>Cash Flows From Operating Activities</b>				
Net loss	\$(13,629,286)	\$(12,259,526)	\$ (9,312,401)	\$ (6,761,174)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	369,312	365,568	293,159	202,641
Inventory reserve	44,854	56,004	20,133	68,496
Stock-based compensation	135,073	252,134	212,667	683,396
Non-cash interest expense related to convertible debt and other financing activities	1,617,074	2,159,234	1,490,921	1,302,136
Change in fair value of warrant liabilities	(361,186)	(454,389)	(421,808)	(593,365)
Loss on sale of fixed assets	1,899	—	—	—
Increase/(decrease) in cash resulting from changes in:				
Accounts receivable	(5,251)	(13,634)	(8,960)	(41,599)
Inventory	(44,854)	(117,287)	(129,147)	(97,342)
Prepaid expenses	(146,584)	77,654	175,929	(25,255)
Other assets	5,000	—	—	269,083
Accounts payable	854,748	354,553	262,503	(120,781)
Accrued liabilities	195,408	730,836	365,388	271,470
Deferred rent	(20,580)	241,837	332,306	(34,749)
Net cash used in operating activities	(10,984,373)	(8,607,016)	(6,719,310)	(4,877,043)
<b>Cash Flows From Investing Activities</b>				
Purchases of fixed assets	(295,373)	(8,046)	(8,046)	(711)
Net cash used in investing activities	(295,373)	(8,046)	(8,046)	(711)
<b>Cash Flows From Financing Activities</b>				
Principal payments on capital lease obligations	(37,813)	—	—	—
Proceeds from exercise of stock options	47,182	—	—	395
Payments for repurchase of shares	—	—	—	(4,111)
Payments on supplier and other third party financings	(135,704)	(164,974)	(184,454)	(61,874)
Proceeds from borrowings on line of credit				1,490,996
Proceeds from issuance of notes payable	—	5,960,000	4,775,000	—
Principal payments on note payable	(180,000)	—	—	—
Proceeds from issuance of convertible notes and warrants	10,511,427	2,570,000	1,775,000	3,570,000
Net cash provided by financing activities	10,205,092	8,365,026	6,364,546	4,995,406
Net increase/(decrease) in Cash and Cash Equivalents	(1,074,654)	(250,036)	(362,810)	117,652
Cash and Cash Equivalents at Beginning of Period	1,509,946	435,292	435,292	185,256
Cash and Cash Equivalents at End of Period	\$ 435,292	\$ 185,256	\$ 72,482	\$ 302,908
<b>Supplemental Disclosures of Cash Flow Information:</b>				
Cash paid during the period for:				
Interest	\$ 84,866	\$ 28,276	\$ 28,276	\$ —
Taxes	\$ 800	\$ 800	\$ 800	\$ 800

**Biocept, Inc.**

**Statements of Cash Flows**

**Non-cash Investing and Financing Activities:**

During 2011, the Company financed additions to fixed assets of \$399,812 through supplier financings.

For the years ended December 31, 2011 and 2012, the Company financed insurance premiums of \$131,528 and \$128,929, respectively, through third party financings. Such financings occur on an annual basis during the three months ended December 31 of each year.

During the nine months ended September 30, 2013, 21,846 shares of common stock, with a par value of \$.0001, were issued for restricted stock units. (unaudited)

During the nine months ended September 30, 2013, convertible notes with a principal balance of \$20,231,000 and accrued interest of \$2,581,000 were converted into 42,245,834 shares of preferred stock. In conjunction with this conversion, \$236,799 of derivative warrant liabilities were reclassified to additional paid-in capital, as the underlying exercise prices on the warrants were determined by the debt conversion. In addition, during the three months ended September 30, 2013, an additional \$144,346 of derivative warrant liabilities were reclassified to additional paid-in capital when their underlying exercise price was fixed. (unaudited)

During the nine months ended September 30, 2013, the Company issued to its landlord a warrant to purchase common shares with a warrant coverage amount of \$502,605 and an exercise price equal to the price per share of the Company's common stock sold in the Company's IPO. The fair value of the warrant as calculated under the Company's probability weighted Black-Scholes valuation model (See Note 7) was approximately \$309,000 at September 30, 2013 which is recorded on the balance sheet as a component of deferred rent and warrant liability.

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



**BIOCEPT, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. The Company and Business Activities**

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

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

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

**2. Going Concern**

At December 31, 2011 and 2012 and September 30, 2013, the Company had an accumulated deficit of approximately \$100,928,000, \$113,188,000, and \$119,949,000, respectively. For the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2013, the Company incurred net losses of approximately \$13,629,000, \$12,260,000, and \$6,761,174, respectively. In addition, as of September 30, 2013, the Company had notes payable and amounts outstanding under a line of credit due within one year totaling approximately \$5,820,614. These factors raise substantial doubt about the Company's ability to continue as a going concern.

In order to continue operations, the Company will need additional operating funds. The Company borrowed a total of \$10,511,000, \$8,530,000, and \$5,061,000 during the years ended December 31, 2011 and 2012 and during the nine months ended September 30, 2013, respectively, under note agreements with certain shareholders and a line of credit. However, additional funding will be required to sustain operations into 2014.

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.

*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. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its equity securities, (2) laboratory service revenue, and (3) short-term borrowings from banks, shareholders or other related party(ies) when needed. Management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

**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.

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### *Use of Estimates*

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

### *Unaudited Interim Financial Information*

The accompanying balance sheet as of September 30, 2013, statements of operations and comprehensive loss and cash flows for the nine months ended September 30, 2012 and 2013, and the statement of shareholders' deficit for the nine months ended September 30, 2013 are unaudited. The unaudited financial statements have been prepared on a basis consistent with the audited financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) considered necessary to fairly state the Company's financial position as of September 30, 2013 and results of operations and cash flows for the nine months ended September 30, 2012 and 2013. The financial data and other information disclosed in the notes to the financial statements related to September 30, 2013 and the nine months ended September 30, 2012 and 2013 are unaudited.

### *Unaudited Pro Forma Information*

The unaudited pro forma balance sheet information as of September 30, 2013 gives effect to (i) the automatic conversion of all outstanding shares of the Company's Series A preferred stock into 1,652,851 shares of common stock, (ii) the conversion of convertible promissory notes and accrued interest in the amount of \$6,106,615 (as of September 30, 2013) into an aggregate of 555,143 shares of the Company's common stock in connection with the closing of the Company's initial public offering, (iii) the issuance of an estimated 68,546 shares of common stock upon such initial public offering pursuant to the settlement of certain restricted stock units (which are currently expressed in shares of preferred stock) in accordance with their terms, (iv) the termination of certain warrants upon the closing of the Company's initial public offering in accordance with their terms and (v) the reclassification to shareholders' deficit of the fair value of certain warrants the exercise price and/or exercisability period length of which will be fixed upon the closing of the Company's initial public offering in accordance with their terms, assuming for all such items an initial public offering price of \$11.00 per share, the midpoint of the price range listed on the cover page of the Company's prospectus.

The unaudited pro forma balance sheet information as of September 30, 2013 assumes that the completion of the Company's initial public offering had occurred as of September 30, 2013 and excludes shares of common stock issued in the initial public offering and any related net proceeds. In October 2013 the Board of Directors approved an amendment of the Company's certificate of incorporation, to be filed in connection with the Company's initial public offering, which would decrease the number of common shares authorized to 40,000,000 and decrease the number of preferred shares authorized to 5,000,000.

The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of the Company's initial public offering determined at pricing.

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

In November 2011, the Company effected a one-for-three reverse stock split of the Company's common shares. In addition, in July 2013, in conjunction with its reincorporation in the state of Delaware, the Company initiated par values for preferred and common shares equal to \$0.0001. As such, all references to share and per share amounts in the financial statements and accompanying notes to the financial statements have been retroactively restated to reflect the 1:3 reverse stock split and the change in par value. See Note 17.

### *Revenue Recognition*

Revenue is recognized in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 605, *Revenue Recognition*, and ASC 954-605 *Health Care Entities, Revenue Recognition* which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. For contract partners, revenue is recorded based upon the contractually

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agreed upon fee schedule. When assessing collectability, the Company considers whether there is sufficient payment history to reliably estimate a payor's individual payment patterns. For new tests where there is limited evidence of payment history at the time the tests are completed, the Company recognizes revenue equal to the amount of cash received until such time as reimbursement experience can be established.

The Company's main source of revenue for the year ended December 31, 2012 and the nine months ended September 30, 2013 is through contracted partners. This revenue is derived from clinical laboratory testing performed in our laboratories under our agreements with such partners. As there is a contractually agreed upon price, and collectability from our partners is reasonably assured, revenues for these tests are earned at the time the test is completed and the results are delivered to our partners or a third party.

### *Cash and Cash Equivalents*

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

### *Fair Value Measurement*

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

As of December 31, 2011 and 2012 and September 30, 2013, the Company classified the fair value measurements of the Company's warrant liability derivative as Level 3. See Note 7 for further details about the inputs and assumptions used to determine the fair value of the warrant liability at each balance sheet date.

The values attributed to such warrants as of December 31, 2011 and 2012, and September 30, 2013 were as follows:

	Fair Value Measurements Using		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Liabilities</b>			
Warrant Liability at December 31, 2011	—	—	\$ 923,325
Warrant Liability at December 31, 2012	—	—	\$ 981,747
Warrant Liability at September 30, 2013 (unaudited)	—	—	\$ 2,039,577

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The following table includes a summary of changes in the fair value of the warrants for the years ended December 31, 2011 and 2012, and for the nine months ended September 30, 2013:

	Fair Value Measurements at Reporting Date Using Significant Unobservable Inputs (Level 3)
Balance at December 31, 2010	\$ —
Warrant liability incurred in 2011	1,284,511
Change in fair value in 2011	(361,186)
Balance at December 31, 2011	923,325
Warrant liability incurred in 2012	512,811
Change in fair value in 2012	(454,389)
Balance at December 31, 2012	981,747
Warrant liability incurred during the nine months ended September 30, 2013 (unaudited)	2,032,340
Warrant liability reclassified to additional paid-in capital during the nine months ended September 30, 2013 (unaudited)	(381,145)
Change in fair value during the nine months ended September 30, 2013 (unaudited)	(593,365)
Balance at September 30, 2013 (unaudited)	\$ 2,039,577

### *Concentration of Risk*

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

In 2012, the Company launched commercial operations in partnership with a commercial partner, Clariant Diagnostic Services, Inc. ("Clariant"), a GE Healthcare Company. For the year ended December 31, 2012, 79% of the revenue earned was billed through this relationship. In addition, at December 31, 2012, 100% of the receivables were due from Clariant. As of September 30, 2013, three customers made up 81%, 12% and 7% of accounts receivable. For the nine months ended September 30, 2013, three customers made up 74%, 13% and 12% of total revenues.

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

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

### *Accounts Receivable*

Accounts receivable are carried at original invoice amounts, less an estimate for doubtful receivables, based on a review of all outstanding amounts on a periodic basis. The estimate for doubtful receivables is determined from an analysis of the accounts receivable on a quarterly basis, and is recorded as bad debt expense. As the Company only recognizes revenue to the extent collection is expected and reasonably assured, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the statement of operations and comprehensive loss. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received. As of December 31, 2011 and 2012 and September 30, 2013, 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 a loss recognition, a new cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

#### *Fixed Assets*

Fixed assets consist of machinery and equipment, furniture and fixtures, computer equipment and software, leasehold improvements, capital leased equipment and construction in process. Fixed assets are stated at cost less accumulated depreciation and amortization. Additions, improvements, and major renewals are capitalized. Maintenance, repairs, and minor renewals are expensed as incurred. Depreciation is determined using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over the life of the lease or the asset, whichever is shorter. Depreciation expense for the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2012 (unaudited) and 2013 (unaudited) was approximately \$369,000, \$366,000, \$293,159 and \$202,641, respectively.

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

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

#### *Warrant Liability*

Warrants for shares that are contingently redeemable and for which the exercise price is not fixed are classified as liabilities on the accompanying balance sheets and carried at their estimated fair value, determined through use of a Black-Scholes valuation model. As of and for the years ended December 31, 2011 and 2012, and as of and for the nine months ended September 30, 2012 and September 30, 2013, the Company evaluated and concluded that the fair value obtained from the Black-Scholes method of valuing the warrant liability does not materially differ from the valuation of such warrants using the Monte Carlo or binomial lattice simulation models, and therefore the use of the Black-Scholes valuation model was considered a reasonable method to value the warrants. At the end of each reporting period, any changes in fair value are recorded as a component of other income (expense). The Company will continue to adjust the carrying value of the warrants until the earlier of the exercise of the warrants or the completion of a liquidation event, including the completion of an initial public offering under the Securities Act ("IPO"), at which time the exercise price will be fixed for the surviving warrants, and the fair value of those warrants will be reclassified to shareholders' deficit.

#### *Stock-based Compensation*

The Company accounts for stock-based compensation under the provisions of FASB ASC Topic 718, *Compensation—Stock Compensation*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes option pricing model ("Black-Scholes valuation model"). The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. The Company estimates forfeitures at the time of grant and revises these estimates in subsequent periods if actual forfeitures differ from those estimates. See additional information in Note 10.

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

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

### *Research and Development*

Research and development costs are expensed as incurred. The amounts expensed in the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2012 (unaudited) and 2013 (unaudited) were approximately \$8,853,000, \$6,562,000, \$5,304,444, and \$2,375,892, 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, 2011 and 2012 and September 30, 2013, and therefore has not recognized any income tax benefit or expense in the periods presented.

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

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties for income taxes on the balance sheets at December 31, 2011 and 2012 and September 30, 2013 (unaudited), and the Company has not recognized interest and/or penalties in the statements of operations for the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2012 (unaudited) and 2013 (unaudited).

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### *Recent Accounting Pronouncements*

In May 2011, the FASB amended its authoritative guidance on the measurement and disclosure for fair value measurements. The amendment clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The guidance is effective prospectively for fiscal years and interim periods within those years, beginning after December 15, 2011 and was effective for the Company's fiscal year beginning January 1, 2012. The Company adopted this amendment on January 1, 2012. The adoption of this new standard did not have a material impact on the Company's financial statements.

In September 2011, the FASB amended its authoritative guidance on the presentation of comprehensive income. Under the amendment, companies have the option to present the components of net income and other comprehensive income either in a single continuous statement of comprehensive income or in separate but consecutive statements. This amendment eliminates the option to present the components of other comprehensive income as part of the statement of changes in shareholders' equity. The amendment does not change the items that companies must report in other comprehensive income or when companies must reclassify an item of other comprehensive income to net income. In December 2011, the FASB issued an update that defers the presentation requirement for other comprehensive income reclassifications on the face of the financial statements. The guidance is effective retrospectively for fiscal years, and interim periods within those years beginning after December 15, 2011, and was effective for the Company's fiscal year beginning January 1, 2012. The Company adopted this amendment on January 1, 2012. As this guidance relates to presentation only, the adoption of this guidance did not have any other effect on the Company's financial statements.

### **4. Balance Sheet Details**

The following provides certain balance sheet details:

	<b>December 31,</b>		<b>September 30,</b>
	<b>2011</b>	<b>2012</b>	<b>2013</b>
			(unaudited)
<b>Fixed Assets</b>			
Machinery and equipment	\$2,753,379	\$2,761,560	\$2,761,560
Furniture and office equipment	209,844	209,844	209,844
Computer equipment and software	681,508	681,508	681,508
Leasehold improvements	373,653	373,653	373,653
Capital lease equipment	677,000	677,000	677,000
Construction in process	11,724	11,588	12,300
	4,707,108	4,715,153	4,715,865
Accumulated depreciation and amortization	3,724,855	4,090,423	4,293,064
Total fixed assets, net	<u>\$ 982,253</u>	<u>\$ 624,730</u>	<u>\$ 422,801</u>
<b>Accrued Liabilities</b>			
Accrued interest	\$ 577,233	\$1,963,007	\$ 389,926
Accrued payroll	252,363	185,150	66,676
Deferred wages	67,656	972,405	1,316,780
Accrued vacation	292,834	224,187	218,558
Other	11,193	2,057	9,268
Total accrued liabilities	<u>\$1,201,279</u>	<u>\$3,346,806</u>	<u>\$ 2,001,208</u>

As of December 31, 2011 and 2012, other non-current assets of \$269,000 consisted solely of deposits for the San Diego building, which is leased under a non-cancelable operating lease. During the nine months ended September 30, 2013, the Company amended its lease agreement and forfeited the balance. See Note 17.

## 5. Line of Credit

In July 2013, the Company entered into a revolving line of credit with UBS Bank USA in the initial amount of \$1.5 million. Interest accrues daily on the outstanding balance and is paid monthly at a variable rate which, as of September 30, 2013, was 2.75% over the 30 day LIBOR rate or an effective annual interest rate of 2.93%. As of September 30, 2013, the amount outstanding under this revolving line of credit is \$1.5 million. Three of the Company's related parties guaranteed the loan and pledged financial assets to the bank to secure their guaranties, as approved by the Company's board of directors. In return, the Company issued common stock warrants to the guarantors. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to the bank, by the exercise price, which will be set at the price per share of the Company's common stock sold in its IPO. See Note 7 for further discussion of the warrant liabilities. The Company has entered into an agreement with the guarantors that provides for reimbursement of any amounts paid by them on their guaranties. This reimbursement obligation is secured by a security interest in the Company's assets.

## 6. Notes Payable

Below is a summary of the Company's short-term and long-term debt obligations as of December 31, 2011 and 2012 and September 30, 2013:

	December 31,		September 30,
	2011	2012	2013 (unaudited)
Note payable to shareholder; principal and interest payable in quarterly installments until maturity on April 2015, bearing interest at a per annum fixed rate of 3.25%. As of June 28, 2013, the note payable was converted into preferred shares. ("Goodman Note") (See Note 7)	\$ 1,935,000	\$ 1,935,000	\$ —
Secured convertible note to a major shareholder, net of discount related to a beneficial conversion of \$45,398 and \$0 and \$0 at December 31, 2011 and 2012 and September 30, 2013, respectively. ("2008 Convertible Note") (See Note 7)	1,354,602	1,400,000	1,400,000
Secured convertible notes, net of discounts related to warrants aggregating to \$186,335 and \$0 and \$0 at December 31, 2011 and 2012 and September 30, 2013, respectively. Total includes convertible notes due to a major shareholder of \$10,000,000 and \$11,250,000 at December 31, 2011 and 2012, respectively. As of June 28, 2013, the notes payable were converted into preferred shares. ("2011 Convertible Bridge Notes") (See Note 7)	10,325,092	12,336,427	—
Notes payable to shareholders issued in 2012, net of discounts related to warrants aggregating to \$0 and \$0 at December 31, 2012 and September 30, 2013, respectively. Includes notes of \$5,810,000 to a major shareholder at December 31, 2012. As of June 28, 2013, the notes payable were converted into preferred shares. ("2012 Revolver Notes") (See Note 7)	—	5,960,000	—



	December 31,		September 30,
	2011	2012	2013
			(unaudited)
Unsecured convertible notes, issued under a note and warrant purchase agreement dated as of June 28, 2013, net of discounts related to warrants aggregating \$0 and \$1,013,863 at December 31, 2012 and September 30, 2013, respectively. Includes notes of \$720,000 and \$2,505,000 to a major shareholder at December 31, 2012 and September 30, 2013, respectively. ("2013 Convertible Bridge Notes") (See Note 7)	—	745,000	3,301,137
Other debt discount (See Notes 5 and 7)	—	—	(371,519)
Total notes payable	13,614,694	22,376,427	4,329,618
Less current portion	12,039,694	21,631,427	4,329,618
Long-term portion	<u>\$ 1,575,000</u>	<u>\$ 745,000</u>	<u>\$ —</u>

Except for the non-current balance of the 2013 Convertible Bridge Notes, all outstanding notes payable and convertible notes payable were classified as current as of December 31, 2012, as the Company was unable to make principal and interest payments on these notes during the year ended December 31, 2012, or prior to the conversion of certain of the notes as of June 28, 2013. None of the lenders had sought any remedy for this default as of December 31, 2012 or prior to the conversion of the notes as of June 28, 2013.

On June 28, 2013, approximately \$20,231,000 of outstanding notes payable and \$2,581,000 of accrued interest were converted into 42,245,834 preferred shares, in accordance with the provisions of the debt conversion agreements of that date. As of September 30, 2013, all remaining principal payments for outstanding notes payable and convertible notes are due within one year.

Total interest expense incurred for all notes, convertible notes, and the line of credit, including amortization of debt discounts, for the year ended December 31, 2011 and 2012 and the nine months ended September 30, 2013 (unaudited) was approximately \$1,683,000, \$2,125,000 and \$1,435,087, respectively, of which approximately \$577,000, \$1,957,000 and \$390,000 was recorded as accrued interest as of December 31, 2011 and 2012 and September 30, 2013 (unaudited), respectively.

## 7. Convertible Notes and Warrants

### Outstanding Warrants – Preferred Shares

#### *Goodman Note*

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

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

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

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

During May 2010, the Company entered into a second amendment and restatement of the Goodman Note in order to extend the maturity date and amend the timing of payments to be made to the lender and to secure the Company's obligations under the note. The secured amended and restated note bears interest at a per annum fixed rate of 3.25% and is due and payable quarterly in arrears on the last business day of each three-month quarter beginning May 1, 2010. On the effective date of the second amendment, the Company paid the lender \$750,000 which was applied to the principal balance of \$3,000,000. Beginning May 1, 2010, principal payments are due and payable quarterly in advance. For principal payments due and payable during the period of May 1, 2010 through January 31, 2011, the quarterly principal payment was equal to \$45,000; for principal payments due and payable during the period of February 1, 2012 through January 31, 2014, the quarterly principal payment is equal to \$90,000; and for principal payments due and payable during the period of February 1, 2014 through the maturity date, the quarterly principal payment is equal to \$150,000. In addition to the \$750,000 principal paid on the effective date of the amendment, the Company paid principal payments of \$135,000 and \$180,000 during the years ended December 31, 2010 and 2011, respectively. No principal payments were made during the year ended December 31, 2012 or the nine months ended September 30, 2013. As of June 28, 2013 the holder of the Goodman Note agreed to convert the total principal balance owed under the Goodman Note of \$1,935,000 and accrued interest of approximately \$105,000 into 3,777,324 preferred shares at a conversion price of \$0.54 per share. Although the conversion price of the debt was greater than the value of the preferred shares at the time of conversion, the Company did not record a gain on the conversion under the troubled debt restructuring accounting guidance since the transaction occurred between related parties, and thus, was treated as a capital transaction.

### *2008 Convertible Note*

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

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

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

A qualifying equity financing occurred during February 2009, which set the 2008 Convertible Note conversion price and the warrant exercise price at \$0.60 per share. The 2008 Convertible Note remains outstanding at December 31, 2011 and 2012, and September 30, 2013.

### *2011 Convertible Bridge Notes*

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

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

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

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants are initially recorded at their fair value and are then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments issued under the note and warrant purchase agreement dated February 2011, the Company used the Black-Scholes valuation model. The Company recorded approximately \$1,400,000 related to the fair value of the warrants at the date of issuance, as a discount to the carrying value of the 2011 Convertible Bridge Notes, accreted as interest expense over the life of the debt. The Company valued the warrants at the date of each issuance using the Black-Scholes valuation model with the following underlying assumptions: contractual term of 5 years, an underlying preferred share price between \$0.25 and \$0.54, an exercise price of \$0.54, an average risk-free interest rate between 0.70% and 2.26%, a dividend yield of 0%, and volatilities between 100.0% and 105.0%. Approximately \$1,098,000 and \$302,000 related to accretion of the discount was recognized as interest expense during the years ended December 31, 2011 and 2012, respectively. The discount was fully accreted as of December 31, 2012.

As of December 31, 2011 and 2012, the Company had issued the 2011 Convertible Bridge Notes with an aggregate principal amount of approximately \$10,511,000 and \$12,336,000, respectively. No further note or warrant issuances were made under this agreement during the nine months ended September 30, 2013. As of December 31, 2012, the Company was in default for payment on the 2011 Convertible Bridge Notes, and no principal payments were made in 2013 prior to their conversion. As of June 28, 2013 the investors under these notes elected to convert the total principal balance owed under the 2011 Convertible Bridge Notes of approximately \$12,336,000 and accrued interest of approximately \$1,832,000 into 26,237,611 preferred shares at a conversion price of \$0.54 per share. Upon the conversion, the exercise price of the related warrants was set at \$0.54 per share, and the \$236,799 fair value of the warrants was reclassified into additional paid-in capital as of June 28, 2013. Although the conversion price of the debt was greater than the value of the preferred shares at the time of conversion, the Company did not record a gain on the conversion under the troubled debt restructuring accounting guidance since the transaction occurred between related parties, and thus, was treated as a capital transaction.

*2012 Revolver Notes*

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

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

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants are initially recorded at their fair value and are then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the 2012 Revolver Notes and warrants issued under the note and warrant purchase agreement dated January 13, 2012, the Company used the Black-Scholes valuation model. The Company recorded approximately \$396,000 related to the fair value of the warrants issued, as a discount to the carrying value of the debt, accreted as interest expense over the life of the debt. The Company valued the warrants at the date of each issuance using the Black-Scholes valuation model with the following underlying assumptions: contractual term of 5 years, an underlying preferred share price between \$0.24 and \$0.30, an exercise price of \$0.54, an average risk-free interest rate between 0.62% and 1.02%, a dividend yield of 0%, and volatility of 105.0%. Approximately \$0 and \$396,000 related to accretion of the discount was recognized as interest expense during the years ended December 31, 2011 and 2012, respectively.

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

*Other*

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

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As of December 31, 2011 and 2012, the warrants to purchase preferred stock are reflected as a liability on the balance sheet, which is adjusted to estimated fair value at the end of each reporting period over the term of the warrants. These warrants were reclassified to additional paid-in capital during the nine months ended September 30, 2013. The fair value of the warrant liability for warrants to purchase preferred stock as of December 31, 2011 and 2012, of approximately \$923,000 and \$982,000, respectively, was estimated using the Black-Scholes valuation model with the following assumptions:

	As of December 31,	
	2011	2012
Stock price	\$ 0.35	\$ 0.25
Exercise price	\$ 0.54	\$ 0.54
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.64% - 0.89%	0.35% - 0.70%
Expected life (in years)	4.08 - 4.92	3.08 - 4.92
Expected volatility	105.0%	105.0%

### Outstanding Warrants – Common Shares

#### *2013 Convertible Bridge Notes*

The Company executed a convertible note and warrant purchase agreement as of June 28, 2013 with several shareholders, including a major shareholder, relating to the Company's borrowing as needed of, and issuance of a series of unsecured convertible notes for, up to \$7,000,000. The Company had borrowed \$745,000 and \$4,315,000 as of December 31, 2012 and September 30, 2013 (unaudited), respectively, against the 2013 Convertible Bridge Notes, including \$720,000 and \$2,505,000, respectively, from a major shareholder. The maturity date of the 2013 Convertible Bridge Notes is May 31, 2014 and may be extended at the option of the respective note holders for two successive six month periods. The 2013 Convertible Bridge Notes bear interest at 8.0% per annum, payable at maturity.

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

In accordance with guidance applicable to accounting for derivative financial instruments that are accounted for as liabilities, the warrants are initially recorded at their fair value and are then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For the warrants for common shares issued under the 2013 Convertible Bridge Notes agreement, the Company used a probability weighted Black-Scholes valuation model. The Company recorded approximately \$1,352,000 related to the fair value of the warrants issued, as a discount to the carrying value of the debt, accreted as interest expense from the date of issuance over the life of the debt. These warrants to purchase common stock were valued as of their date of issuance, using the following assumptions: exercise price of between \$3.08 and \$14.28 per share, contractual term of 5 years, a risk-free interest rate of between 1.38% and 1.40%, a dividend yield of 0%, and volatility of 105.0%. The value of the warrants using the probability weighted Black-Scholes valuation model accounted for a probability of 80%, while a fair value of \$0 was weighted 20%. The fair value of the warrants is recorded as a liability of approximately \$1,355,000 at September 30, 2013 (unaudited).

*Line of Credit*

Three of the Company's related parties guaranteed the Company's Line of Credit (see Note 5) and pledged financial assets to the bank to secure their guaranties, as approved by the Company's board of directors. In return, the Company issued common stock warrants to the guarantors. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to the bank, by the exercise price, which will be set at the price per share of the Company's common stock sold in its IPO.

These warrants to purchase common stock were valued as of their date of issuance, using the following assumptions: exercise price of between \$3.08 and \$14.28 per share, contractual term of 2 years, a risk-free interest rate of 1.38%, a dividend yield of 0%, and volatility of 105.0%. The value of the warrants using the probability weighted Black-Scholes valuation model accounted for a probability of 75%, while a fair value of \$0 was weighted 25%. The fair value of the warrants is recorded as a liability of approximately \$372,000 at September 30, 2013 (unaudited).

*Other*

On September 10, 2013, the Company, as part of a lease amendment for its non-cancellable operating lease for its office, laboratory, and warehouse space at its San Diego, California facility, issued a warrant to its landlord. The warrant coverage amount was \$502,605. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount by the exercise price, which will be set at the price per share of the Company's common stock sold in its IPO.

These warrants to purchase common stock were valued as of their date of issuance, using the following assumptions: exercise price of between \$3.08 and \$14.28 per share, contractual term of 5 years, a risk-free interest rate of 1.38%, a dividend yield of 0%, and volatility of 105.0%. The value of the warrants using the probability weighted Black-Scholes valuation model accounted for a probability of 75%, while a fair value of \$0 was weighted 25%. The fair value of the warrants is recorded as a liability of approximately \$309,000 at September 30, 2013 (unaudited).

Change in estimated fair value of warrant liability

The change in the estimated fair value of the total liability outstanding for all outstanding warrants was approximately \$361,000, \$454,000, \$421,808 and \$593,000 was recognized as a noncash gain and included in total other income/(expense) in the Company's statements of operations and comprehensive loss for the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2012 (unaudited) and 2013 (unaudited), respectively.

## 8. Supplier Financing

In 2011, the Company purchased certain laboratory equipment under financing agreements with a supplier, a business owned by a member of the Company's board of directors, totaling approximately \$256,000. Financing was granted for the purchase of the equipment at a stated interest rate of 0.0%. The Company has utilized its average interest rate for 2011 and 2012 of 8.0% to amortize the payments and record interest expense of approximately \$10,000, \$17,000, \$10,000 and \$3,000, for the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2012 (unaudited) and 2013 (unaudited), respectively. The remaining balance owed under these financing agreements was approximately \$138,000, \$60,000 and \$60,000 as of December 31, 2011 and 2012 and September 30, 2013 (unaudited), respectively. The remaining balance owed under these financing agreements is due in 2013.

In 2011, the Company purchased laboratory software under a financing agreement with a supplier for approximately \$177,000. This software financing agreement bears an interest rate of 7.4% per annum. The remaining balance owed under these financing agreements was approximately \$149,000, \$62,000 and \$0 as of December 31, 2011 and 2012 and September 30, 2013 (unaudited), respectively.

In 2011 and 2012, the Company obtained third-party financing for certain business insurance premiums. The financing bears an interest rate of 5.95% per annum, and all financing is due within one year. The remaining balances under these annual financing arrangements were approximately \$108,000, \$129,000, and \$0 as of December 31, 2011 and 2012 and September 30, 2013 (unaudited), respectively.

## 9. Shareholders' Deficit

### *(a) Common Stock*

In November of 2011, the Company amended and restated its articles of incorporation to decrease the number of authorized shares of common stock from 44,260,000 to 14,600,000. The authorized number shares of common stock at December 31, 2011 and 2012 was 14,600,000. In conjunction with the amendment, the Company declared a 1:3 reverse stock split for all common shares. All references to share and per share amounts in the financial statements and accompanying notes to the financial statements have been retroactively restated to reflect the 1:3 reverse stock split and the change in par value. See Note 17.

On July 22, 2013, the Company amended its articles of incorporation to increase the number of authorized shares of common stock from 14,600,000 to 53,000,000. The authorized number of shares of common stock at September 30, 2013 was 53,000,000. In addition, on July 30, 2013, the Company assigned a par value to its common shares of \$0.0001 in conjunction with its reincorporation in Delaware. The new par value per common share has been retroactively reflected in the financial statements for all periods presented.

### *(b) Preferred Stock*

In November of 2011, the Company amended and restated its articles of incorporation so that each share of the issued and outstanding Series AA preferred stock and each share of the issued and outstanding Series BB preferred stock of the Company was converted into one share of Series A preferred stock. As of December 31, 2011 and 2012, all 36,460,000 authorized shares of preferred stock are designated as Series A preferred stock. On July 22, 2013, the Company amended its articles of incorporation to increase the number of authorized preferred shares from 14,600,000 to 100,000,000. In addition, on July 30, 2013, the Company assigned a par value to its preferred shares of \$0.0001 in conjunction with its reincorporation in Delaware. The new par value per preferred share has been retroactively reflected in the financial statements for all periods presented.

Holders of the Company's preferred shares are entitled to receive, when and as declared by the board of directors and in preference to common shareholders, non-cumulative cash dividends at the rate of 8% per annum of the applicable original issue price on each outstanding preferred share. The original issue price of each share of Series A preferred stock was \$0.60. No dividends were declared during 2011 or 2012 or in the first nine months of 2013. Dividends cannot be granted for common shareholders while shares of preferred stock remain outstanding.



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

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

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

In October 2011, a major shareholder elected to convert 2,064,520 shares of the Company's preferred stock into 49,155 shares of the Company's common shares. No such conversions occurred in the year ended December 31, 2012 or in the first nine months of 2013.

During the nine months ended September 30, 2013, 42,245,834 shares of Series A preferred stock were issued for the conversion of approximately \$20,231,000 of debt and \$2,581,000 of accrued interest, primarily to related parties. See Notes 6 and 7.

## **10. Accounting for Stock-Based Compensation Expense**

### *2007 Equity Incentive Plan*

The 2007 Equity Incentive Plan ("2007 Plan") authorizes the grant of the following types of awards: (i) nonstatutory stock options, or NSOs, (ii) incentive stock options, or ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards, or RSUs, (v) stock appreciation rights, or SARs, (vi) performance awards, and (vii) other stock awards. Awards may be granted to employees, officers, non-employee board members, consultants, and other service providers of the Company. However, ISOs may not be granted to non-employees. Prior to November 2011, the Company was authorized to issue 7,500,000 options under the 2007 Plan. In conjunction with the 1:3 reverse common stock split in November 2011, the number of shares authorized under the 2007 Plan decreased to 2,500,000 shares and further reduced to 178,571 shares as a result of the 1:14 reverse split in November 2013. As of December 31, 2012 and September 30, 2013, shares available for grant under the 2007 Plan were 50,127 and 69,531.

### *2013 Equity Incentive Plan*

In July 2013, the Company adopted a new stock-based compensation plan entitled the 2013 Equity Incentive Plan ("2013 Plan"). The 2013 Plan authorizes the grant of the following types of awards: (i) nonstatutory stock options, (ii) ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards, (v) stock appreciation rights, and (vi) performance compensation awards. Awards may be granted to employees, officers, non-employee board members, consultants, and other service providers of the Company. However, ISOs may not be granted to non-employees. The Company has authorized a total of 403,571 shares of common stock for issuance pursuant to all awards granted under the 2013 Equity Incentive Plan, subject to an increase of 800,000 shares upon the completion of an IPO, and subject to additional increases every January 1 equal to the lesser of (i) 5% of the Company's

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outstanding common stock on such January 1, or (ii) a number of shares determined by the Company's board of directors in its discretion for use on such particular January 1. As of September 30, 2013 (unaudited), 401,640 stock options and RSUs have been granted under the 2013 Plan, and 1,931 shares are available for grant under the 2013 Plan.

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

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

The assumptions used in the Black-Scholes pricing model for options granted during the years ended December 31, 2011 and 2012 and during the nine months ended September 30, 2013 are as follows:

	For the years ended December 31,		For the nine months ended
	2011	2012	September 30, 2013 (unaudited)
Volatility	106.9% - 107.7%	96.8%	105.0%
Risk-free interest rate	1.03% - 2.62%	0.79% - 1.15%	1.19%
Dividend yield	0.00%	0.00%	0.00%
Expected term (years)	6.02 - 6.08	6.08	4.33 - 4.39
Expected forfeiture rate	0.00%	0.00%	0.00%

Using the assumptions described above, the weighted average estimated fair value of options granted in 2011, 2012 and the nine months ended September 30, 2013 were approximately \$3.36, \$1.82, and \$4.06, respectively.

A summary of stock option activity for 2011 and 2012 and the nine months ended September 30, 2013 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2010	65,048	\$ 18.48	
Granted	36,261	4.62	
Exercised	(10,212)	4.62	
Cancelled/forfeited/expired	(12,110)	77.14	
Outstanding at December 31, 2011	78,987	4.90	8.3
Granted	330	4.62	
Exercised	—	—	
Cancelled/forfeited/expired	(15,799)	4.92	
Outstanding at December 31, 2012	63,518	4.97	6.2
Granted	300,440	5.18	
Exercised	(94)	4.68	
Cancelled/forfeited/expired	(19,299)	5.35	
Outstanding at September 30, 2013 (unaudited)	344,565	5.13	9.2

The total intrinsic value of options exercised during the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2013 was zero due to the difference between the exercise price and the Company's share value at each exercise date.

Further information about the options outstanding and exercisable at December 31, 2012 and September 30, 2013 is as follows:

Options Outstanding and Exercisable at December 31, 2012				
Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Weighted Average Exercise Price	Total Shares Exercisable
\$4.62	33,031	7.2	\$ 4.62	16,173
\$5.04	30,408	5.1	\$ 5.04	28,244
\$125.58	79	1.1	\$ 125.58	79
	63,518			44,496
Options Outstanding and Exercisable at September 30, 2013 (unaudited)				
Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Weighted Average Exercise Price	Total Shares Exercisable
\$4.62	24,358	6.2	\$ 4.62	16,615
\$5.04	19,769	3.7	\$ 5.04	19,763

\$5.18	300,438	9.8	\$	5.18	92,793
	<u>344,565</u>				<u>129,171</u>

*Restricted Stock Units (“RSUs”)*

In November 2010, the Company issued to a member of the board of directors a restricted stock unit award for 390,000 shares of Series BB preferred stock. In November 2011, these RSUs were modified to be redeemable for Series A preferred stock under the same terms and conditions of the original grant. The shares will not vest unless a change in control, as defined, or IPO occurs within 10 years of the vesting commencement date of October 2010. There will be no expense to record for these awards unless and until it becomes probable that the award will vest. As of December 31, 2012 and September 30, 2013, it is not probable that these awards will vest and therefore, no expense was recorded during the year ended December 31, 2012 or the nine months ended September 30, 2013.

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In March 2011, the Company awarded a restricted stock unit award to a member of the board of directors for 428,597 shares of Series BB preferred stock. Also in March 2011, the Company awarded an additional performance-based restricted stock unit award for an estimated 574,108 shares of Series BB preferred stock to the same member. In November 2011, these RSUs were modified to be redeemable for Series A preferred stock under the same terms and conditions of the original grant. The number of shares in the restricted stock units is based on certain milestones to be achieved. None of the shares under either award vest unless a change in control or IPO occurs within 10 years after January 1, 2011. There will be no expense to record for these awards until it becomes probable that an award will vest. As of December 31, 2012 and September 30, 2013, it is not probable that these awards will vest and therefore, no expense was recorded during the year ended December 31, 2012 or the nine months ended September 30, 2013.

The board of directors approved a resolution in December 2010, that each January 1 each person (other than two identified individuals) who is serving as a non-employee director on such January 1 shall be automatically granted an annual restricted stock unit award covering a number of common shares equal to 0.25% of the fully diluted outstanding common stock of the Company as of the December 31 immediately preceding such January 1. These restricted stock unit awards will be granted automatically on each January 1 and will vest in equal monthly installments over 12 months from the date of the grant. Additionally, in January 2012, each person (other than two identified individuals) who is serving as a non-employee director is to be granted a “true up grant” in addition to the annual grant covering a number of common shares equal to 0.25% of the fully diluted outstanding common shares of the Company as of the immediately preceding December 31. These grants will vest 100% on the date of the grant. In January 2012 and 2011, five restricted stock unit awards for a total of 20,930 and 12,755 common shares, respectively, were granted in accordance with this resolution. In addition, on January 1, 2012, an additional five restricted stock unit awards were granted to non-employee directors for a total of 20,930 common shares, vesting immediately upon grant. Although vested, shares are only delivered on the earlier of (i) the date that is 10 years from the grant date, (ii) the date of a change in control, (iii) the date of termination of the holder from the Company, (iv) the date of death or disability, or (v) the date of an unforeseeable emergency as described in Internal Revenue Code section 409A.

The RSU awards due to be granted on January 1, 2013 were not granted during the nine months ended September 30, 2013. In lieu of this issuance, RSU awards for 8,735 shares of common stock each were granted to three directors and an RSU award for 14,285 shares of common stock was granted to another director, on July 31, 2013. All RSUs issued in July 2013 vest in equal monthly installments over five months beginning August 1, 2013. The shares underlying the 2013 awards, if vested, would be distributed no later than August 20, 2014.

In August 2013, 60,712 RSU awards were granted to certain executive employees. These awards vest 50% on the date of grant, with the remaining 50% vesting in equal monthly installments over twenty-four months beginning August 31, 2013.

### *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:

	<b>For the years ended December 31,</b>		<b>For the nine months ended September 30,</b>	
	<b>2011</b>	<b>2012</b>	<b>2012</b>	<b>2013</b>
			<b>(unaudited)</b>	<b>(unaudited)</b>
<b><u>Stock Options</u></b>				
Research and development expenses	\$ 27,392	\$ 32,210	\$ 16,288	\$ 253,828
General and administrative expenses	44,615	22,530	24,158	155,197
Sales and marketing expenses	4,134	3,994	2,996	—
Total expenses related to stock options	76,141	58,734	43,442	409,025
<b><u>RSUs</u></b>				
General and administrative expenses	58,932	193,400	169,225	274,871
Total stock-based compensation	<u>\$ 135,073</u>	<u>\$ 252,134</u>	<u>\$ 212,667</u>	<u>\$ 683,896</u>

## 11. 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, 2011 and 2012 and the nine months ending September 30, 2012 and 2013, the outstanding shares of Series A preferred stock, RSUs, convertible debt, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted loss per share are the same.

In November 2011, the Company effected a 1:3 reverse stock split of all common shares outstanding. The calculation of weighted average shares outstanding has been adjusted for this reverse split as if it had occurred on January 1, 2011.

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 years ended December 31,		For the nine months ended September 30,	
	2011	2012	2012 (unaudited)	2013 (unaudited)
Series A preferred (number of common stock equivalents)	647,007	647,007	647,007	1,652,851
Preferred warrants outstanding (number of common stock equivalents)	122,048	192,262	174,939	192,262
Notes payable convertible into preferred shares (number of common stock equivalents)	366,169	599,466	603,435	232,558
Preferred share RSUs (number of common stock equivalents)	33,158	33,158	33,158	68,546
Common warrants outstanding	—	—	—	630,110
Notes payable convertible into common shares	—	665,178	—	741,857
Common share RSUs	12,755	54,615	54,615	133,971
Common options outstanding	78,987	63,518	70,009	344,565
Total anti-dilutive common share equivalents	<u>1,260,124</u>	<u>2,255,204</u>	<u>1,583,163</u>	<u>3,996,720</u>

## 12. 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.

## 13. Income Taxes

For the year ended December 31, 2011 and 2012, the provision for income taxes was calculated as follows:

	For the years ended December 31,	
	2011	2012
<b>Current:</b>		
Federal	\$ —	\$ —
State	800	800
Total	<u>800</u>	<u>800</u>
<b>Deferred</b>		
Federal	—	—
State	—	—
Total	<u>—</u>	<u>—</u>
Provision for income tax	<u>\$ 800</u>	<u>\$ 800</u>

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 years ended December 31,	
	2011	2012
Income tax at statutory rate	\$ (4,633,685)	\$ (4,167,967)
State liability	(710,970)	(602,296)
Permanent items	436,228	543,993
Expiration of net operating losses	116,651	146,175
Book to provision and other	339,880	80
Research and development credit	(229,897)	(215,502)
Valuation allowance	4,682,593	4,296,317
Provision for income tax	<u>\$ 800</u>	<u>\$ 800</u>

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Deferred income taxes are provided for temporary differences in recognizing certain income and expense items for financial and tax reporting purposes. The deferred tax assets consisted primarily of the income tax benefits from net operating loss carryforwards, deferred rent, and research and development credits. Valuation allowances have been recorded to fully offset deferred tax assets at December 31, 2011 and 2012, as it is more likely than not that the assets will not be utilized.

At December 31, 2012, the Company has federal net operating loss carryforwards of approximately \$104,456,000 expiring beginning in 2020 and California net operating loss carryforwards of approximately \$95,735,000 expiring beginning in 2013. Additionally, at December 31, 2012, the Company has research and development credits of approximately \$2,887,000 and \$3,047,000 for federal and California purposes, respectively. The federal research and development tax credits will begin to expire in 2018. The California research and development tax credits do not expire.

For the years ended December 31, 2011 and 2012, the Company has evaluated the various tax positions reflected in their income tax returns for both federal and state jurisdictions, and all open tax years in these 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, 2011 or 2012. The Company is subject to taxation in the United States and California. The Company's federal filings prior to 2009 and the Company's California filings prior to 2008 are no longer subject to examination.

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

	For the years ended December 31,	
	2011	2012
Net operating loss carryforward	\$ 37,255,099	\$ 41,100,511
Research and development credits	4,682,553	4,898,055
Accruals and other	549,022	688,089
Deferred rent	107,129	203,463
	42,593,803	46,890,118
Less valuation allowance	(42,593,803)	(46,890,118)
Net deferred tax assets	\$ —	\$ —

The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since its 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. Based on a preliminary assessment, the Company believes that an ownership change occurred in 2010. The Company estimates that if such a change did occur, the federal and state net operating loss carryforwards and research and development credits that can be utilized in the future will be significantly limited.

The American Taxpayer Relief Act of 2012 was enacted on January 2, 2013. Included with this legislation was an extension of the research and development credit which had previously expired on December 31, 2011. This legislation retroactively reinstates and extends the credit from the previous expiration date through December 31, 2013. As the legislation was not enacted until after the close of the year ended December 31, 2012, the income tax impact of the retroactive reinstatement and extension will not be recognized until 2013. If the tax impact of the research and development credit was recognized, the Company does not anticipate any federal income tax benefit due to the existence of the valuation allowance offsetting any deferred tax asset which may have arose.

#### **14. Collaborative Agreement**

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

Under this agreement, the Company invoices Clariant for the performance of each of the Diagnostic Tests at a contractually agreed-upon rate. Clariant is responsible for billing the patient, provider and/or payer for each completed test, and bears all collection risk related to such billings. Sales of Diagnostic Tests under this agreement did not commence until 2012, and thus no revenue related to this collaboration was recognized for the year ended December 31, 2011. The total amount of revenue the Company earned under this agreement was approximately \$86,000 for the year ended December 31, 2012 and \$13,000 for the nine months ended September 30, 2013 (unaudited).

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

#### **15. Related Party Transactions**

During 2005, the Company executed the Goodman Note in favor of an investor which became a beneficial owner of more than 5% of the Company's common stock. As of December 31, 2011 and 2012, the Company had \$1,935,000 outstanding on this note. In June 2013, the investor converted the entire principal amount of \$1,935,000 and accrued interest of approximately \$105,000 due on the Goodman Note into 3,777,324 shares of Series A preferred stock.

During 2008, the Company executed the 2008 Convertible Note with an affiliate of a major shareholder who is a member of the board of directors in the amount of \$1,400,000. A warrant to purchase preferred shares was issued along with the convertible promissory note (see Notes 6 and 7). In July 2013, the Company amended the 2008 Convertible Note with a principal balance of \$1,400,000, held by a related party, to provide that all principal of and accrued interest on the note would automatically convert into common stock upon the closing of an IPO at the price per share at which common stock is sold in such IPO.

As of December 31, 2011 and 2012 and September 30, 2013, the Company had \$10,000,000, \$17,780,000, and \$3,905,000, respectively, of notes payable outstanding to affiliates of a major shareholder who is a member of the board of directors under several note and warrant purchase agreements (see Notes 6 and 7). As of June 28, 2013, \$17,060,000 of principal and \$2,339,000 of interest due on a portion of these notes was converted into shares of 35,923,845 Series A preferred stock.

As of December 31, 2011 and 2012 and September 30, 2013, the Company had approximately \$250,000, \$1,000,000, and \$1,358,000, respectively, of notes payable outstanding with other board members under several different note and warrant purchase agreements (see Notes 6 and 7). As of June 28, 2013, approximately \$975,000 of principal and \$101,000 of interest due on a portion of these notes were converted into 1,993,591 preferred shares.

In September 2013, the Company issued warrants to three shareholders in conjunction with their guarantees on the Company's borrowings under the Company's line of credit. (See Notes 5 and 7).

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During 2011, the Company entered into two supplier financing arrangements with a business owned by a member of the board of directors totaling \$256,000, of which \$138,000, \$60,000, and \$60,000 is outstanding as of December 31, 2011 and 2012 and September 30, 2013, respectively.

A member of the Company's management is the controlling person of Aegea Biotechnologies, Inc. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement with Aegea Biotechnologies, Inc.

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. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent.

For the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2012 and 2013, rent expense was approximately \$901,000, \$937,000, \$703,000, and \$848,000, respectively. As of December 31, 2012 the Company owed rent in arrears of approximately \$185,000. As of September 30, 2013, the Company owed no rent in arrears. This amount is included in accounts payable on the balance sheet.

In September 2013, the Company amended its non-cancellable operating lease for its office, laboratory, and warehouse space at its San Diego, California facility. The amendment extends the maturity date of the lease through July 31, 2020. As part of this amendment, the landlord waived the lease payments due from August 1, 2013 through December 31, 2013 of approximately \$503,000. In conjunction with this amendment, the Company granted to the landlord a warrant to purchase common shares with a warrant coverage amount of \$502,605 and an exercise price equal to the price per share of the Company's common stock sold in the Company's IPO (See Note 7).

The future minimum lease payments under the amended lease agreement as of September 30, 2013 (unaudited) are as follows:

2013	\$ 0
2014	1,233,846
2015	1,270,861
2016	1,308,987
2017	1,348,257
Thereafter	3,674,206
Total	<u>\$8,836,157</u>

### *Employment Agreements*

Under the terms of certain employment agreements with executive officers, the Company would incur additional cash compensation expense of \$150,000 immediately, and \$225,000 annually, upon the closing of an initial public offering or the Company's receipt of aggregate proceeds of \$15,000,000 or more from the sales of equity securities.



*Legal Proceedings*

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

The Company's former Vice President of Operations filed an administrative proceeding against the Company with the California Labor Commissioner in September 2013, seeking approximately \$62,000 in damages for alleged unpaid wages and penalties. A hearing was held on August 19, 2013 which resulted in a finding against the Company in the amount noted above. This amount was accrued as of September 30, 2013. (unaudited)

**17. Subsequent Events**

The Company has evaluated all events or transactions that occurred after the balance sheet dates of December 31, 2012 and September 30, 2013, through January 8, 2014.

In July 2013, the Company satisfied its commitment to issue 42,245,834 shares of Series A preferred stock upon conversion of the Goodman Note, the 2011 Convertible Bridge Notes and the 2012 Revolver Notes, when its articles of incorporation were amended to increase the authorized number of shares of Series A preferred stock from 36,460,000 to 100,000,000.

In July 2013, the Company amended the 2008 Convertible Note with a principal balance of \$1,400,000, held by a related party, to provide that all principal of and accrued interest on the note would automatically convert into common stock upon the closing of an IPO at the price per share at which common stock is sold in such IPO.

In July 2013, the Company entered into a revolving line of credit with UBS Bank USA in the initial amount of \$1,500,000. Interest accrues daily on the outstanding balance and is paid monthly at a variable rate which, as of July 31, 2013, is 2.75% over the 30 day LIBOR rate or a current effective annual interest rate of 2.942%. As of December 31, 2013, the amount outstanding under this revolving line of credit is \$2.0 million. Three of the Company's related parties guaranteed the loan and pledged financial assets to the bank to secure their guaranties, as approved by the Company's board of directors. In return, the Company issued common stock warrants to the guarantors. The number of shares subject to the common stock warrants will be determined by dividing the warrant coverage amount, which is 50% of the fair market value of the collateral provided by the respective guarantors to secure their respective guaranty obligations to the bank, by the exercise price, which will be set at the price per share of the Company's common stock sold in its IPO. The Company has entered into an agreement with the guarantors that provides for reimbursement of any amounts paid by them on their guaranties. This reimbursement obligation is secured by a security interest in the Company's assets.

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.

In June 2013, a beneficial owner of more than 5% of the Company's common stock converted the entire principal amount of \$1,935,000 and accrued interest of approximately \$105,000 due on a secured promissory note held by it (the Goodman Note) into 3,777,324 shares of Series A preferred stock. (These shares of Series A preferred stock are included in the number of shares of Series A preferred stock issued in July 2013, as described in the second paragraph of this Note 17.) In July 2013, in connection with this conversion, the Company issued to such beneficial owner a warrant to purchase 23,809 shares of common stock at an exercise price which will be set at the price per share of the Company's common stock sold in the Company's IPO. The warrants will be exercisable for a two-year period beginning with the closing of the Company's IPO.

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In July 2013, the Company adopted a new stock-based compensation plan entitled the 2013 Equity Incentive Plan (“2013 Plan”). The 2013 Plan authorizes the grant of the following types of awards: (i) nonstatutory stock options, (ii) ISOs, (iii) restricted stock awards, (iv) restricted stock unit awards, (v) stock appreciation rights, and (vi) performance compensation awards. Awards may be granted to employees, officers, non-employee board members, consultants, and other service providers of the Company. However, ISOs may not be granted to non-employees. The Company has authorized a total of 403,571 shares of common stock for issuance pursuant to all awards granted under the 2013 Equity Incentive Plan, subject to an increase of 800,000 shares upon the completion of an IPO, and subject to additional increases every January 1 beginning January 1, 2015 equal to the lesser of (i) 5% of the Company’s outstanding common stock on such January 1, or (ii) a number of shares determined by the Company’s board of directors in its discretion for use on such particular January 1. As of December 31, 2013, no shares have been issued under the 2013 Plan, 401,640 stock options and RSUs have been granted under the 2013 Plan, and 1,931 shares are available for grant under the 2013 Plan.

In September 2013, the Company amended its non-cancellable operating lease for its office, laboratory, and warehouse space at its San Diego, California facility. The amendment extends the maturity date of the lease through July 31, 2020. As part of this amendment, the landlord waived the lease payments due from August 1, 2013 through December 31, 2013 of approximately \$503,000, and the Company forfeited its security deposit of approximately \$269,000. In conjunction with this amendment, the Company granted to the landlord a warrant to purchase common shares with a warrant coverage amount of \$502,605 and an exercise price equal to the price per share of the Company’s common stock sold in the Company’s IPO. The future minimum lease payments under the amended lease agreement as of September 30, 2013 are as follows:

2013	\$ 0
2014	1,233,846
2015	1,270,861
2016	1,308,987
2017	1,348,257
Thereafter	3,674,206
Total	<u>\$8,836,157</u>

In September 2013, the board of directors approved an amendment for all outstanding warrants issued in connection with the 2012 Revolver Notes to fix the exercise price at \$0.54 per share. All warrant amendments were signed by the warrant holders in September 2013.

Subsequent to June 30, 2013, the Company has borrowed approximately \$1,334,000 under the 2013 Convertible Bridge Notes.

In January 2014, the maximum amount of the Company’s line of credit discussed in Note 5 above was increased to approximately \$2.2 million. As of December 31, 2013, the amount outstanding under the revolving line of credit referenced above is \$2.0 million.

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

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In conjunction with the 1:14 reverse common stock split in November 2013, the number of shares authorized under the 2007 Plan decreased to 178,571 shares and the number of shares authorized under the 2013 Plan decreased to 403,571 shares.

Subsequent to September 30, 2013, the Company has borrowed approximately \$675,000 under the 2013 Convertible Bridge Notes.

**1,818,181 Shares**

**Common Stock**



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**PROSPECTUS**

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**Aegis Capital Corp**

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Through and including \_\_\_\_\_, 2014 (the 25th day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable in connection with the sale and distribution of the securities being registered. All amounts are estimated except the SEC registration fee, the FINRA filing fee and the NASDAQ listing fee.

Item	Amount
SEC registration fee	3,592
FINRA filing fee	5,000
NASDAQ listing fee	55,000
Legal fees and expenses	385,000
Accounting fees and expenses	200,000
Printing and engraving expenses	40,000
Transfer agent and registrar fees and expenses	4,000
Miscellaneous fees and expenses	7,408
<i>Total</i>	<u><u>\$700,000</u></u>

**Item 14. Indemnification of Directors and Officers**

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act.

The Company's amended certificate of incorporation provides for indemnification of its directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law, and the Company's amended and restated bylaws provide for indemnification of its directors and executive officers to the maximum extent permitted by the Delaware General Corporation Law.

In addition, the Company has entered into indemnification agreements with each of its current directors and executive officers. These agreements will require the Company to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. The Company also intends to enter into indemnification agreements with its future directors and executive officers.

In any underwriting agreement the Company enters into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, the Company's directors, the Company's officers and persons who control us, within the meaning of the Securities Act, against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

Since July 1, 2010, the Registrant made sales of the unregistered securities discussed below. All common stock share, option, warrant and RSU amounts (and the exercise price of all common stock options and warrants) reflect (i) the 1-for-3 reverse common stock split effected on November 3, 2011, and (ii) the 1-for-14 reverse common stock split effected on November 1, 2013. The offers, sales and issuances of the securities described below were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act and/or, in the case of compensatory issuances, Securities Act Rule 701, and/or, in the case of conversions, Section 3(a)(9) of the Securities Act. No commissions were paid.

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### ***Preferred Stock Financing***

From August 2010 to September 2010, the Company sold 8,939,990 shares of its Series BB preferred stock (convertible, post-recapitalization and post-reverse-splits, into 213,571 shares of the Company's common stock), to 15 accredited investors, for aggregate gross proceeds of \$5.364 million.

### ***Note/ Warrant Financings***

In 30 closings from February 2011 to November 2012, the Company sold secured convertible promissory notes with an aggregate principal amount of \$12,336,247, together with warrants to purchase 4,569,030 shares of its preferred stock (convertible, post-reverse-splits, into 108,786 shares of the Company's common stock), to 11 accredited investors, for aggregate gross proceeds of \$12,336,247.

In 21 closings from January 2012 to December 2012, the Company sold promissory notes with an aggregate principal amount of \$5,960,000, together with warrants to purchase 2,207,401 shares of its preferred stock (convertible, post-reverse-splits, into 52,557 shares of the Company's common stock) to five accredited investors, for aggregate gross proceeds of \$5,960,000.

In 52 closings from December 2012 to December 31, 2013, the Company sold promissory notes with an aggregate principal amount of \$4,990,000, together with warrants to purchase an indeterminate number of shares of the Company's common stock, to 12 accredited investors, for aggregate gross proceeds of \$4,990,000.

### ***Compensatory Issuances***

In the last six months of 2010 the Company issued 50,600 common stock options (at a \$4.62 exercise price per share) and 390,000 preferred stock restricted stock units to service providers.

In 2011 the Company issued 36,260 common stock options (at a \$4.62 exercise price per share), 12,753 common stock restricted stock units and 1,002,705 preferred stock restricted stock units to service providers.

In 2012 the Company issued 332 common stock options (at a \$4.62 exercise price per share) and 41,857 common stock restricted stock units to service providers.

In 2013, the Company issued 300,438 common stock options (at a \$5.18 exercise price per share) and 101,559 common stock restricted stock units to approximately 35 service providers.

### ***Inducement Warrants***

In September 2012, the Company issued 66,666 Series A preferred stock warrants, at an exercise price of \$0.60 per share, to its landlord in exchange for certain real estate lease accommodations.

In June 2013, the Company issued 23,810 common stock warrants, at an exercise price to be determined in accordance with contract, to a lender (a 5% beneficial shareholder) in connection with a note conversion.

In July through October 2013, the Company issued an indeterminate number of common stock warrants, at an exercise price to be determined in accordance with contract, to three guarantors in connection with their guaranties of its UBS Bank USA revolving line of credit.

In September 2013, the Company issued an indeterminate number of common stock warrants, at an exercise price to be determined in accordance with contract, to its landlord in connection with a lease amendment.

### ***Recapitalization***

In November 2011, the Company effected a recapitalization in which all outstanding shares of, and warrants to purchase and restricted stock units to obtain, the Company's outstanding Series AA preferred stock and Series BB preferred stock were converted into the same number of shares of, warrants to purchase and restricted stock units to obtain, Series A preferred stock. At the same time, the Company effected the 1-for-3 reverse split of its common stock.

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### **Conversions and Exercises**

In November 2011, the Company's Executive Chairman exercised 10,204 common stock options, paying an aggregate exercise price of \$47,183.

In October 2011, a major shareholder converted 2,064,520 shares of Series AA preferred stock into 49,155 shares of common stock.

In March and April 2013, two employees exercised 85 common stock options, paying an aggregate exercise price of \$395.

In June 2013, the holders of promissory notes with an aggregate principal balance of approximately \$20,231,000 and accrued but unpaid interest of approximately \$2,591,000 voluntarily converted such principal and interest into 42,245,834 shares of the Company's Series A preferred stock.

In the fourth quarter of 2013, four employees exercised 3,937 common stock options, paying an aggregate exercise price of \$19,710.

### **Item 16. Exhibits and Financial Statement Schedules.**

#### **(a) Exhibits**

### **EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description of Exhibit</u></b>
1.1##	Form of Underwriting Agreement between us and Aegis Capital Corp., as representative of the several underwriters.
3.1	Certificate of Incorporation.
3.1.1	Certificate of Ownership and Merger, filed July 30, 2013.
3.1.2	Certificate of Ownership, filed July 30, 2013.
3.1.3#	Certificate of Amendment of Certificate of Incorporation, filed November 1, 2013.
3.1.4#	Form of Certificate of Amendment of Certificate of Incorporation, comprising amended Certificate of Incorporation, to be in effect upon closing of this offering.
3.2	Bylaws.
3.2.1	Amended and Restated Bylaws, to be in effect upon closing of this offering.
4.1#	Specimen Common Stock certificate of Biocept, Inc.
4.2##	Form of Representative's Warrant.
5.1##	Opinion of Stradling Yocca Carlson & Rauth, P.C.
10.1+	2007 Equity Incentive Plan.
10.1.1+	Form of Stock Option Grant Notice and Option Agreement under 2007 Equity Incentive Plan.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.1.2+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2007 Equity Incentive Plan.
10.2+##	2013 Equity Incentive Plan.
10.2.1+	Form of Notice of Stock Option Grant under 2013 Equity Incentive Plan.
10.2.2+	Form of Stock Option Agreement under 2013 Equity Incentive Plan.
10.2.3+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan.
10.2.4+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for senior officers: as used August 8, 2013).
10.2.5+#	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for non-employee directors: as used August 8, 2013).
10.3+	Form of Indemnification Agreement between us and our officers and directors.
10.4+	Form of Indemnity Agreement between Biocept, Inc., a California corporation, and its officers and directors.
10.5+	Employment Agreement, between us and David F. Hale, dated March 10, 2011.
10.6+	Employment Agreement, between us and Michael W. Nall, effective as of August 26, 2013.
10.7+	Employment Agreement, between us and Lyle J. Arnold, dated April 30, 2011.
10.8+	Employment Agreement, between us and William G. Kachioff, dated August 1, 2011.
10.9+#	Employment Agreement, between us and Michael J. Dunn, dated February 15, 2011.
10.10+	Form of Amended and Restated Salary Reduction and Contingent Payment Agreement.
10.11#	Lease, between us and Nexus Equity VIII LLC, dated March 31, 2004.
10.11.1	First Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated November 1, 2011.
10.11.2	Second Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated September 10, 2012.
10.11.3	Warrant to Purchase Preferred Stock, dated September 10, 2012, issued by us in favor of ARE-SD Region No. 18, LLC.



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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.11.4	Third Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated as of January 31, 2013, and effective as of January 1, 2013.
10.11.5	Fourth Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated as of September 10, 2013, and effective as of August 1, 2013.
10.11.6	Warrant to Purchase Common Stock, dated September 10, 2013, issued by us in favor of ARE-SD Region No. 18, LLC.
10.12	Amended and Restated Investor Rights Agreement, dated as of October 31, 2011, among us and certain investors named therein.
10.13†###	Collaboration Agreement dated as of November 2, 2012 between us and Life Technologies Corporation.
10.14###	Collaboration Agreement dated as of August 17, 2011 between us and Clariant Diagnostic Services, Inc.
10.14.1	Laboratory Services Agreement dated July 29, 2013, effective as of May 1, 2013, between us and Clariant Diagnostic Services, Inc.
10.15†#	Master Laboratory Research Support and Services Agreement dated as of July 9, 2012 between us and Dana Farber Partners Cancer Care, Inc.
10.16	Note and Warrant Purchase Agreement dated as of December 22, 2008 between us and The Reiss Family GST Exempt Marital Deduction Trust.
10.16.1	Secured Convertible Promissory Note (original principal amount of \$1,400,000), dated December 22, 2008, issued by us in favor of The Reiss Family GST Exempt Marital Deduction Trust.
10.16.1.1	Amendment of Secured Convertible Promissory Note, dated July 15, 2013.
10.16.2	Warrant to Purchase Preferred Stock dated December 22, 2008, issued by us in favor of The Reiss Family GST Exempt Marital Deduction Trust.
10.16.3	Security Agreement dated as of December 22, 2008 between us and The Reiss Family GST Exempt Marital Deduction Trust.
10.17#	Amended and Restated Loan Agreement dated as of May 18, 2010 between us and Goodman Co. Ltd.
10.17.1	Warrant to Purchase Preferred Stock dated as of January 21, 2009, issued by us in favor of Goodman Co. Ltd.
10.17.2	Loan Conversion Agreement dated as of June 28, 2013 between us and Goodman Co. Ltd. [Pursuant to this Agreement, indebtedness was converted into 3,777,324 shares of our Series A Preferred Stock.]
10.17.3	Warrant to Purchase Common Stock dated as of July 31, 2013, issued by us in favor of Goodman Co. Ltd.
10.18#	Note and Warrant Purchase Agreement dated as of February 1, 2011 between us and various investors.
10.18.1	First Amendment to Note and Warrant Purchase Agreement, dated as of July 1, 2011.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.18.2	Second Amendment to Note and Warrant Purchase Agreement, dated as of August 1, 2011.
10.18.3#	Omnibus Amendment Agreement, dated as of September 30, 2011.
10.18.4	Amendment to Note and Warrant Purchase Agreement, dated as of June 23, 2012.
10.18.5	Amendment to Note and Warrant Purchase Agreement, dated as of November 8, 2012.
10.18.6	Form of Secured Convertible Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of February 1, 2011.
10.18.6.1#	The several Note Conversion Agreements, each dated as of June 28, 2013. [Pursuant to such Agreements, indebtedness was converted into 2,234,922 shares of our Series A Preferred Stock.]
10.18.6.2	Note Conversion Agreement dated as of June 28, 2013, among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988 and The Reiss Family GST Exempt Marital Deduction Trust. [Pursuant to this Agreement, indebtedness was converted into 35,923,845 shares of our Series A Preferred Stock.]
10.18.7	Form of Warrant to Purchase Preferred Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of February 1, 2011.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.19	Note and Warrant Purchase Agreement dated as of January 13, 2012 between us and various investors.
10.19.1	Omnibus Amendment Agreement dated as of November 8, 2012 between us and various investors.
10.19.2	Form of Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012.
10.19.2.1#	The several Note Conversion Agreements, each dated as of June 28, 2013. [Pursuant to such Agreements, indebtedness was converted into 309,743 shares of our Series A Preferred Stock.]
10.19.2.2	Note Conversion Agreement dated as of June 28, 2013, among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988 and The Reiss Family GST Exempt Marital Deduction Trust. (Included as Exhibit 10.18.6.2.)
10.19.3	Form of Warrant to Purchase Preferred Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012.
10.19.4	Form of Amendment of Warrant to Purchase Preferred Stock, dated as of September 13, 2013.
10.20	Form of Note and Warrant Purchase Agreement dated as of June 28, 2013 between us and various investors.
10.20.1	Form of Convertible Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013.
10.20.2	Form of Warrant to Purchase Common Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013.
10.21	Reimbursement Agreement dated as of July 11, 2013 among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988, Edward Neff and Hale Biopharma Ventures, LLC.
10.21.1	Form of Warrant to Purchase Common Stock, issued by us in favor of various guarantors under the Reimbursement Agreement dated as of July 11, 2013.
10.21.2	Subordination Agreement dated as of July 11, 2013 between us and The Reiss Family GST Exempt Marital Deduction Trust UDT dated December 19, 1988.
10.22†###	Assignment and Exclusive Cross-License Agreement between us and Aegea Biotechnologies, Inc. dated June 2, 2012.
10.23+	Restricted Stock Unit Grant Notice / Agreement between us and Ivor Royston, dated as of November 8, 2010, as amended on February 15, 2012.
21.1	List of Subsidiaries.
23.1###	Consent of Mayer Hoffman McCann P.C.
23.2##	Consent of Stradling Yocca Carlson & Rauth, P.C. (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page of the original Form S-1 filing)

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- 
- # Filed with the issuer's November 5, 2013 Amendment No. 2 to Registration Statement on Form S-1.
  - ## Filed with the issuer's November 20, 2013 Amendment No. 3 to Registration Statement on Form S-1
  - ### Filed herewith.
  - + Indicates management contract or compensatory plan.
  - † Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

All exhibits not marked with a single, double or triple pound sign (#) were filed with the issuer's September 23, 2013 Registration Statement on Form S-1.

### (b) Financial Statement Schedules

No financial statement schedules are provided because the information is not required or is shown either in the financial statements or the notes thereto.

**Item 17. Undertakings**

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by one of our directors, officers or controlling persons in the successful defense of any action, suit, or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes to provide to the underwriters, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

The undersigned Registrant hereby undertakes that:

- (i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective;
- (ii) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; and
- (iii) For the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the Registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

## SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Amendment No. 6 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 8th day of January, 2014.

BIOCEPT, INC.

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

Pursuant to the requirements of the Securities Act, this Amendment No. 6 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael W. Nall</u> Michael W. Nall	Chief Executive Officer, President and Director (Principal Executive Officer)	January 8, 2014
<u>/s/ William G. Kachioff</u> William G. Kachioff	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	January 8, 2014
<u>/s/ David F. Hale*</u> David F. Hale	Executive Chairman and Director	January 8, 2014
<u>/s/ Marsha A. Chandler*</u> Marsha A. Chandler	Director	January 8, 2014
<u>/s/ Bruce E. Gerhardt*</u> Bruce E. Gerhardt	Director	January 8, 2014
<u>/s/ Bruce A. Huebner*</u> Bruce A. Huebner	Director	January 8, 2014
<u>/s/ Edward Neff*</u> Edward Neff	Director	January 8, 2014
<u>/s/ Ivor Royston*</u> Ivor Royston	Director	January 8, 2014
<u>/s/ M. Faye Wilson*</u> M. Faye Wilson	Director	January 8, 2014

\* By Michael W. Nall, as the indicated Director's attorney-in-fact

**EXHIBIT INDEX**

<b><u>Exhibit No.</u></b>	<b><u>Description of Exhibit</u></b>
1.1##	Form of Underwriting Agreement between us and Aegis Capital Corp., as representative of the several underwriters.
3.1	Certificate of Incorporation.
3.1.1	Certificate of Ownership and Merger, filed July 30, 2013.
3.1.2	Certificate of Ownership, filed July 30, 2013.
3.1.3#	Certificate of Amendment of Certificate of Incorporation, filed November 1, 2013.
3.1.4#	Form of Certificate of Amendment of Certificate of Incorporation, comprising amended Certificate of Incorporation, to be in effect upon closing of this offering.
3.2	Bylaws.
3.2.1	Amended and Restated Bylaws, to be in effect upon closing of this offering.
4.1#	Specimen Common Stock certificate of Biocept, Inc.
4.2##	Form of Representative's Warrant.
5.1##	Opinion of Stradling Yocca Carlson & Rauth, P.C.
10.1+	2007 Equity Incentive Plan.
10.1.1+	Form of Stock Option Grant Notice and Option Agreement under 2007 Equity Incentive Plan.
10.1.2+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2007 Equity Incentive Plan.
10.2+##	2013 Equity Incentive Plan.
10.2.1+	Form of Notice of Stock Option Grant under 2013 Equity Incentive Plan.
10.2.2+	Form of Stock Option Agreement under 2013 Equity Incentive Plan.
10.2.3+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan.
10.2.4+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for senior officers: as used August 8, 2013).
10.2.5+#	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for non-employee directors: as used August 8, 2013).

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.3+	Form of Indemnification Agreement between us and our officers and directors.
10.4+	Form of Indemnity Agreement between Biocept, Inc., a California corporation, and its officers and directors.
10.5+	Employment Agreement, between us and David F. Hale, dated March 10, 2011.
10.6+	Employment Agreement, between us and Michael W. Nall, effective as of August 26, 2013.
10.7+	Employment Agreement, between us and Lyle J. Arnold, dated April 30, 2011.
10.8+	Employment Agreement, between us and William G. Kachioff, dated August 1, 2011.
10.9+#	Employment Agreement, between us and Michael J. Dunn, dated February 15, 2011.
10.10+	Form of Amended and Restated Salary Reduction and Contingent Payment Agreement.
10.11#	Lease, between us and Nexus Equity VIII LLC, dated March 31, 2004.
10.11.1	First Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated November 1, 2011.
10.11.2	Second Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated September 10, 2012.
10.11.3	Warrant to Purchase Preferred Stock, dated September 10, 2012, issued by us in favor of ARE-SD Region No. 18, LLC.



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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.11.4	Third Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated as of January 31, 2013, and effective as of January 1, 2013.
10.11.5	Fourth Amendment to Lease, between us and ARE-SD Region No. 18, LLC, dated as of September 10, 2013, and effective as of August 1, 2013.
10.11.6	Warrant to Purchase Common Stock, dated September 10, 2013, issued by us in favor of ARE-SD Region No. 18, LLC.
10.12	Amended and Restated Investor Rights Agreement, dated as of October 31, 2011, among us and certain investors named therein.
10.13†###	Collaboration Agreement dated as of November 2, 2012 between us and Life Technologies Corporation.
10.14###	Collaboration Agreement dated as of August 17, 2011 between us and Clariant Diagnostic Services, Inc.
10.14.1	Laboratory Services Agreement dated July 29, 2013, effective as of May 1, 2013, between us and Clariant Diagnostic Services, Inc.
10.15†#	Master Laboratory Research Support and Services Agreement dated as of July 9, 2012 between us and Dana Farber Partners Cancer Care, Inc.
10.16	Note and Warrant Purchase Agreement dated as of December 22, 2008 between us and The Reiss Family GST Exempt Marital Deduction Trust.
10.16.1	Secured Convertible Promissory Note (original principal amount of \$1,400,000), dated December 22, 2008, issued by us in favor of The Reiss Family GST Exempt Marital Deduction Trust.
10.16.1.1	Amendment of Secured Convertible Promissory Note, dated July 15, 2013.
10.16.2	Warrant to Purchase Preferred Stock dated December 22, 2008, issued by us in favor of The Reiss Family GST Exempt Marital Deduction Trust.
10.16.3	Security Agreement dated as of December 22, 2008 between us and The Reiss Family GST Exempt Marital Deduction Trust.
10.17#	Amended and Restated Loan Agreement dated as of May 18, 2010 between us and Goodman Co. Ltd.
10.17.1	Warrant to Purchase Preferred Stock dated as of January 21, 2009, issued by us in favor of Goodman Co. Ltd.
10.17.2	Loan Conversion Agreement dated as of June 28, 2013 between us and Goodman Co. Ltd. [Pursuant to this Agreement, indebtedness was converted into 3,777,324 shares of our Series A Preferred Stock.]
10.17.3	Warrant to Purchase Common Stock dated as of July 31, 2013, issued by us in favor of Goodman Co. Ltd.
10.18#	Note and Warrant Purchase Agreement dated as of February 1, 2011 between us and various investors.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.18.1	First Amendment to Note and Warrant Purchase Agreement, dated as of July 1, 2011.
10.18.2	Second Amendment to Note and Warrant Purchase Agreement, dated as of August 1, 2011.
10.18.3#	Omnibus Amendment Agreement, dated as of September 30, 2011.
10.18.4	Amendment to Note and Warrant Purchase Agreement, dated as of June 23, 2012.
10.18.5	Amendment to Note and Warrant Purchase Agreement, dated as of November 8, 2012.
10.18.6	Form of Secured Convertible Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of February 1, 2011.
10.18.6.1#	The several Note Conversion Agreements, each dated as of June 28, 2013. [Pursuant to such Agreements, indebtedness was converted into 2,234,922 shares of our Series A Preferred Stock.]
10.18.6.2	Note Conversion Agreement dated as of June 28, 2013, among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988 and The Reiss Family GST Exempt Marital Deduction Trust. [Pursuant to this Agreement, indebtedness was converted into 35,923,845 shares of our Series A Preferred Stock.]
10.18.7	Form of Warrant to Purchase Preferred Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of February 1, 2011.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.19	Note and Warrant Purchase Agreement dated as of January 13, 2012 between us and various investors.
10.19.1	Omnibus Amendment Agreement dated as of November 8, 2012 between us and various investors.
10.19.2	Form of Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012.
10.19.2.1#	The several Note Conversion Agreements, each dated as of June 28, 2013. [Pursuant to such Agreements, indebtedness was converted into 309,743 shares of our Series A Preferred Stock.]
10.19.2.2	Note Conversion Agreement dated as of June 28, 2013, among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988 and The Reiss Family GST Exempt Marital Deduction Trust. (Included as Exhibit 10.18.6.2.)
10.19.3	Form of Warrant to Purchase Preferred Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012.
10.19.4	Form of Amendment of Warrant to Purchase Preferred Stock, dated as of September 13, 2013.
10.20	Form of Note and Warrant Purchase Agreement dated as of June 28, 2013 between us and various investors.
10.20.1	Form of Convertible Promissory Note, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013.
10.20.2	Form of Warrant to Purchase Common Stock, issued by us in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013.
10.21	Reimbursement Agreement dated as of July 11, 2013 among us, The Reiss Family Survivor's Trust UDT dated December 19, 1988, Edward Neff and Hale Biopharma Ventures, LLC.
10.21.1	Form of Warrant to Purchase Common Stock, issued by us in favor of various guarantors under the Reimbursement Agreement dated as of July 11, 2013.
10.21.2	Subordination Agreement dated as of July 11, 2013 between us and The Reiss Family GST Exempt Marital Deduction Trust UDT dated December 19, 1988.
10.22†###	Assignment and Exclusive Cross-License Agreement between us and Aegea Biotechnologies, Inc. dated June 2, 2012.
10.23+	Restricted Stock Unit Grant Notice / Agreement between us and Ivor Royston, dated as of November 8, 2010, as amended on February 15, 2012.
21.1	List of Subsidiaries.
23.1###	Consent of Mayer Hoffman McCann P.C.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
23.2##	Consent of Stradling Yocca Carlson & Rauth, P.C. (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page of the original Form S-1 filing)
#	Filed with the issuer's November 5, 2013 Amendment No. 2 to Registration Statement on Form S-1.
##	Filed with the issuer's November 20, 2013 Amendment No. 3 to Registration Statement on Form S-1.
###	Filed herewith.
+	Indicates management contract or compensatory plan.
†	Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

All exhibits not marked with a single, double or triple pound sign (#) were filed with the issuer's September 23, 2013 Registration Statement on Form S-1.

[\*\*] Confidential portions omitted and filed separately with the Securities and Exchange Commission.

## COLLABORATION AGREEMENT

THIS COLLABORATION AGREEMENT (the “*Agreement*”) is entered into as of November 2, 2012 (the “*Effective Date*”) by and between **BIOCEPT, INC.**, a California corporation having an address of 5810 Nancy Ridge Drive, Suite 150, San Diego, CA 92121 (“*Biocept*”), and **LIFE TECHNOLOGIES CORPORATION**, a Delaware corporation having an address of 5791 Van Allen Way, Carlsbad, California 92008 (“*Life Technologies*”).

**WHEREAS**, Life Technologies, through its Medical Sciences Division, is engaged in the development and commercialization of diagnostic systems, tests and laboratory services, including in oncology;

**WHEREAS**, Biocept has developed expertise and proprietary technology in enrichment, extraction and analysis of circulating tumor cells (CTCs) for use in laboratory developed tests used for the non-invasive and early stage detection and characterization of primary, metastatic or recurrent cancers; and

**WHEREAS**, Life Technologies and Biocept desire to collaborate so that Biocept will develop and commercialize one or more Tests, as defined herein, for Non-Small Cell Lung Cancer (NSCLC), using their respective technologies and expertise, on the terms and subject to the conditions set forth herein. Life Technologies and Biocept will both promote the test and perform different components of the test, and Life Technologies will provide test results in the form of reports to physicians.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and intending to be legally bound, the parties hereby agree as follows:

### 1. DEFINITIONS

**1.1 “Affiliate”** shall mean any company or entity controlled by, controlling, or under common control with a party hereto and shall include any company more than 50% of whose voting stock or participating profit interest is owned or controlled, directly or indirectly, by a party, and any company which owns or controls, directly or indirectly, more than 50% of the voting stock of a party.

**1.2 “Assay”** shall mean Biocept’s OncoCEE-LU™ (and OncoCEE-LU™ with Mutation Analysis) laboratory developed assay for characterization and profiling of CTCs from NSCLC patients, which shall incorporate, as Phase 1, CTC enumeration by cytokeratin and CD45 (and CEE-Enhanced™ when available), EML4/Alk1 fusions and EGFR amplification by fluorescence in situ hybridization (determined by Biocept); and as Phase 2, the additional detection of mutations for relevant genes, e.g., K-RAS, EGFR and B-RAF, as agreed by the parties, on captured CTCs and/or cell-free circulating DNA, as agreed by the parties, and employing technologies that potentially may include Biocept’s Selector technology, and any improvements or enhancements thereto, exclusive of new analytes (which are discussed in Section 3.5(f) under Collaboration Assays) or applications to primary screening.

**1.3 “Biocept Trademarks”** shall mean Biocept, Inc., “OncoCEE-LU™”, “OncoCEE™”, “CEE-Sure™”, CEE-Enhanced™”, and/or such other trademarks and trade names owned or licensed, and used, by Biocept and/or its Affiliates in the Territory to identify the Tests, in each case, whether or not registered.

**1.4 “Life Technologies Trademarks,”** shall mean Life Technologies™, Life Technologies Medical Sciences and/or such other trademarks and trade names owned or licensed and used by Life Technologies to identify the Tests, in each case, whether or not registered.

**1.5 “CLIA”** shall mean the Clinical Laboratory Improvement Amendments of 1988, as it may be amended from time to time.

**1.6 “Collaboration”** shall have the meaning provided Section 3.1.

**1.7 “Collaboration Assay(s)”** shall have the meaning provided in Section 3.5(e).

**1.8 “CPT Code”** shall mean the American Medical Association’s (“AMA”) “Current Procedural Terminology” as published in the AMA’s CPT Process Manual, Fourth Edition and any such future editions, for procedures used in performance of the Assay, and amounts reimbursed by Medicare for such procedures for location 99, as modified annually.

**1.9 “Designated Executive Officer”** shall mean the executive officers of each party designated in writing by each party as being responsible for resolving disputes related to the Collaboration, which shall initially be David Hale on behalf of Biocept and Ronnie Andrews on behalf of Life Technologies.

**1.10 “FDA”** shall mean the United States Food and Drug Administration, or any successor federal agency thereto.

**1.11 “HIPAA”** shall mean, collectively, the Health Insurance Portability and Accountability Act of 1996, as amended, and all regulations promulgated thereunder at 45 C.F.R. parts 160 through 164, and the Health Information Technology for Economic and Clinical Health Act of 2009 and related regulations and guidelines.

**1.12 “Intellectual Property Rights”** means all now or hereafter existing patents, patent applications, copyrights, trademarks (including service marks), trade secrets, know-how, mask work rights and design rights, whether registered or unregistered, and all rights or forms of protection of a similar nature having equivalent or similar effect to any of the foregoing, which may subsist anywhere in the world.

**1.13 “Launch”** shall mean formal commercial availability and offering to physicians of a Test, as mutually agreed upon by the parties.

**1.14 “Laws”** shall mean all federal, state and local laws and regulations that apply to this Agreement including, without limitation, (i) the Bayh-Dole Act (ii) the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.) (iii) the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)) (iv) the Stark Law (42 U.S.C. § 1395nn) (v) the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)) (vi) the civil False Claims Act (31 U.S.C. §§ 3729 et seq.) (vii) the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)) (viii) the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), (ix) the exclusion laws (x) SSA § 1128 (42 U.S.C. § 1320a-7) (xi) Medicare (Title XVIII of the Social Security Act), (xii) Medicaid (Title XIX of the Social Security Act); (xiii) the Clinical Laboratory Improvements Act of 1988 (CLIA); and (xiv) data security, protection and privacy laws in the applicable jurisdictions.

**1.15 “Professional Component”** shall mean the performance of the professional component of the steps of the Assay, which is the interpretation of results (generated in the Technical Component) of an Assay by a pathologist, and is covered by CPT codes from the Professional Fee Schedule with the modifier “26”.

**1.16 “Technical Component”** shall mean the performance of the technical component of the steps of the Assay, which is the physical performance of the Assay procedure up to the interpretation of results, and is covered by CPT codes from the Professional Fee Schedule without the modifier “26”, and typically with a modifier “TC”.

**1.17 “Term”** shall have the meaning provided in Section 11.1.

**1.18 “Test(s)”** shall mean the Assay, which is a laboratory developed test, and/or any Collaboration Assay which is added to this Agreement pursuant to Section 3.5(e), performed as a clinical reference laboratory test.

**1.19 “Territory”** shall mean the United States of America, and other countries of the world, contingent in the latter case on the parties agreeing in writing on an appropriate strategy to access them in accordance with Section 3.2.

**1.20 “Third Party(ies)”** shall mean any entity other than Biocept or Life Technologies or an Affiliate of Biocept or Life Technologies.

## **2. APPOINTMENT; LICENSES**

**2.1 Appointment.** Upon the terms and conditions set forth in this Agreement, Biocept hereby grants Life Technologies during the Term the non-exclusive right, as further defined in Section 2.3, to promote the Tests in the Territory and to perform the Professional Component of the Tests sold by the parties in the Territory, in accordance with the terms of this Agreement.

**2.2 Trademark Licenses.** The parties hereby grant to each other non-exclusive, fully-paid, royalty-free licenses to utilize the other party’s trademarks, as follows:

(a) **Biocept Trademarks.** To facilitate the promotion and performance of Tests, during the Term Biocept hereby grants Life Technologies a non-exclusive, royalty-free, non-transferable license to use the Biocept Trademarks solely for

use in connection with the promotion and performance of the Tests in the Territory. All materials associated with the Tests and used by Life Technologies in connection with the promotion of the Tests, including web-based, shall be co-branded with such Biocept Trademarks as approved by Biocept prior to distribution. All use of Biocept Trademarks by Life Technologies hereunder (including all goodwill arising as a result of such use) shall inure to the benefit of Biocept, and these rights, whether registered or not registered, at all times shall remain the sole property of Biocept. Biocept shall provide Life Technologies with copies of the Biocept Trademarks in an appropriate form for the uses contemplated in this Agreement. Life Technologies shall provide Biocept with samples of all proposed use of the Biocept Trademarks in advance of such proposed use and Biocept shall have the right to approve the appearance and placement of Biocept Trademarks by Life Technologies for the purpose of protecting and maintaining the standards of quality maintained by Biocept for products sold under the Biocept Trademarks and for use of the Biocept Trademarks. If Biocept at any time finds that Life Technologies is not in compliance with this Section, then Biocept may notify Life Technologies in writing of such deficiencies, and if Life Technologies fails to correct such deficiencies within thirty (30) days after receipt of such notice, Biocept may, at its election and in addition to any other remedies, terminate the license granted to Life Technologies with respect to the Biocept Trademarks. Life Technologies shall display the <sup>TM</sup> or <sup>®</sup> symbol, as directed by Biocept, in connection with Life Technologies' use of the Biocept Trademarks.

(b) **Life Technologies Trademarks.** To facilitate the promotion and performance of Tests, during the Term Life Technologies hereby grants Biocept a non-exclusive, royalty-free, non-transferable license to use the Life Technologies Trademarks solely for use in connection with the promotion and performance of the Tests in the Territory. Materials associated with the Tests and used by Biocept in connection with the promotion of Tests, including web-based materials, may be co-branded with such Life Technologies Trademarks as approved by the parties prior to distribution. All use of Life Technologies Trademarks by Biocept hereunder including all goodwill arising as a result of such use) shall inure to the benefit of Life Technologies, and these rights, whether registered or not registered, at all times shall remain the sole property of Life Technologies. Life Technologies shall provide Biocept with copies of the Life Technologies Trademarks in an appropriate form for the uses contemplated in this Agreement. Biocept shall provide Life Technologies with samples of all proposed use of the Life Technologies Trademarks in advance of such proposed use and Life Technologies shall have the right to approve the appearance and placement of Life Technologies Trademarks by Biocept for the purpose of protecting and maintaining the standards of quality maintained by Life Technologies for products sold under the Life Technologies Trademarks and for use of the Life Technologies Trademarks. If Life Technologies at any time finds that Biocept is not in compliance with this Section, then Life Technologies may notify Biocept in writing of such deficiencies, and if Biocept fails to correct such deficiencies within thirty (30) days after receipt of such notice, Life Technologies may, at its election and in addition to any other remedies, terminate the license granted to Biocept with respect to the Life Technologies Trademarks. Biocept shall display the <sup>TM</sup> or <sup>®</sup> symbol, as directed by Life Technologies, in connection with Biocept's use of the Life Technologies Trademarks.



**2.3 Exclusivity.** During the Term, the parties will promote and perform Tests for the clinical testing market on a non-exclusive basis in the Territory, except as otherwise provided for below. Biocept will have sole responsibility for performing the Technical Component of all Tests sold by the parties, until and unless Life Technologies obtains the right from Biocept to independently develop its own Tests in accordance with all applicable FDA regulatory requirements, as provided for in Section 7.1. Life Technologies will be authorized to perform the Professional Component of all Tests sold by the parties, although Biocept may engage other groups in promotion, marketing and performance arrangements for the Tests, at the discretion of Biocept. Biocept shall provide thirty (30) days written notice to Life Technologies before entering into any such promotion, marketing and performance arrangement.

### **3. COLLABORATION**

**3.1 Purpose.** During the Term, the parties agree to cooperate and collaborate to develop, promote and commercialize the Tests for the clinical testing market in the Territory and in accordance with the terms of this Agreement (the “**Collaboration**”). The principal objective of the parties hereunder is to maximize the commercialization of the Tests in the Territory. The parties shall deploy each of their respective sales forces in accordance with the terms of this Agreement in an effort to promote the Tests in the Territory in the manner as agreed to by the parties, under the direction of the Joint Steering Committee.

**3.2 Commercialization of Tests Outside the USA.** At any time for up to two (2) years after the Effective Date, should Life Technologies desire to offer for sale any Test outside the USA, it shall first discuss with Biocept an appropriate strategy and plan for such effort. Such strategy and plan may involve the development of, and obtaining all applicable regulatory authorizations for, an in vitro diagnostic kit, instruments or similar systems, in collaboration with Biocept (with funding support, and more fully described in Section 7.2), such strategy and plan to be reduced to writing and approved by the parties. If such written plan is not approved by the parties within two (2) years of the Effective Date, the Territory shall revert to only the USA, unless otherwise agreed to by the parties.

**3.3 Life Technologies Responsibilities.** Life Technologies shall use commercially reasonable efforts to promote the Tests in the Territory, in accordance with Section 3.2, using sales channels and methods, and adhering to substantially similar standards that it generally employs with respect to its laboratory developed tests. Without limiting the foregoing, Life Technologies’ responsibilities with respect to marketing and promotion of the Tests in the Territory during the Term shall include the following:

(a) **Life Technologies Customers.** Life Technologies shall use commercially reasonable efforts to promote the Tests to the appropriate healthcare professionals.

(b) **Test Performance.** Life Technologies shall have the responsibility, subject to its capacity to support in its reasonable discretion (of which capacity Life Technologies shall notify Biocept in writing at least sixty (60) days before launch of the Assay, and use diligent efforts to notify Biocept at least thirty (30) days before discovery of any decreases or increases in such capacity), for performing the Professional Component of the Assays sold by either party in the Territory. In particular, the laboratory director of the Life Technologies CLIA laboratory will be responsible for issuing and signing off on the report.

**(c) Sales, Marketing and Customer Service.**

(i) Life Technologies shall, at its sole expense and in accordance with Section 2.2, develop and deliver to customers marketing materials for the Tests. Life Technologies shall use, as appropriate, Biocept's "OncoCEE-LU™", "OncoCEE™", "CEE-Enhanced™" and "CEE-Sure™" brand and the Biocept corporate name and logo, together with any Life Technologies branding, as part of the marketing materials for the marketing of the Tests and, where appropriate, in its other public presentations and disclosures concerning the Assay or Tests. Biocept shall have the right to review all such materials prior to their initial use.

(ii) Life Technologies shall cause its sales force to use commercially reasonable efforts to promote the Tests.

(iii) Life Technologies shall use commercially reasonable efforts to promote the sale of the Tests by including the Tests in its menu of services and by incorporating marketing materials regarding the Tests into its own marketing materials.

(iv) Life Technologies shall keep Biocept reasonably informed of its planned marketing activities with respect to the Tests to allow Biocept to forecast its needs for reagents, equipment, laboratory space, personnel, computing, and testing reporting capabilities, including at each Joint Steering Committee meeting as indicated in Section 4, and will discuss and consider in good faith Biocept's suggestions for marketing the Tests.

(v) Life Technologies will provide customer service and support for the Professional Component of the Tests using substantially similar methods and adhering to substantially similar standards that it generally employs with respect to its other products and tests.

**(d) Samples and Logistics.**

(i) Life Technologies will be responsible for the logistics associated with its marketing efforts and performance of the Professional Components of the Tests; provided, however, that Biocept will send the sample collection systems directly to customers identified by Life Technologies who order the Test, at Life Technologies' expense. Biocept will further work with Life Technologies to facilitate transport of collected samples from the customer to Biocept's CLIA laboratory. Life

Technologies will work collaboratively with Biocept on patient referral, billing and collections in accordance with Section 3.5(c) (iii), reporting of results and reporting quality control, and insurance or patient reimbursement.

(e) **Demand Forecast.** Within sixty (60) days of the Effective Date, Life Technologies will prepare a draft one-year rolling forecast of Life Technologies' expectation for physician requests for the Assay (the "**Demand Forecast**"), broken down into quarterly demand for the Assay (with respect to each quarter, the "**Quarterly Forecast**") which will be attached hereto as **Exhibit A**, and will be finalized three (3) months before Launch. Beginning on the first day of the second (2<sup>nd</sup>) full calendar quarter following the date of Launch, the Demand Forecast shall be updated on a quarterly basis. The Demand Forecast and Quarterly Forecasts shall be a good faith but non-binding forecast. In the event the parties develop a Collaboration Assay under the terms of this Agreement, demand for such Collaboration Assay shall be included in the Demand Forecast at all times following the Launch of such Collaboration Assay. A Performance Standard, mutually agreed to in accordance with Section 3.5(i), shall take effect beginning with the second (2<sup>nd</sup>) full calendar quarter after the launch of any Test.

(f) **Technical Developments.** Life Technologies shall keep Biocept fully informed as to all discoveries and technical developments (including, without limitations, any inventions) made by Life Technologies during the Term related to the Assay or Tests.

(g) **Billing, Reporting, Auditing.**

(i) In all cases where Life Technologies performs the Professional Component of the Assay, Life Technologies shall be responsible for billing the patient, the provider and/or the payer for the Test, including both the Technical Component and the Professional Component of the Assay, and the collection of such amounts with respect to each Test performed. Biocept shall bill Life Technologies directly once a month for the Technical Component of each Assay (including the cost for sample collection in accordance with Section 3.5(b)), based on pricing and reimbursement as agreed by the parties through the Joint Steering Committee within sixty (60) days of the Effective Date, generally based on each applicable CPT Code actually used in the performance of such Technical Component, employing the Medicare rates for the applicable year as described on **Exhibit B** for the initial one (1) year period, and Life Technologies shall pay Biocept within sixty (60) days following the invoice date. The parties shall disclose actual reimbursement for each Test, and shall reconcile or "true-up" any differences between the amounts actually received by Life Technologies for each billing item or code and amounts paid to Biocept on a quarterly basis. If the allocation of reimbursement is ambiguous with respect to billing codes or a Technical Component/Professional Component split, amounts received by Life Technologies that differ from the amounts agreed by the parties, or Medicare rates, shall be shared by the parties on the same ratio as the Technical Component/Professional Component ratio for Medicare. The Medicare rates used by the parties as the basis for determining the amount Life Technologies will pay Biocept for the Technical Component of the Assay before the quarterly true-up will be adjusted annually at the beginning of the calendar year to reflect

changes to such Medicare rates. Should Medicare change the basis for reimbursement of the Assay, the parties shall agree to negotiate a structure for revenue sharing that generally accomplishes the result achieved above. Both parties agree to strictly adhere to all applicable Laws with respect to billing practices.

(ii) This Section 3.3(g) shall survive any termination or expiration of this Agreement for at least twelve (12) months following the effective date of such termination or expiration.

**3.4 Biocept Responsibilities.** Biocept shall use commercially reasonable efforts to promote the sale of the Tests in the Territory, using at least the same sales channels and methods and adhering to at least the same standards that it generally employs with respect to its other clinical tests. Without limiting the foregoing, Biocept's responsibilities during the Term shall include the following:

(a) **Biocept Customers.** Biocept shall use commercially reasonable efforts to promote the Tests to appropriate healthcare professionals.

(b) **Assay Performance.** Biocept shall be responsible for performing all Technical Components of all Assays sold by either party unless and until the parties agree to enable Life Technologies to independently develop, validate and perform the Test at Life Technologies' CLIA laboratory, in accordance with all applicable FDA regulatory requirements and Section 7.1. Until such point of transfer, Biocept shall comply with all CLIA requirements, including validation of the Assay.

**(c) Sales, Marketing and Customer Service.**

(i) Biocept shall cause its sales force to promote the Assay.

(ii) Biocept shall keep Life Technologies reasonably informed of its planned marketing activities with respect to the Assay to allow Life Technologies to forecast its needs for equipment, space, personnel, computing, and test reporting capabilities, including at each Joint Steering Committee meeting as indicated in Section 4, and will discuss and consider in good faith Life Technologies' suggestions for marketing the Assay.

(iii) Biocept will provide customer service and support for the Assay using substantially similar methods and adhering to substantially similar standards that it generally employs with respect to its other tests.

(d) **Samples and Logistics.** Biocept will be responsible for the logistics associated with its own marketing efforts and performance of the Technical Component of the Assay, including distribution of shipping materials and sample collection systems by its sales representatives, patient referral and customer service.

**(e) Training and Education.**

(i) Biocept shall provide sales and technical training and technical support, including assistance with customer education and customer consultations, to Life Technologies' personnel, with the frequency and content of the training to be determined by agreement between Biocept and Life Technologies.

(ii) Biocept will share its service educational materials and scientific publications to utilize in patient education with Life Technologies, and hereby grants Life Technologies rights to use such materials as are reasonably necessary for Life Technologies to carry out its obligations under this Agreement. Life Technologies may not alter or revise these materials without the prior written consent of Biocept.

**(f) Regulatory Approval.** Biocept has licenses enabling it to perform and obtain reimbursement for the Assay in all states in the Territory except New York, where it is currently seeking such license. Biocept will maintain all such licenses which are reasonably required to perform the Assay during the Term. For any Collaboration Assay, Biocept will use commercially reasonable efforts to obtain or maintain licenses enabling it to perform such Collaboration Assay and obtain reimbursement therefore, in accordance with each amendment to this Agreement entered in accordance with Section 3.5(f). Life Technologies will cooperate with Biocept so that Life Technologies' marketing and sales efforts are conducted only in those states or regions of the Territory in which Biocept has obtained any necessary regulatory licenses to provide Tests.

**(g) Technical Developments.** Biocept shall keep Life Technologies fully informed as to all discoveries and technical developments (including, without limitations, any inventions) made by Biocept during the Term related to the Tests.

**3.5 Joint Responsibilities.** The parties shall use commercially reasonable efforts to cooperate and collaborate to develop the market for the Tests in the Territory. Without limiting the generality of the foregoing, the parties shall collaborate to provide the following:

**(a) Test Development.** The parties shall mutually agree on the content and composition of Phase II of the Assay, and any Collaboration Assays as defined in Section 3.5(f), including specific analytes to be included in the Assay. Consideration for selection of analytes shall include medical need, clinical utility, technical feasibility, costs, reimbursement, and intellectual property status, e.g., the need for Third Party licenses to specific analytes. The parties shall agree on the Phase II Assay content at least six (6) months before anticipated Launch.

**(b) Test Materials and Shipping.** Subject to Section 3.3(c)(i), Life Technologies shall design and order all test materials, including test requisition forms, test reports and collateral sales and marketing (advertising and promotional) materials to be used by Life Technologies, which shall be approved by Biocept prior to use. Biocept shall design, order and provide to Life Technologies the collection systems to be used by Life Technologies, and Life Technologies shall pay for such collection systems used by

its sales representatives under this Agreement at cost (direct materials and direct labor) plus ten percent (10%), as well as shipping costs of collection systems from ordering physicians to Biocept.

**(c) Performance of Tests.**

(i) The parties will work together to develop a plan to implement detailed operation protocols for the Test within [\*\*] of the Effective Date for each aspect of sample logistics, including ordering, shipping, accessioning, sample handling, testing, data generation, data evaluation and reporting. These sample logistics shall be agreed upon by the parties through the Joint Steering Committee and, once agreed upon by the parties in writing, deemed to be attached hereto as Exhibit C without any additional action required on the part of either party. Information, data and images shall be transferred between the parties as indicated for this purpose, and the parties will seek to make their respective laboratory information management systems and data transfer capabilities compatible. Life Technologies' lab director at the CLIA lab will sign off on the reports for Tests.

(ii) If Life Technologies desires to utilize the Tests in support of any clinical trial or research program for a pharmaceutical or biotechnology company(ies) in the Territory, Life Technologies shall notify Biocept in writing of such desired use. The terms and conditions (including pricing and revenue sharing) of each such use shall be covered by a separate written agreement which the parties agree to negotiate in good faith.

(iii) Each party will use commercially reasonable efforts to support the other in the account to best meet the needs and expectations of each customer.

**(d) Communication Plan.** Life Technologies and Biocept shall develop a communications plan through the Joint Steering Committee for the announcement and ongoing promotion of the Tests to customers, with all communication plan materials, including test requisition forms, being co-branded with Biocept and Life Technologies corporate names and logos in accordance with Sections 2.2 and 3.3(c)(i).

**(e) Data Sharing.** Life Technologies and Biocept have entered into this Agreement to, among other things, establish individual databases of results from the Tests performed, which databases will include patient information such as demographic, disease characterization, treatment and outcome information. To that end, to the extent permitted by applicable law and as mutually agreed by the parties, where available each party will share all patient data, Test data and results, and corresponding tissue data with the other party, as well as any follow up or outcome data that may become available or provided by the physician or patient for Tests performed and will cooperate in good faith with the other party to agree upon procedures for sharing such information. Such information may be used only for longitudinal reporting, outcomes correlation and related research, shall be handled in accordance with all applicable Laws, including, without limitation, HIPAA, and applicable institutional review board guidelines, and shall not be used for the purpose of obtaining information about the other party's clients or customers. To the extent feasible, all such information will be properly de-identified.

[\*\*] Confidential portions omitted and filed separately with the Commission.

(f) **Collaboration Assays.** During the Term, Biocept shall keep Life Technologies reasonably apprised of its plans to add analytes to the Assay. In addition, Life Technologies may desire for Biocept to develop a specific new analytes for the Assay (for example, the inclusion of additional mutations to the mutation analysis component of the Assay), to be offered by the parties as an additional Test under this Agreement. In either case, the parties shall negotiate in good faith an amendment to this Agreement that will govern the development (as needed) and commercialization of such Tests with new analytes (each a **“Collaboration Assay”**), which amendment may include financial support, contributions of and access to each party’s technology and/or clinical samples, milestones, timing of the development effort, exclusivity and ownership rights. Any such agreed upon Collaboration Assay development shall be performed by Biocept or jointly as the parties may agree. Once the parties have agreed upon a plan relating to the development of a particular Collaboration Assay, if development is needed (each, a **“Project”**), the parties shall reduce such agreement to writing, which shall include a project plan which will set forth each party’s obligations with respect to the Project (each, a **“Project Plan”**) and thereafter, such Collaboration Assay shall be deemed a Test for all purposes under this Agreement and shall be subject to the terms of this Agreement as amended. Each such Project Plan shall be attached as a part of Exhibit D to this Agreement following written acceptance thereof by both parties without any additional action required on the part of either party. Any amendments or revisions to a Project Plan shall be mutually agreed upon by the parties in writing.

(g) **Costs and Expenses.** Unless otherwise specified herein or in a Project Plan attached hereto, each party shall perform its activities under this Agreement at its sole cost and expense.

(h) **Training and Education.**

(i) The parties shall work together to develop and implement a training program for client services and the sales and marketing representatives of each party to ensure that a clear and consistent message is delivered to all prospective customers. Following such implementation, each party agrees to train its client services and sales and marketing representatives in accordance with such training program.

(ii) Representatives of each party, where deployed, shall each educate physicians, clinical and support personnel on the Tests, their applications and benefits, and the procedures for providing samples for the Tests. The Joint Steering Committee will approve all presentation and meeting materials. In addition, the parties will each be responsible for providing customer support related to test logistics, billing and reimbursement, and for establishing a call center to handle inquiries related to the Tests. For purposes of clarity, the parties acknowledge and agree that Life Technologies will not be required to establish a dedicated web portal, but all results of Tests will be made available through an existing Life Technologies portal solution, once commercially available for use, as determined by Life Technologies at its sole discretion. Technical or

process questions regarding the Tests received by Life Technologies can be referred to Biocept. Each party will cover its own costs related to physician education, customer support, and any travel related thereto and comply with all federal and state regulations regarding the same.

(i) **Performance Standards.** Each party shall conduct its activities under this Agreement and any Project Plan in a professional and workmanlike manner, and in compliance in all material respects with the requirements of applicable Laws and regulations, to attempt to achieve the objectives of this Agreement efficiently and expeditiously. Each party shall contribute such personnel and resources, and shall maintain such laboratories and other facilities, as are reasonably necessary to carry out the activities to be performed under this Agreement, including any Project Plans. In conformity with standard industry practices and the terms and conditions of this Agreement, each party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to activities conducted by such party under this Agreement, including any Project Plans. In addition, the parties shall work together to establish minimum agreed upon performance standards with respect to the promotion, sales and performance of the Tests, including the Demand Forecast, and the timely supply, accuracy, reliability and reporting of the Tests, as well as responsiveness to customer inquiries related to the Tests throughout the Territory (collectively, “**Performance Standards**”). In the event that one or more Performance Standards are not met by a party, the parties will work quickly and efficiently to (i) identify the cause of the failure, (ii) develop a plan to remediate the issue, and (iii) implement the remediation plan. If the parties are unable to successfully resolve a Performance Standards issue by this procedure, such failure to maintain Performance Standards shall constitute a material breach by the party failing to maintain such Performance Standards, and the other party may terminate this Agreement in accordance with Section 11.2.

(j) **Bundling.** Neither party shall bundle its assays (including the Tests) with any assays of the other party, without the prior written approval of that party.

#### **4. JOINT STEERING COMMITTEE**

**4.1 Purpose and Membership.** Promptly following the Effective Date, Biocept and Life Technologies will create a Joint Steering Committee for the purpose of facilitating communications between the parties regarding, and providing direction and leadership to, the Collaboration. The Joint Steering Committee shall be composed of six (6) representatives, three (3) each from Biocept and Life Technologies, each of whom shall have appropriate experience, knowledge and authority within such party’s organization to carry out the duties and obligations of the Joint Steering Committee. Each party will designate one of its representatives as the primary contact for that party with respect to Joint Steering Committee-related matters, and such representatives shall serve as co-chairpersons of the Joint Steering Committee. Each party may change its representatives to the Joint Steering Committee or its primary contact from time to time in its sole discretion, effective upon notice to the other party of such change. These representatives shall have appropriate technical credentials, experience and knowledge. A reasonable number of additional representatives of a party may attend meetings of the Joint Steering Committee in a non-voting capacity.



**4.2 Duties.** The Joint Steering Committee shall meet in person or by teleconference or videoconference no less than monthly during the Term or as otherwise mutually agreed by the parties from time to time, with attendees other than Joint Steering Committee members permitted to participate in or observe the meetings. The Joint Steering Committee shall be responsible for (a) monitoring the progress of the Collaboration, including discussions relating to Collaboration Assays, (b) physician education with respect to the Tests, (c) marketing, sales and account coordination, (d) any regulatory inquiries or requirements and other issues that affect the availability of the Tests, and (e) reimbursement issues (including annual review of relevant CPT Codes and changes thereto), logistical considerations, and other topics as necessary. The Joint Steering Committee shall serve as the principal forum for each party to (i) keep the other party informed of the results of its Collaboration activities; (ii) to discuss Test commercialization strategies, and (iii) generally to encourage and facilitate ongoing cooperation between the parties with respect to the Collaboration, including the business relationship and/or any other matter relating to the Collaboration and resolving disputes between the parties with respect to Intellectual Property Rights; provided, however, that (A) nothing in this Agreement shall limit either party's right to seek immediate equitable or injunctive relief where appropriate without any obligation to first submit the dispute to the Joint Steering Committee; and (B) any decision concerning medical necessity and patient care with respect to Test sold by or performed on behalf of the parties shall be the responsibility of each party's Medical Director, with the two Medical Directors working together to coordinate efforts and address concerns.

**4.3 Decisions; Disputes.** Decisions of the Joint Steering Committee shall be made by unanimous vote, with each party's representatives on the Joint Steering Committee collectively having one vote. In the event that the Joint Steering Committee cannot or does not, after good faith efforts, reach agreement on an issue, such issue shall first be referred to the Designated Executive Officers, who shall meet promptly thereafter and shall attempt in good faith to resolve such issue. In the event that the Designated Executive Officers cannot or do not, after good faith efforts, reach agreement on an issue, the issue shall be submitted to voluntary mediation. The Designated Executive Officers of each party shall select a mediator who is an expert with no less than seven years of experience in the subject matter to which the dispute relates. In the event that the Designated Executive Officers of the parties are unable to agree upon a mediator within twenty (20) days, then the Designated Executive Officers shall contact the San Diego County office of JAMS to select a mediator from the JAMS panel. If they are unable to agree, JAMS shall provide a list of three available mediators and each party may strike one. The remaining one will serve as the mediator. The mediation shall be conducted under JAMS rules. The parties agree that they shall share equally the cost of the mediation filing and hearing fees, and the cost of the mediators that constitute the panel. Each party shall bear its own attorneys' and expert fees and all associated costs and expenses.

## 5. REGULATORY COMPLIANCE

**5.1 Compliance with Laws.** Biocept and Life Technologies and their respective Affiliates each agree to perform their respective obligations under this Agreement in compliance with all applicable Laws, in the Territory, including but not limited to applicable regulations, rules, and policies of third party payers that pay for the Assay.

**5.2 Privacy.** Biocept and Life Technologies and their respective Affiliates agree to protect the privacy and provide for the security of any information that relates to a patient's past, present, or future physical or mental health or condition in accordance with HIPAA, and any other applicable federal and state privacy laws and regulations in the Territory. Each party agrees to execute one or more Business Associate Agreements (as defined under HIPAA) as the other party, or its providers or payers, may from time to time request.

**5.3 Licenses and Certifications.** Biocept and, to the extent applicable, Life Technologies shall have at all times during the Term, all necessary federal, state and local licenses, qualifications and certifications to operate a laboratory and perform their respective components of the Test(s), including, but not limited to, state laboratory licenses, CLIA certification, CAP (College of American Pathologists) certification, FDA registration, and any other licenses or certification required by state and/or federal law. All Assays performed by Biocept, and, to the extent applicable, Life Technologies, shall be in accordance with applicable state and federal testing requirements for clinical reference laboratories.

## 6. MATERIALS TRANSFER

In order to facilitate the Collaboration, either party may provide to the other party certain biological materials or chemical compounds including, but not limited to, samples (collectively, "**Materials**") for use by the other party in furtherance of the Collaboration. Except as expressly provided under this Agreement, all such Materials delivered to the other party will remain the sole property of the supplying party, will be used only in furtherance of the Collaboration and solely under the control of the other party, will not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying party, and will not be used in research or testing involving human subjects except as permitted by applicable law. The Materials supplied hereunder must be used with prudence and appropriate caution in any experimental work and in accordance with all applicable laws.

## 7. OPTIONS AND FUTURE DISCUSSIONS

**7.1 Option to License Assay.** If Biocept does not obtain at least ten million dollars (\$10,000,000) in equity financing by December 31, 2012, then Life Technologies shall have the non-exclusive option, exercisable by written notice to Biocept given no later than January 15, 2013, to negotiate with Biocept for a license (unless the parties mutually agree to a different transaction structure) to all necessary Intellectual Property

Rights and know-how to independently commercialize the Assay in accordance with applicable Laws. Biocept will provide notice to Life Technologies on December 31, 2012 if the conditions for the option apply, and if Life Technologies delivers written notice of exercise of such right of negotiation to Biocept on or before January 15, 2013, the parties will negotiate in good faith to conclude a license agreement no later than February 28, 2013. If such license has not been entered into by the parties by February 28, 2013, there are no further obligations for either party under this Section 7.1.

**7.2 Option for System Development.** The parties have discussed potential adaptation of the Assay to an in vitro diagnostic format, based on a “system” concept that could include specially manufactured equipment, consumables and reagents that would be sold to physicians and laboratories, and linked to the “informatics engine” that Life Technologies is developing. Such systems may be used to commercialize the Assay outside the USA. Biocept grants to Life Technologies a non-exclusive option, exercisable during the two (2) year period beginning on the Effective Date, to develop plans, and negotiate with Biocept, for the co-development with Biocept of such systems for the Assay, employing or based on Biocept technologies. Such agreement is expected to include some or all of the following components: an upfront license fee, R&D funding, development and commercial milestone payments, royalties and/or revenue sharing, and supply/sale to Life Technologies by Biocept of proprietary components and consumables.

## **8. INTELLECTUAL PROPERTY**

**8.1 Existing Technology.** Each party acknowledges that the other party owns certain technology and Intellectual Property Rights which have been independently developed by, or at the request of, such other party, whether prior to, during or subsequent to the Term. Except as expressly provided in this Agreement, neither this Agreement nor the activities performed hereunder, shall give either party any rights or interest in or to the technology or Intellectual Property Rights of the other party (or of any Materials provided by such party). Each party owns, and shall continue to own, all right, title and interest in and to its respective technology, including, without limitation, all Intellectual Property Rights relating thereto. Without limiting the generality of the foregoing, at all times during and after the Term, Biocept shall own all rights to its CEE™ technology, Selector technology (if utilized) and any improvements related thereto, generated during the performance of this Agreement. Biocept and Life Technologies shall promptly notify the other in writing upon becoming aware of any alleged or threatened third party infringement of any Intellectual Property Rights related to the Tests. Biocept shall have the right to bring and control any action or proceeding with respect to any such infringement at its own expense and by counsel of its own choice. If Biocept elects not to bring any such action or proceeding with respect to such infringement, it shall promptly notify Life Technologies of the same and agrees to consider, in good faith a request by Life Technologies to bring any such action or proceeding. Any agreement allowing Life Technologies to bring such action or proceeding on behalf of Biocept shall be set forth in a separate written agreement between the parties. Except as expressly provided above, the parties shall be under no obligation to enforce any of their Intellectual Property Rights against any actual or threatened Third Party infringements.

**8.2 Biocept Technology.** Without limiting the generality of the foregoing, Biocept owns, and Life Technologies acknowledges Biocept's ownership of, (i) the Assay and the Selector technology, and (ii) all Intellectual Property Rights in the Assay and the Selector technology, and Life Technologies agrees that it shall not do or suffer to be done any act or thing or undertake any action anywhere that in any manner might infringe, or impair the validity, scope, or title of Biocept in the Assay, the Selector technology or Intellectual Property Rights owned by Biocept. Nothing herein shall limit Life Technologies' ability to prosecute fully any and all Intellectual Property Rights owned by Life Technologies with any patent office or related government agency or to respond fully to any government agency inquiry with respect to its Intellectual Property Rights, products, and services.

**8.3 New Technology.** In the course of the activities conducted by the parties, Biocept and/or Life Technologies may conceive of inventions or discoveries or create works that constitute intellectual property and may be patentable or registerable as a copyright or other intellectual property right (all of the foregoing, including such intellectual property rights therein, collectively, "**Developments**"). Inventorship of all inventions and discoveries, whether or not patentable, will be determined in accordance with United States patent laws. Authorship of all copyrightable works will be determined in accordance with United States copyright laws. Subject to Section 8.2, as between the parties, Developments will be owned consistent with such determination of inventorship or authorship. To the extent any Development owned by Life Technologies relates directly to the practice of, or constitutes an improvement to, the Assay, Life Technologies hereby grants to Biocept, during the Term of this Agreement, and, except in the case of termination of this Agreement by Life Technologies for Biocept's uncured material breach, after expiration or termination of this Agreement, a non-exclusive, worldwide, royalty-free, fully-paid license, including the right to sublicense, under Life Technologies' Intellectual Property Rights in such Developments, solely to develop, make, have made, use, sell, have sold, offer for sale, import, perform and provide the Assay. To the extent any Development owned by Biocept relates directly to the practice of, or constitutes an improvement to, the Assay, Biocept hereby grants to Life Technologies, during the Term of this Agreement, a non-exclusive license under Biocept's Intellectual Property Rights in such Development, solely to promote the Assay in the Territory and to perform the Professional Component of the Assay sold by the parties in the Territory, in accordance with the terms of this Agreement.

**8.4 Technology Licenses.** To the extent that any Third Party Intellectual Property Rights related to the capture and detection of CTCs must be licensed to perform the Assay, such royalty shall be paid by Biocept. To the extent that either party owns Intellectual Property Rights to specific biomarkers, targets, kits, dyes or technology utilized in the Assay other than for the capture and detection of CTCs, it will, to the extent it is able, grant during the Term of the Agreement, a non-exclusive license to the other party to practice these Intellectual Property Rights for the Assay. To the extent that either party has licensed or will license Intellectual Property Rights from Third Parties related to specific biomarkers, targets, kits, dyes or technology utilized in the Assay other than for the capture and detection of CTCs, it will, to the extent it is able, grant, during the Term of the Agreement, a non-exclusive license to the other party, or ensure that the

other party is covered under its license, to practice these Intellectual Property Rights for the Assay. In the event of the foregoing, then, subject to Section 8.5, the parties agree to negotiate in good faith an allocation of expenses for such Third Party licenses directly associated with the Assay.

**8.5 Infringement.** If any Third Party claims or brings an action alleging that performance of the Assay or Test by Biocept or Life Technologies or their Affiliates under this Agreement infringe (directly or indirectly) any of such Third Party's patent rights, Biocept shall use commercially reasonable efforts to address such claims. If Biocept determines to seek a license or otherwise obtain the right to use such Third Party intellectual property rights on behalf of Biocept and Life Technologies, then (i) if the Third Party intellectual property rights relate to the capture and detection of CTCs or the Phase I Assay analytes, then Biocept shall bear the costs of such licenses, including the payment of licensing fees, royalties or other payments, or (ii) if the Third Party intellectual property rights relate to specific biomarkers, targets, kits, dyes or technologies for the Phase II Assay, then the parties agree to negotiate in good faith an allocation of costs for such licenses, including payment of licensing fees, royalties or other payments that may be due to such Third Party, unless the parties agree otherwise in writing. If Biocept and Life Technologies determine to seek a license or otherwise obtain rights to use Third Party intellectual property rights for any Collaboration Assay(s), the parties similarly agree to negotiate in good faith an allocation of costs for such licenses, including payment of licensing fees, royalties or other payments that may be due to such Third Party, unless the parties agree otherwise in writing.

**8.6 Data and Results.** All data and results from performance of a Test on samples provided by Life Technologies shall be used by the parties solely to the extent necessary to perform its obligations under this Agreement and in accordance with Section 3.5(d).

#### **8.7 Trademarks.**

(a) Biocept shall be responsible for and bear the expense of any filing, prosecution, maintenance and enforcement of the Biocept Trademarks as it may determine in its sole discretion, without obligation. Life Technologies shall not, during the Term or thereafter, use or seek to register the trademarks or any trademark or trade name similar to or confusing with the Biocept Trademarks, or any translation thereof, in any jurisdiction. Life Technologies agrees that, if Life Technologies at any time obtains, in any jurisdiction, any right, title or interest in any mark, symbol or phrase which shall be identical to, similar to or likely to be confused with any Biocept Trademark or any translation thereof, then Life Technologies shall have acted or shall act as an agent and for the benefit of Biocept for the limited purpose of obtaining such registrations and assigning such registration (and all right, title and interest in such mark, symbol or phrase) to Biocept.

(b) Life Technologies shall be responsible for and bear the expense of any filing, prosecution, maintenance and enforcement of the Life Technologies Trademarks as it may determine in its sole discretion, without obligation. Biocept shall

not, during the Term or thereafter, use or seek to register the trademarks or any trademark or trade name similar to or confusing with the Life Technologies Trademarks, or any translation thereof, in any jurisdiction. Biocept agrees that, if Biocept at any time obtains, in any jurisdiction, any right, title or interest in any mark, symbol or phrase which shall be identical to, similar to or likely to be confused with any Life Technologies Trademark or any translation thereof, then Biocept shall have acted or shall act as an agent and for the benefit of Life Technologies for the limited purpose of obtaining such registrations and assigning such registration (and all right, title and interest in such mark, symbol or phrase) to Life Technologies.

## **9. REPRESENTATIONS AND WARRANTIES**

**9.1 Mutual Representations and Warranties.** Each party represents and warrants to the other that: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; (c) this Agreement is legally binding upon it, enforceable in accordance with its terms; and (d) the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

### **9.2 Biocept Warranties on Assay.**

(a) As of the Effective Date, the Assay employs Biocept's most current CTC-based technology, and will be validated for performing CTC enumeration and the detection of the indicated analytes in the Assay on a timeline as agreed by the parties within sixty (60) days of the Effective Date.

(b) Biocept represents and warrants to Life Technologies that: (1) the Assay constitutes an original work of Biocept; and (2) except as previously disclosed to Life Technologies, Biocept is the lawful owner or licensee of all materials used in connection with the development of the Assay, and Biocept has the rights to make, use and sell the Assay, and to allow Life Technologies to use the results of the Technical Component of the Assay to perform the Professional Component of the Assay, and to sell the Assay.

(c) Biocept has full power and authority and has obtained all Third Party consents, approvals, assignments and/or other authorizations required to enter into this Agreement and to carry out its obligations hereunder.

(d) There are no existing contracts, agreements, commitments, proposals, offers, or rights with, to, or in any person to acquire any of the rights under the Assay which would prevent or materially and adversely alter the performance of the obligations hereunder.

**9.3 Third Party Infringement.** In the event that the Tests, or any part thereof becomes the subject of any claim, suit or proceeding for infringement of the Intellectual Property Rights of any Third Party, or if the Test, or any part thereof, is held or otherwise determined to infringe any Intellectual Property Rights of any Third Party such that Biocept can no longer perform its obligations under this Agreement, Biocept shall in its sole discretion either: (1) secure for itself and Life Technologies the right to continue using the Test in accordance with Section 8.4; (2) replace or modify the Test to make it non-infringing without degrading its performance or utility; or (3) notify Life Technologies that it will perform neither (1) nor (2), in which case either party shall thereafter have the right to terminate this Agreement immediately upon written notice to the other party. Notwithstanding the foregoing, and subject to Section 8.5, the indemnification rights of Life Technologies with respect to the Tests as set forth in Section 12.2 shall survive such termination.

**9.4 Disclaimer.** Except as expressly set forth herein, THE TECHNOLOGY, MATERIALS AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED “AS IS,” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

**9.5 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section shall neither (a) apply to any liability for damages arising from breach of any obligations of confidentiality under Article 10, nor (b) limit the indemnification obligations of the parties arising under Article 12 of this Agreement.

## **10. CONFIDENTIALITY**

**10.1 Confidential Information.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, each party agrees that, during the Term and for five (5) years thereafter, such party (the “**Receiving Party**”) shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose, other than as expressly provided for in this Agreement, any information furnished to it by or on behalf of the other party (the “**Disclosing Party**”) pursuant to this Agreement (collectively, “**Confidential Information**”). The Receiving Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its, and its Affiliates’, employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party will promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information.

**10.2 Exceptions.** Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party at the time of receiving such information, as evidenced by its written records; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the use of Confidential Information of the Disclosing Party, as evidenced by the Receiving Party's written records maintained in the ordinary course of business.

**10.3 Authorized Disclosure.** Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) enforcing such party's rights under this Agreement;
- (b) prosecuting or defending litigation as permitted by this Agreement;
- (c) complying with applicable court orders or governmental regulations;

(d) disclosure to Affiliates, contractors, employees and consultants who need to know such information for the development and commercialization of the Test in accordance with this Agreement, on the condition that any such Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than the terms of this Agreement; and

(e) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.

Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 10.3(b) or Section 10.3(c), it will, except where impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

**10.4 Confidentiality of this Agreement.** Except as otherwise provided in this Section 10, each party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other party hereto, except that each party may disclose the terms of this Agreement that are otherwise made public prior to the date of such disclosure or to the extent such disclosure is permitted under Section 10.3.



**10.5 Press Releases; Public Announcements.** Neither party shall make a press release or public announcement that includes information relating to the Collaboration without the approval of the other party. At least five (5) days prior to any such press release or public announcement the party proposing to make such press release or public announcement (the **“Releasing Party”**) shall provide to the other party a draft copy thereof for its review and approval. The Releasing Party may not distribute such press release or public announcement without obtaining the other party’s prior written approval. In addition, the Releasing Party shall, at the other party’s request, remove therefrom any Confidential Information of such other party. The contribution of each party shall be noted in all scientific publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

## **11. TERM AND TERMINATION**

**11.1 Term.** The term of this Agreement will commence on the Effective Date and continue for a period of three (3) years after the Effective Date (the **“Initial Term”**). Thereafter, this Agreement can be renewed by mutual written agreement of the parties for successive one (1) year periods (each, a **“Renewal Term”** and together with the Initial Term, the **“Term”**).

### **11.2 Termination.**

(a) **Material Breach.** Either party shall have the right to terminate this Agreement before the end of the Term upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (the **“Cure Period”**) after notice from the terminating party requesting cure of the breach. Any such termination shall become effective at the end of such Cure Period unless the breaching party has cured such breach prior to the end of such Cure Period. Any right to terminate under this Section 11.2(a) shall be stayed and the Cure Period tolled in the event that, during any Cure Period, the party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 13 with respect to the alleged breach, which stay and tolling shall continue until such dispute resolution procedures have been completed in accordance with Article 13. Nothing herein is intended to prevent either party from seeking immediate equitable or injunctive relief.

(b) **Termination for Convenience.** Both parties shall have the right to terminate this Agreement at any time, for any or for no reason, upon one hundred twenty (120) days written notice to the other party. In the event a party undergoes a Change of Control Event as defined in Section 14.5, the other party may terminate the Agreement upon thirty (30) days written notice to the party undergoing the Change of Control.

### 11.3 Effect of Termination; Surviving Obligations.

(a) Upon any termination or expiration of this Agreement, all licenses granted hereunder shall automatically terminate and revert to the granting party and all other rights and obligations of the parties under this Agreement shall terminate, except as provided in Sections 11.3(b) and 11.4.

(b) Upon termination or expiration of this Agreement, each party will use their best efforts to return to the other party or destroy all tangible copies of the other party's Confidential Information in such party's possession or control and will erase from its computer systems all electronic copies thereof; provided, however, that each party may retain one archival copy of the other party's Confidential Information solely for purposes of monitoring compliance with its obligations under Article 10 hereof.

**11.4 Survival.** Expiration or early termination of this Agreement shall not relieve either party of any obligation accruing prior to such expiration or termination. In addition, Sections 3.3(g), 4.3, 5.1, 5.2 (to the extent required by law) 9.1, 9.2, 9.3, 9.5, 11.3 and 11.4, and Articles 1, 8, 10, 12, 13 and 14 will survive any expiration or termination of this Agreement.

## 12. INDEMNIFICATION

**12.1 Indemnification by Life Technologies.** Life Technologies hereby agrees to defend, indemnify and hold harmless Biocept, its Affiliates and their respective officers, directors, employees, consultants and agents (the "**Biocept Indemnitees**"), from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees resulting from any threat, claim, demand, action or other proceeding by any Third Party ("**Losses**") to the extent such Losses arise directly or indirectly out of: (a) the gross negligence or willful misconduct of any Life Technologies Indemnatee (defined below); (b) the material breach by Life Technologies of any warranty, representation, covenant or agreement made by it in this Agreement; or (c) the performance by Life Technologies of the Professional Component; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Biocept Indemnatee or the material breach by Biocept of any warranty, representation, covenant or agreement made by it in this Agreement.

**12.2 Indemnification by Biocept.** Biocept hereby agrees to defend, indemnify and hold harmless Life Technologies, its Affiliates and their respective officers, directors, employees, consultants and agents (the "**Life Technologies Indemnitees**"), from and against any and all Losses to the extent such Losses arise directly or indirectly out of: (a) the gross negligence or willful misconduct of any Biocept Indemnatee; (b) the material breach by Biocept of any warranty, representation, covenant or agreement made by it in this Agreement; or (c) the performance by Biocept of the Technical Component of the Assay or Test; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Life Technologies Indemnatee or the material breach by Life Technologies of any warranty, representation, covenant or agreement made by it in this Agreement.

**12.3 Procedure.** In the event a party seeks indemnification under Section 12.1 or 12.2, it shall inform the other party (the **“Indemnifying Party”**) of a claim as soon as reasonably practicable after such party (the **“Indemnified Party”**) receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 12.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party; in each case, without the prior written consent of the Indemnified Party.

**12.4 Insurance.** Each party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with industry standards during the Term and shall name the other party as an additional insured with respect to such insurance. Each party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other party upon request.

### **13. DISPUTE RESOLUTION**

**13.1 Dispute Resolution.** The parties recognize that disputes as to certain matters may arise from time to time during the Term. The parties shall first submit the dispute to the Joint Steering Committee for resolution in accordance with Section 4.3 hereof. In the event that the Joint Steering Committee is unable to resolve the dispute, the parties shall be entitled to seek relief in a court of competent jurisdiction. Notwithstanding the foregoing, to the full extent allowed by law, either party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect the parties’ rights or enforce the parties’ obligations under this Agreement pending resolution of any claims related thereto by the Joint Steering Committee.

### **14. GENERAL PROVISIONS**

**14.1 Governing Law.** This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of California, USA, without regard to the conflicts of law provisions thereof.

**14.2 Entire Agreement; Modification.** This Agreement, including the Exhibits hereto, is both a final expression of the parties’ agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior

and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be amended, modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

**14.3 Relationship Between the Parties.** The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

**14.4 Non-Waiver.** The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

**14.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (a **"Change of Control Event"**). The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

**14.6 No Third Party Beneficiaries.** This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

**14.7 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

**14.8 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earlier of: (a) the date of actual receipt; or (b) if mailed, five calendar days after the date of postmark.

If to Biocept, notices must be addressed to:

Biocept, Inc.  
5810 Nancy Ridge Drive, Suite 150  
San Diego, CA 92121  
Attention: David Hale  
Executive Chairman  
Telephone: (858) 320-8200  
Facsimile: (858) 320-8225

If to Life Technologies, notices must be addressed to:

Life Technologies Corp.  
5791 Van Allen Way  
Carlsbad, CA 92008  
Attention: David Daly  
Head of Oncology  
Telephone: (760) 268-5556

**14.9 Force Majeure.** Each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control, including but not limited to, Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, any strike or labor disturbance. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within five (5) calendar days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute. In the event of a force majeure that persists for thirty (30) days or more, then either party may terminate this Agreement upon written notice to the other party.

**14.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first set forth above.

**BIOCEPT, INC.**

**LIFE TECHNOLOGIES CORPORATION**

By: /s/ Michael J. Dunn

By: /s/ David J. Daly

Name: Michael Dunn

Name: David J. Daly

Title: Senior Vice President, Corp. Dev.

Title: Head of Oncology

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**EXHIBIT A - CTC Volume Projections**

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[\*\*] Confidential portions omitted and filed separately with the Commission.

## Exhibit B

<u>Test ID</u>	<u>CPT</u>	<u>Description</u>	<u>2012 Medicare Allowable (Per Unit)*</u>	<u>Unit</u>
<b>Enumeration</b>				
Capture/Stain	88346	Immunofluorescent study, each Ab, direct	\$ 120.57	3
	88346-TC	Immunofluorescent study, each Ab, direct	\$ 72.36	3
	88346-26	Immunofluorescent study, each Ab, direct	\$ 48.21	3
DAPI	88313	Special stains, Group II	\$ 78.22	1
	88313-TC	Special stains, Group II	\$ 61.20	1
	88313-26	Special stains, Group II	\$ 17.02	1
<b>FISH</b>				
ALK1, EGFR	88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$ 314.28	4
	88368-TC	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$ 221.90	4
	88368-26	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$ 92.38	4
<b>Mutations**</b>				
EGFR		Detection of EGFR mutation	\$ 538.23	1
K-ras		Detection of K-ras mutation	\$ 294.63	1
B-raf		Detection of B-raf mutation	\$ 232.40	1

- 2012 rates for southern California region (region 26); may differ for Sacramento
- No PC (26) code; on MolDx Laboratory Fee Schedule, with rates calculated as average reimbursement for 5 clinical testing labs performing these tests



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### Exhibit C

[The parties will work together to develop a plan to implement detailed operation protocols for the Test within [\*\*] of the Effective Date for each aspect of sample logistics, including ordering, shipping, accessioning, sample handling, testing, data generation, data evaluation and reporting. These sample logistics shall be agreed upon by the parties through the Joint Steering Committee and, once agreed upon by the parties in writing, deemed to be attached hereto as **Exhibit C** without any additional action required on the part of either party.]

[\*\*] Confidential portions omitted and filed separately with the Commission.

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## Exhibit D

[Once the parties have agreed upon a plan relating to the development of a particular Collaboration Assay, if development is needed (each, a “Project”), the parties shall reduce such agreement to writing, which shall include a project plan which will set forth each party’s obligations with respect to the Project (each, a “Project Plan”) and thereafter, such Collaboration Assay shall be deemed a Test for all purposes under this Agreement and shall be subject to the terms of this Agreement as amended. Each such Project Plan shall be attached as a part of **Exhibit D** to this Agreement following written acceptance thereof by both parties without any additional action required on the part of either party.]

## COLLABORATION AGREEMENT

**THIS COLLABORATION AGREEMENT** (the “**Agreement**”) is entered into as of August 17, 2011 (the “**Effective Date**”) by and between **BIOCEPT, INC.**, a California corporation having an address of 5810 Nancy Ridge Drive, Suite 150, San Diego, CA 92121 (“**Biocept**”), and **CLARIANT DIAGNOSTIC SERVICES, INC.**, a Delaware corporation having an address of 31 Columbia, Aliso Viejo, California 92656 (“**Clariant**”).

**WHEREAS**, Clariant is engaged in the business of providing oncology laboratory testing services for community hospitals and pathologists and oncologists;

**WHEREAS**, Biocept has developed expertise and proprietary technology in enrichment, extraction and analysis of circulating tumor cells for use in diagnostic tests used for the non-invasive and early stage detection of metastatic or recurrent cancers; and

**WHEREAS**, Clariant and Biocept desire to collaborate to develop and commercialize one or more Diagnostic Tests, as defined herein, using their respective technologies and expertise, on the terms and subject to the conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, and intending to be legally bound, the parties hereby agree as follows:

### 1. DEFINITIONS

**1.1 “Affiliate”** shall mean any company or entity controlled by, controlling, or under common control with a party hereto and shall include any company more than 50% of whose voting stock or participating profit interest is owned or controlled, directly or indirectly, by a party, and any company which owns or controls, directly or indirectly, more than 50% of the voting stock of a party. Affiliates of Clariant shall be deemed to include entities forming part of the GE Healthcare business only and shall not include any other entities whose ultimate parent is General Electric Company.

**1.2 “Assay”** shall mean Biocept’s OncoCEE-BR™ assay which incorporates circulating tumor cell enumeration by cytokeratin (and CEE-Enhanced™ when available and validated by Biocept), HER2 by fluorescence in situ hybridization, and estrogen receptor / progesterone receptor by immunocytochemistry, and any improvements or enhancements thereto, appropriately validated, exclusive of new analytes.

**1.3 “Biocept Trademarks”** shall mean Biocept, Inc., “OncoCEE-BR™”, “OncoCEE™”, “CEE-Sure™”, CEE-Enhanced™”, and/or such other trademarks and trade names owned or licensed, and used, by Biocept and/or its Affiliates in the Territory to identify the Diagnostic Tests, in each case, whether or not registered.

**1.4 “Clariant Trademarks,”** shall mean Clariant™, Clariant Diagnostic Services, Inc., and/or such other trademarks and trade names owned or licensed and used by Clariant to identify the Diagnostic Tests, in each case, whether or not registered.

**1.5 “CLIA”** shall mean the Clinical Laboratory Improvement Amendments of 1988, as it may be amended from time to time.

**1.6 “Collaboration”** shall have the meaning provided Section 3.1.

**1.7 “Collaboration Assay(s)”** shall have the meaning provided in Section 3.5(e).

**1.8 “CPT Code”** shall mean the American Medical Association’s (“AMA”) “Current Procedural Terminology” as published in the AMA’s CPT Process Manual, Fourth Edition and any such future editions, for procedures used in performance of the Assay, and amounts reimbursed by Medicare for such procedures for location 26, as modified annually.

**1.9 “Designated Executive Officer”** shall mean the executive officers of each party designated in writing by each party as being responsible for resolving disputes related to the Collaboration, which shall initially be David Hale on behalf of Biocept and Dave Daly on behalf of Clariant.

**1.10 “Diagnostic Test(s)”** shall mean the Assay, and/or any Collaboration Assay which is added to this Agreement pursuant to Section 3.5(e), performed as a clinical reference laboratory test.

**1.11 “FDA”** shall mean the United States Food and Drug Administration, or any successor federal agency thereto.

**1.12 “HIPAA”** shall mean, collectively, the Health Insurance Portability and Accountability Act of 1996, as amended, and all regulations promulgated thereunder at 45 C.F.R. parts 160 through 164, and the Health Information Technology for Economic and Clinical Health Act of 2009 and related regulations and guidelines.

**1.13 “Intellectual Property Rights”** means all now or hereafter existing patents, patent applications, copyrights, trademarks (including service marks), trade secrets, know-how, mask work rights and design rights, whether registered or unregistered, and all rights or forms of protection of a similar nature having equivalent or similar effect to any of the foregoing, which may subsist anywhere in the world.

**1.14 “Launch”** shall mean formal commercial availability and offering to physicians of a Diagnostic Test, as mutually agreed upon by the parties.

**1.15 “New Assay(s)”** shall mean any CEE™-based circulating tumor cell assay products developed in accordance with Section 3.5(e).

**1.16 “Professional Component”** shall mean the performance of the professional component of the assay steps of the Assay, and Collaboration Assays as agreed, which are covered by CPT codes from the Professional Fee Schedule with the modifier “26”.

**1.17 “Technical Component”** shall mean the performance of the technical component of the assay steps of the Assay, and Collaboration Assays as agreed, which are covered by CPT codes from the Professional Fee Schedule without the modifier “26”.

**1.18 “Term”** shall have the meaning provided in Section 10.1.

**1.19 “Territory”** shall mean the United States of America.

**1.20 “Third Party(ies)”** shall mean any entity other than Biocept or Clariant or an Affiliate of Biocept or Clariant.

## **2. APPOINTMENT; LICENSES**

**2.1 Appointment.** Upon the terms and conditions set forth in this Agreement, Biocept hereby grants Clariant during the Term the exclusive right, except as limited by Sec. 2.3 (a), to promote Diagnostic Tests in the Territory, together with Biocept, for the clinical testing market, and to perform the Professional Component of the Diagnostic Tests in the Territory, in accordance with the terms of this Agreement. For purposes of clarity, the clinical testing market means performance of the Assay for patient care excluding testing for pharmaceutical companies.

**2.2 Trademark Licenses.** The parties hereby grant to each other non-exclusive, fully-paid, royalty-free licenses to utilize the other party’s trademarks, as follows:

(a) **Biocept Trademarks.** To facilitate the promotion and performance of Diagnostic Tests, during the Term Biocept hereby grants Clariant a non-exclusive, royalty-free, non-transferable license to use the Biocept Trademarks solely for use in connection with the promotion and performance of the Diagnostic Tests in the Territory. All materials associated with the Diagnostic Tests and used by Clariant in connection with the promotion and performance of the Diagnostic Tests, including web-based, shall be co-branded with such Biocept Trademarks as approved by Biocept prior to distribution. All use of Biocept Trademarks by Clariant hereunder shall inure to the benefit of Biocept, and these rights, whether registered or not registered, at all times shall remain the sole property of Biocept. Biocept shall provide Clariant with copies of the Biocept Trademarks in an appropriate form for the uses contemplated in this Agreement. Clariant shall provide Biocept with specimens of all proposed use of the Biocept Trademarks in advance of such proposed use and Biocept shall have the right to approve the appearance and placement of Biocept Trademarks by Clariant for the purpose of protecting and maintaining the standards of quality maintained by Biocept for products sold under the Biocept Trademarks and for use of the Biocept Trademarks. If Biocept at any time finds that Clariant is not in compliance with this Section, then Biocept may notify Clariant in writing of such deficiencies, and if Clariant fails to correct such deficiencies within thirty (30) days after receipt of such notice, Biocept may, at its election and in addition to any other remedies, terminate the license granted to Clariant with respect to the Biocept Trademarks. Clariant shall display the <sup>TM</sup> or <sup>®</sup> symbol, as directed by Biocept, in connection with Clariant’s use of the Biocept Trademarks.

(b) **Clariant Trademarks.** To facilitate the promotion and performance of Diagnostic Tests, during the Term Clariant hereby grants Biocept a non-exclusive, royalty-free, non-transferable license to use the Clariant Trademarks solely for use in connection with the promotion and performance of the Diagnostic Tests in the Territory. All materials associated with the Diagnostic Tests and used by Biocept in connection with the promotion and performance of the Diagnostic Tests, including web-based, shall be co-branded with such Clariant Trademarks as approved by Clariant prior to distribution. All use of Clariant Trademarks by Biocept hereunder shall inure to the benefit of Clariant, and these rights, whether registered or not registered, at all times shall remain the sole property of Clariant. Clariant shall provide Biocept with copies of the Clariant Trademarks in an appropriate form for the uses contemplated in this Agreement. Biocept shall provide Clariant with specimens of all proposed use of the Clariant Trademarks in advance of such proposed use and Clariant shall have the right to approve the appearance and placement of Clariant Trademarks by Biocept for the purpose of protecting and maintaining the standards of quality maintained by Clariant for products sold under the Clariant Trademarks and for use of the Clariant Trademarks. If Clariant at any time finds that Biocept is not in compliance with this Section, then Clariant may notify Biocept in writing of such deficiencies, and if Biocept fails to correct such deficiencies within thirty (30) days after receipt of such notice, Clariant may, at its election and in addition to any other remedies, terminate the license granted to Biocept with respect to the Clariant Trademarks. Biocept shall display the <sup>TM</sup> or <sup>®</sup> symbol, as directed by Clariant, in connection with Biocept's use of the Clariant Trademarks.

### **2.3 Exclusivity.**

(a) During the Term, the parties will promote and perform the Diagnostic Tests for the clinical testing market on an exclusive basis in the Territory, except as otherwise provided for below. Biocept will have sole responsibility for performing the Technical Component of all Diagnostic Tests sold by the parties. Clariant will have sole responsibility for performing the Professional Component of Diagnostic Tests sold by the parties. Biocept may engage other groups in promotion and marketing arrangements for the Diagnostic Tests for customers or clients not traditionally called on by Clariant, but such groups shall not perform any aspect of the Diagnostic Tests, including, without limitation, Technical Components or Professional Components. Biocept shall provide thirty (30) days written notice to Clariant before entering into any such promotion and marketing arrangement.

(b) During the Term, neither party nor any Affiliate of a party shall commercialize (including either by license or sale), distribute, promote, market or offer for sale a CTC diagnostic test that is competitive with the Diagnostic Tests in the clinical testing market. The foregoing restriction shall not apply to Clariant's or its Affiliates' use or sale of the CellSearch test that is either requested by name from a customer or client of Clariant or its Affiliates, or in the context of development and commercialization of Clariant's Assist Digital Pathology system.

### 3. COLLABORATION

**3.1 Purpose.** During the Term, the parties agree to cooperate and collaborate to promote and commercialize the Diagnostic Tests for the clinical testing market in the Territory and in accordance with the terms of this Agreement (the “**Collaboration**”). The principal objective of the parties hereunder is to maximize the commercialization of the Diagnostic Tests in the Territory. The parties shall deploy each of their respective sales forces in accordance with the terms of this Agreement in an effort to promote and perform the Diagnostic Tests in the Territory in the manner as agreed to by the parties, under the direction of the Joint Steering Committee.

**3.2 Expansion of Territory.** At any time during the Term, should Biocept desire to sell, transfer, assign or license the Assay or any Collaboration Assay to one or more Third Parties on an exclusive basis for any country or other area outside of the Territory, it shall first provide written notice thereof to Clariant.

**3.3 Clariant Responsibilities.** Clariant shall use commercially reasonable efforts to promote the Diagnostic Tests in the Territory, generally using substantially similar sales channels and methods and adhering to substantially similar standards that it generally employs with respect to its other products and tests. Without limiting the foregoing, Clariant’s responsibilities with respect to marketing and promotion of the Diagnostic Tests in the Territory during the Term shall include the following:

(a) **Clariant Customers.** Clariant shall use commercially reasonable efforts and be responsible to promote the Diagnostic Tests to its existing customer base, which shall be focused primarily on community hospital pathologists and community oncologists.

(b) **Test Performance.** Clariant shall have responsibility for performing, or having performed on its behalf, all Professional Components of the Diagnostic Tests sold by either party, or by any Third Party in accordance with Section 2.3(a).

**(c) Sales, Marketing and Customer Service.**

(i) Clariant shall, at its sole expense and in accordance with Section 2.2, develop and deliver to customers marketing materials for the Diagnostic Tests. Clariant shall use, as appropriate, Biocept’s “OncoCEE-BR™”, OncoCEE™, “CEE-Enhanced™” and “CEE-Sure™” brand and the Biocept corporate name and logo, together with any Clariant branding, as part of the marketing materials for the marketing of the Diagnostic Tests and, where appropriate, in its other public presentations and disclosures concerning the Diagnostic Tests. Biocept shall have the right to review all such materials prior to their initial use.

(ii) Clariant shall cause its sales force to promote the Diagnostic Tests.

(iii) Clariant shall promote the sale of the Diagnostic Tests by including the Diagnostic Tests in its menu of services and by incorporating marketing materials regarding the Diagnostic Tests into its own marketing materials.

(iv) Clariant shall keep Biocept reasonably informed of its planned marketing activities with respect to the Diagnostic Tests to allow Biocept to forecast its needs for reagents, equipment, laboratory space, personnel, computing, and testing reporting capabilities, including at each Joint Steering Committee meeting as indicated in Section 4, and will discuss and consider in good faith Biocept's suggestions for marketing the Diagnostic Tests.

(v) Clariant will provide customer service and support for the Diagnostic Tests using substantially similar methods and adhering to substantially similar standards that it generally employs with respect to its other products and tests.

**(d) Samples and Logistics.**

(i) Clariant will be responsible for the logistics associated with its own marketing efforts and performance of Professional Components of the Diagnostic Tests, including distribution of sample shipping kits, sample transport to Biocept, patient referral, billing and collections in accordance with Section 3.5(b)(iii), reporting of results and reporting quality control, and insurance or patient reimbursement.

(ii) Clariant will, at its discretion and to the extent it is able, provide clinical samples to Biocept for the development and validation of the Diagnostic Tests at no cost, and will, at its discretion, test, for comparative purposes in research and validation studies only and not for provision of the results to patients, reasonable numbers of such clinical samples, and samples sourced by Biocept, using the CellSearch technology, at cost plus ten percent (10%).

(e) **Demand Forecast.** Within thirty (30) days of the Launch of the Assay, Clariant shall deliver to Biocept a two-year rolling forecast of Clariant's expectation for physician requests for the Diagnostic Tests (the "**Demand Forecast**"), which Demand Forecast shall be broken down into quarterly demand for the Assay (with respect to each quarter, the "**Quarterly Forecast**") and shall be attached hereto as **Exhibit A**. Beginning on the first day of the second (2<sup>nd</sup>) full calendar quarter following the date of Launch, the Demand Forecast shall be updated on a quarterly basis. During the first two (2) full calendar quarters following the launch of the Assay, the Demand Forecast shall be a good faith but non-binding forecast for Assay demand, and beginning with the third (3<sup>rd</sup>) full calendar quarter following launch, the Quarterly Forecast for such calendar quarter shall become binding, and the parties shall mutually agree upon a Performance Standard in accordance with Section 3.5(h). In the event the parties develop a Collaboration Assay under the terms of this Agreement, demand for such Collaboration Assay shall be included in the Demand Forecast at all times following the Launch of such Collaboration Assay, and the Quarterly Forecast for such Collaboration Assay shall similarly become binding, and a Performance Standard mutually agreed to in accordance with Section 3.5(h), beginning with the third (3<sup>rd</sup>) full calendar quarter after the launch of such Collaboration Assay.



(f) **Technical Developments.** Clariant shall keep Biocept fully informed as to all discoveries and technical developments (including, without limitations, any inventions) made by Clariant during the Term related to the Diagnostic Tests.

(g) **Billing, Reporting, Auditing.**

(i) Clariant shall be solely responsible for billing the patient, the provider and/or the payer for the Assay, including both the Technical Component and the Professional Component of the Assay, and the collection of such amounts with respect to each Assay performed. Biocept shall bill Clariant directly up to no more than twice a month for the Technical Component of each Assay, based on each applicable CPT Code actually used in the performance of such Technical Component, employing the Medicare rates for 2008 as described on **Exhibit B** for the initial one (1) year period, and Clariant shall pay Biocept within sixty (60) days following the invoice date. Clariant shall bear all collection risk for reimbursement for the Assay, and shall pay Biocept for the Technical Component of invoiced Assays regardless of whether Clariant receives payment for them. The Medicare rates used for determining the amount Clariant will pay Biocept for the Technical Component of the Assay will be adjusted annually on each anniversary of the date of Launch, i.e. the Medicare rates for each Assay invoiced in each subsequent year of the Agreement will employ the applicable CPT Code rates for the year that is three (3) years prior (e.g., in 2012, the Medicare rates for 2009 will be used).

(ii) This Section 3.3(g) shall survive any termination or expiration of this Agreement for at least twelve (12) months following the effective date of such termination or expiration.

**3.4 Biocept Responsibilities.** Biocept shall use commercially reasonable efforts to promote the sale of the Diagnostic Tests in the Territory, generally using at least the same sales channels and methods and adhering to at least the same standards that it generally employs with respect to its other products and tests. Without limiting the foregoing, Biocept's responsibilities during the Term shall include the following:

(a) **Biocept Customers.** Biocept shall use commercially reasonable efforts and be responsible to promote the Diagnostic Tests primarily to cancer centers and their associated key opinion leaders, medical oncologists and surgical oncologists.

(b) **Test Performance.** Biocept shall be responsible for performing all Technical Components of all Diagnostic Tests sold by either party, or by any Third Party in accordance with Section 2.3(a).

(c) **Sales, Marketing and Customer Service.**

(i) Biocept shall cause its sales force to promote the Diagnostic Tests.

(ii) Biocept shall keep Clariant reasonably informed of its planned marketing activities with respect to the Diagnostic Tests to allow Clariant to forecast its needs for equipment, space, personnel, computing, and testing reporting

capabilities, including at each Joint Steering Committee meeting as indicated in Section 4, and will discuss and consider in good faith Clariant's suggestions for marketing the Diagnostic Tests.

(iii) Biocept will provide customer service and support for the Diagnostic Tests using substantially similar methods and adhering to substantially similar standards that it generally employs with respect to its other products.

(d) **Samples and Logistics.** Biocept will be responsible for the logistics associated with its own marketing efforts and performance of the Technical Components of the Diagnostic Tests, including shipping materials and kits, patient referral and customer service.

(e) **Training and Education.**

(i) Biocept shall provide sales and technical training and technical support, including assistance with customer education and customer consultations, to Clariant's personnel, with the frequency and content of the training to be determined by agreement between Biocept and Clariant.

(ii) Biocept will share its product and service educational materials and scientific publications to utilize in patient education through Clariant, and hereby grants Clariant rights to use such materials as are reasonably necessary for Clariant to carry out its obligations under this Agreement. Clariant may not alter or revise these materials without the prior written consent of Biocept.

(f) **Regulatory Approval.** Biocept has licenses enabling it to perform and obtain reimbursement for the Assay in all states in the Territory except New York and Rhode Island, where it is currently seeking such licenses. Biocept will maintain all such licenses which are reasonably required to perform the Assay during the Term. For any Collaboration Assay, Biocept will use commercially reasonable efforts to obtain or maintain licenses enabling it to perform such Collaboration Assay and obtain reimbursement therefor, in accordance with each amendment to this Agreement entered in accordance with Section 3.5(e). Clariant will cooperate with Biocept so that Clariant's marketing and sales efforts are conducted only in those states or regions of the Territory in which Biocept has obtained any necessary regulatory licenses to provide the Diagnostic Tests.

(g) **Technical Developments.** Biocept shall keep Clariant fully informed as to all discoveries and technical developments (including, without limitations, any inventions) made by Biocept during the Term related to the Diagnostic Tests.

**3.5 Joint Responsibilities.** The parties shall use commercially reasonable efforts to cooperate and collaborate to develop the market for the Diagnostic Tests in the Territory. Without limiting the generality of the foregoing, the parties shall collaborate to provide the following:

(a) **Test Materials and Shipping.** Subject to Section 3.3(c)(i), Clariant shall design and order all test materials, including test requisition forms, test reports and collateral sales and marketing (advertising and promotional) materials to be used by Clariant, which shall be approved by Biocept prior to use. Biocept shall design and order sample shipping kits, to be used by the parties and Clariant shall pay fifty percent (50%) of Biocept's actual cost for such sample kits used by the parties under this Agreement.

**(b) Performance of Tests.**

(i) The parties will work together to develop a plan to implement detailed operation protocols within sixty (60) days of the Effective Date for each aspect of sample logistics, including CLIA validation testing, ordering, shipping, accessioning, sample handling, testing, data generation, data evaluation and reporting. These sample logistics shall be agreed upon by the parties through the Joint Steering Committee and, once agreed upon by the parties in writing, deemed to be attached hereto as Exhibit C without any additional action required on the part of either party. Information, data and images shall be transferred between the parties as indicated for this purpose, and the parties will seek to make their respective laboratory information management systems and data transfer capabilities compatible.

(ii) If Clariant desires to utilize any Diagnostic Tests in support of any clinical trial or research program for a pharmaceutical or biotechnology company(ies) in the Territory, Clariant shall notify Biocept in writing of such desired use. The terms and conditions (including pricing) of each such use shall be covered by a separate written agreement which the parties agree to negotiate in good faith.

(iii) Each party will use commercially reasonable efforts to support the other in the account to best meet the needs and expectations of each customer.

(c) **Communication Plan.** Clariant and Biocept shall develop a communications plan through the Joint Steering Committee for the announcement and ongoing promotion of the Diagnostic Tests to customers, with all communications plan materials, including test requisition forms, being co-branded with Biocept and Clariant corporate names and logos in accordance with Sections 2.2 and 3.3(c)(i).

(d) **Data Sharing.** Clariant acknowledges that Biocept has entered into this Agreement to, among other things, establish a database of results from the Diagnostic Tests it performs, which database will include patient information such as disease characterization, treatment and outcome information. To that end, to the extent permitted by applicable law and as mutually agreed by the parties, where available each party will share patient data, Diagnostic Test data and results, and corresponding tissue data with the other party, as well as any follow up or outcome data that may become available or provided by the physician or patient for Diagnostic Tests performed and will cooperate in good faith with the other party to agree upon procedures for sharing such information. Such information may be used only for longitudinal reporting, outcomes correlation and related research, shall be handled in accordance with all applicable laws,

including, without limitation, HIPAA, and applicable institutional review board guidelines, and shall not be used for the purpose of obtaining information about the other party's clients or customers. To the extent feasible, all such information will be properly de-identified.

(e) **New Assays.**

(i) During the Term, Biocept shall keep Clariant reasonably apprised of its plans for New Assays for the clinical testing market. Clariant shall hold any such disclosure regarding such New Assay on a confidential basis and will not disclose such information to any Third Party without the consent of Biocept. If at any time Biocept desires to commercialize a New Assay with one or more Third Parties, either by license, sale, transfer or assignment of any such New Assay, Biocept shall first offer to Clariant the right to negotiate an agreement with respect to the commercialization of such New Assay by delivering written notice thereof to Clariant (each an "**Option Notice**"). Clariant shall have thirty (30) days from the date of such Option Notice to notify Biocept in writing of whether it desires to negotiate an agreement with Biocept to commercialize such New Assay. If Clariant indicates it has no interest in such New Assay, or does not respond within thirty (30) days of the date of such Option Notice, or such longer period as the parties may otherwise mutually agree, Biocept shall be free to pursue the commercialization of such New Assay with one or more Third Parties. Should Clariant indicate it does have interest in the New Assay within the thirty (30) day or other mutually agreed to period, the parties shall negotiate in good faith for up to sixty (60) days, or such longer period as the parties may otherwise mutually agree, an amendment to this Agreement to set forth the terms and conditions that would govern the marketing and commercialization of such New Assay, including regulatory or licensing requirements. If the parties successfully conclude such amendment to this Agreement covering a New Assay, such New Assay shall be deemed a "**Collaboration Assay**" for all purposes under this Agreement and shall be subject to the terms of this Agreement as amended, and if the parties are unsuccessful in concluding such amendment to this Agreement, Biocept shall be free to pursue the commercialization of such New Assay with one or more Third Parties.

(ii) In addition, should Clariant desire for Biocept to develop a specific New Assay to be offered by the parties as a Diagnostic Test under this Agreement, the parties shall negotiate in good faith an amendment to this Agreement that will govern the development and commercialization of such New Assay, which amendment may include financial support, contributions of and access to each party's technology and/or clinical samples, milestones, timing of the development effort, exclusivity and ownership rights. Any such agreed upon New Assay development shall be performed by Biocept or jointly as the parties may agree. Once the parties have agreed upon a plan relating to the improvement or development of a particular New Assay (each, a "**Project**"), the parties shall reduce such agreement to writing, which shall include a project plan which will set forth each party's obligations, with respect to the Project (each, a "**Project Plan**") and thereafter, such New Assay shall be deemed a "**Collaboration Assay**" for all purposes under this Agreement and shall be subject to the terms of this Agreement as amended. Each such Project Plan shall be attached as a part

of Exhibit C to this Agreement following written acceptance thereof by both parties without any additional action required on the part of either party. Any amendments or revisions to a Project Plan shall be mutually agreed upon by the parties in writing.

(f) **Costs and Expenses.** Unless otherwise specified herein or in a Project Plan attached hereto, each party shall perform its activities under this Agreement at its sole cost and expense.

(g) **Training and Education.**

(i) The parties shall work together to develop and implement a training program for client services and the sales and marketing representatives of each party to ensure that a clear and consistent message is delivered to all prospective customers. Following such implementation, each party agrees to train its client services and sales and marketing representatives in accordance with such training program.

(ii) Representatives of each party, where deployed, shall each educate physicians on the Diagnostic Tests, their applications and benefits, and the procedures for providing samples for the Diagnostic Tests. The parties will jointly approve all presentation and meeting materials. In addition, the parties will each be responsible for providing customer support related to test logistics, billing and reimbursement, and for establishing a call center / web portal to handle inquiries related to the Assay. For purposes of clarity, the parties acknowledge and agree that Clariant will not be required to establish a dedicated web portal, but all results of Diagnostic Tests will be made available in its Pathsite portal. Technical or process questions regarding the Assay received by Clariant can be referred to Biocept. Each party will cover its own costs related to physician education, customer support, and any travel related thereto and comply with all federal and state regulations regarding the same.

(h) **Performance Standards.** Each party shall conduct its activities under this Agreement and any Project Plan in a professional and workmanlike manner, and in compliance in all material respects with the requirements of applicable laws and regulations, to attempt to achieve the objectives of this Agreement efficiently and expeditiously. Each party shall contribute such personnel and resources, and shall maintain such laboratories and other facilities, as are reasonably necessary to carry out the activities to be performed under this Agreement, including any Project Plans. In conformity with standard industry practices and the terms and conditions of this Agreement, each party shall prepare and maintain, or shall cause to be prepared and maintained, complete and accurate written records, accounts, notes, reports and data with respect to activities conducted by such party under this Agreement, including any Project Plans. In addition, the parties shall work together to establish minimum agreed upon performance standards with respect to the promotion and performance of the Diagnostic Tests, and the timely supply, accuracy, reliability and reporting of the Diagnostic Tests, as well as responsiveness to customer inquiries related to the Diagnostic Tests throughout the Territory (collectively, "**Performance Standards**"). In the event that one or more Performance Standards are not met, the parties will work quickly and efficiently to (i) identify the cause of the failure, (ii) develop a plan to remediate the issue, and (iii)

implement the remediation plan. If the parties are unable to successfully resolve a Performance Standards issue by this procedure, such failure to maintain Performance Standards shall constitute a material breach, and either party may terminate this Agreement in accordance with Section 10.2.

#### **4. JOINT STEERING COMMITTEE**

**4.1 Purpose and Membership.** Promptly following the Effective Date, Biocept and Clariant will create a Joint Steering Committee for the purpose of facilitating communications between the parties in the course of the Collaboration. The Joint Steering Committee shall be composed of an equal number of representatives of each of Biocept and Clariant, each of whom shall have appropriate experience, knowledge and authority within such party's organization to carry out the duties and obligations of the Joint Steering Committee. Each party will designate one of its representatives as the primary contact for that party with respect to Joint Steering Committee-related matters, which such representatives shall serve as co-chairpersons of the Joint Steering Committee. Each party may change its representatives to the Joint Steering Committee or its primary contact from time to time in its sole discretion, effective upon notice to the other party of such change. These representatives shall have appropriate technical credentials, experience and knowledge. A reasonable number of additional representatives of a party may attend meetings of the Joint Steering Committee in a non-voting capacity.

**4.2 Duties.** The Joint Steering Committee shall meet in person or by teleconference or videoconference no less than quarterly during the Term or as otherwise mutually agreed by the parties from time to time. The responsibilities of the Joint Steering Committee shall be responsible for (i) monitoring the progress of the collaboration, including discussions relating to New Assays and Collaboration Assays, (b) physician education with respect to the Diagnostic Tests, (c) marketing, sales and account coordination, (d) any regulatory inquiries or requirements and other issues that affect the availability of the Diagnostic Tests, and (e) reimbursement issues (including annual review of actual amounts received by Clariant for relevant CPT Codes), logistical considerations, and other topics as necessary. The Joint Steering Committee shall serve as the principal forum for each party to (i) keep the other party informed of the results of its Collaboration activities; (ii) to discuss Diagnostic Test commercialization strategies, and (iii) generally to encourage and facilitate ongoing cooperation between the parties with respect to the Collaboration, including the business relationship and/or any other matter relating to the Collaboration and resolving disputes between the parties with respect to Intellectual Property Rights; provided, however, that (A) nothing in this Agreement shall limit either party's right to seek immediate equitable or injunctive relief where appropriate without any obligation to first submit the dispute to the Joint Steering Committee; and (B) any decision concerning medical necessity and patient care with respect to Diagnostic Tests sold by or performed on behalf of Clariant shall be the sole responsibility of Clariant's Medical Director.

**4.3 Decisions; Disputes.** Decisions of the Joint Steering Committee shall be made by unanimous vote, with each party's representatives on the Joint Steering

Committee collectively having one vote. In the event that the Joint Steering Committee cannot or does not, after good faith efforts, reach agreement on an issue, such issue shall first be referred to the Designated Executive Officers, who shall meet promptly thereafter and shall attempt in good faith to resolve such issue. In the event that the Designated Executive Officers cannot or do not, after good faith efforts, reach agreement on an issue, the issue shall be submitted to voluntary mediation. The Designated Executive Officers of each party shall select a mediator who is an expert with no less than seven years of experience in the subject matter to which the dispute relates. In the event that the Designated Executive Officers of the parties are unable to agree upon a mediator within twenty (20) days, then the Designated Executive Officers shall contact the San Diego County office of JAMS to select a mediator from the JAMS panel. If they are unable to agree, JAMS shall provide a list of three available mediators and each party may strike one. The remaining one will serve as the mediator. The mediation shall be conducted under JAMS rules. The parties agree that they shall share equally the cost of the mediation filing and hearing fees, and the cost of the mediators that constitute the panel. Each party shall bear its own attorneys' and expert fees and all associated costs and expenses.

## **5. REGULATORY COMPLIANCE**

**5.1 Compliance with Laws.** Biocept and Clariant and their respective Affiliates each agree to perform their respective obligations under this Agreement in material compliance with applicable federal, state and local laws, rules, and regulations in the Territory, including but not limited to applicable regulations, rules, and policies of third party payers that pay for the Diagnostic Tests.

**5.2 Privacy.** Biocept and Clariant and their respective Affiliates agree to protect the privacy and provide for the security of any information that relates to a patient's past, present, or future physical or mental health or condition in accordance with HIPAA, and any other applicable federal and state privacy laws and regulations in the Territory. Each party agrees to execute one or more Business Associate Agreements (as defined under HIPAA) as the other party, or its providers or payers, may from time to time request.

**5.3 Licenses and Certifications.** Biocept and, to the extent applicable, Clariant shall have at all times during the Term, all necessary federal, state and local licenses, qualifications and certifications to operate a laboratory and perform their respective components of the Diagnostic Tests, including, but not limited to, state laboratory licenses, CLIA certification, CAP (College of American Pathologists) certification, FDA registration, and any other licenses or certification required by state and/or federal law. All Diagnostic Tests performed by Biocept, and, to the extent applicable, Clariant, shall be in accordance with applicable state and federal testing requirements for clinical reference laboratories.

## 6. MATERIALS TRANSFER

In order to facilitate the Collaboration, either party may provide to the other party certain biological materials or chemical compounds including, but not limited to, samples (collectively, “**Materials**”) for use by the other party in furtherance of the Collaboration. Except as expressly provided under this Agreement, all such Materials delivered to the other party will remain the sole property of the supplying party, will be used only in furtherance of the Collaboration and solely under the control of the other party, will not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying party, and will not be used in research or testing involving human subjects except as permitted by applicable law. The Materials supplied hereunder must be used with prudence and appropriate caution in any experimental work and in accordance with all applicable laws.

## 7. INTELLECTUAL PROPERTY

**7.1 Existing Technology.** Each party acknowledges that the other party owns certain technology and Intellectual Property Rights which have been independently developed by, or at the request of, such other party, whether prior to, during or subsequent to the Term. Except as expressly provided in this Agreement, neither this Agreement nor the activities performed hereunder, shall give either party any rights or interest in or to the technology or Intellectual Property Rights of the other party (or of any Materials provided by such party). Each party owns, and shall continue to own, all right, title and interest in and to its respective technology, including, without limitation, all Intellectual Property Rights relating thereto. Without limiting the generality of the foregoing, at all times during and after the Term, Biocept shall own all rights to its CEE™ technology and any improvements related thereto, generated during the performance of this Agreement. Biocept and Clariant shall promptly notify the other in writing upon becoming aware of any alleged or threatened infringement of any Intellectual Property Rights related to a Diagnostic Test. Biocept shall have the right to bring and control any action or proceeding with respect to any such infringement at its own expense and by counsel of its own choice. If Biocept elects not to bring any such action or proceeding with respect to such infringement, it shall promptly notify Clariant of the same and agrees to consider, in good faith a request by Clariant to bring any such action or proceeding. Any agreement allowing Clariant to bring such action or proceeding on behalf of Biocept shall be set forth in a separate written agreement between the parties. Except as expressly provided above, the parties shall be under no obligation to enforce any of their Intellectual Property Rights against any actual or threatened Third Party infringements.

**7.2 Biocept Technology.** Without limiting the generality of the foregoing, Biocept owns, and Clariant acknowledges Biocept’s ownership of, (i) the Assay, and (ii) all Intellectual Property Rights in the Assay, and Clariant agrees that it shall not do or suffer to be done any act or thing or undertake any action anywhere that in any manner might infringe, or impair the validity, scope, or title of Biocept in the Assay or Intellectual Property Rights owned by Biocept. Nothing herein shall limit Clariant’s ability to prosecute fully any and all Intellectual Property Rights owned by Clariant with any patent office or related government agency or to respond fully to any government agency inquiry with respect to its Intellectual Property Rights, products, and services.



**7.3 Infringement.** If any Third Party claims or brings an action alleging that any activities of Biocept or Clariant or their Affiliates under this Agreement infringe any of such Third Party's patent rights, Biocept shall use commercially reasonable efforts to address such claims. If Biocept determines to seek a license or otherwise obtain the right to use such Third Party patent rights on behalf of Biocept and Clariant, then Biocept shall be solely responsible for the payment of any reasonable royalties or other payments that may be due to such Third Party, unless the parties agree otherwise in writing.

**7.4 Data and Results.** All data and results from performance of Diagnostic Tests on samples provided by Clariant shall be owned by the patient for whom the Diagnostic Test was performed, and each party shall be entitled to use such data and results to the extent necessary to perform its obligations under this Agreement and in accordance with Section 3.5(d).

**7.5 Trademarks.**

(a) Biocept shall be responsible and bear the expense of any filing, prosecution, maintenance and enforcement of the Biocept Trademarks as it may determine in its sole discretion, without obligation. Clariant shall not, during the Term or thereafter, use or seek to register the trademarks or any trademark or trade name similar to or confusing with the Biocept Trademarks, or any translation thereof, in any jurisdiction. Clariant agrees that, if Clariant at any time obtains, in any jurisdiction, any right, title or interest in any mark, symbol or phrase which shall be identical to, similar to or likely to be confused with any Biocept Trademark or any translation thereof, then Clariant shall have acted or shall act as an agent and for the benefit of Biocept for the limited purpose of obtaining such registrations and assigning such registration (and all right, title and interest in such mark, symbol or phrase) to Biocept.

(b) Clariant shall be responsible and bear the expense of any filing, prosecution, maintenance and enforcement of the Clariant Trademarks as it may determine in its sole discretion, without obligation. Biocept shall not, during the Term or thereafter, use or seek to register the trademarks or any trademark or trade name similar to or confusing with the Clariant Trademarks, or any translation thereof, in any jurisdiction. Biocept agrees that, if Biocept at any time obtains, in any jurisdiction, any right, title or interest in any mark, symbol or phrase which shall be identical to, similar to or likely to be confused with any Clariant Trademark or any translation thereof, then Biocept shall have acted or shall act as an agent and for the benefit of Clariant for the limited purpose of obtaining such registrations and assigning such registration (and all right, title and interest in such mark, symbol or phrase) to Clariant.

**8. REPRESENTATIONS AND WARRANTIES**

**8.1 Mutual Representations and Warranties.** Each party represents and warrants to the other that: (a) it is duly organized and validly existing under the laws of

its jurisdiction of incorporation or formation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action; (c) this Agreement is legally binding upon it, enforceable in accordance with its terms; and (d) the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

## **8.2 Biocept Warranties.**

(a) As of the Effective Date, the Assay is Biocept's most current CTC based technology that has been validated for performing tests for CTC enumeration and the detection of the indicated analytes in breast cancer.

(b) Biocept represents and warrants to Clariant that: (1) the Assay constitutes an original work of Biocept (or is duly licensed by Biocept for the purposes for which it is offered); (2) Biocept is the lawful owner or licensee of all materials used in connection with the development of the Assay and has the rights to use the Assay, and to allow Clariant to use the results of the Technical Component of the Diagnostic Tests and otherwise perform Clariant's responsibilities under this Agreement; (3) to Biocept's knowledge, after a commercially reasonable investigation comprised of a freedom to operate analysis commensurate with its resources, the Assay does not infringe the Intellectual Property Rights of any Third Party.

(c) Biocept has full power and authority and has obtained all Third Party consents, approvals, assignments and/or other authorizations required to enter into this Agreement and to carry out its obligations hereunder.

(d) Biocept owns all right, title and interest in and to the Assay.

(e) There are no existing contracts, agreements, commitments, proposals, offers, or rights with, to, or in any person to acquire any of the rights under the Assay which would prevent or materially and adversely alter the performance of the obligations hereunder.

**8.3 Third Party Infringement.** In the event that the Assay, or any part thereof becomes the subject of any claim, suit or proceeding for infringement of the Intellectual Property Rights of any Third Party, or if the Assay, or any part thereof, is held or otherwise determined to infringe any Intellectual Property Rights of any Third Party such that Biocept can no longer perform its obligations under this Agreement, Biocept shall in its sole discretion either: (1) secure for Clariant the right to continue using the Assay; (2) replace or modify the Assay to make it non-infringing without degrading its performance or utility; or (3) notify Clariant that it will perform neither (1) nor (2), in which case either party shall thereafter have the right to terminate this Agreement immediately upon written notice to the other party.

**8.4 Disclaimer.** Except as expressly set forth herein, THE TECHNOLOGY, MATERIALS AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED “AS IS,” AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

**8.5 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided, however, that this Section shall neither (a) apply to any liability for damages arising from breach of any obligations of confidentiality under Article 9, nor (b) limit the indemnification obligations of the parties arising under Article 11 of this Agreement.

## **9. CONFIDENTIALITY**

**9.1 Confidential Information.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, each party agrees that, during the Term and for 10 years thereafter, such party (the “*Receiving Party*”) shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose, other than as expressly provided for in this Agreement, any information furnished to it by or on behalf of the other party (the “*Disclosing Party*”) pursuant to this Agreement (collectively, “*Confidential Information*”). The Receiving Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. The Receiving Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its, and its Affiliates’, employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party will promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information.

**9.2 Exceptions.** Confidential Information shall not include any information which the Receiving Party can prove by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (b) is known by the Receiving Party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the Receiving Party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the Receiving Party, without the use of Confidential Information of the Disclosing Party, as evidenced by the Receiving Party’s written records maintained in the ordinary course of business.

**9.3 Authorized Disclosure.** Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) enforcing such party's rights under this Agreement;
- (b) prosecuting or defending litigation as permitted by this Agreement;
- (c) complying with applicable court orders or governmental regulations;

(d) disclosure to Affiliates, contractors, employees and consultants who need to know such information for the development and commercialization of the Diagnostic Tests in accordance with this Agreement, on the condition that any such Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than the terms of this Agreement; and

(e) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use.

Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 9.3(b) or Section 9.3(c), it will, except where impracticable, give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

**9.4 Confidentiality of this Agreement.** Except as otherwise provided in this Section 9, each party agrees not to disclose to any Third Party the terms of this Agreement without the prior written consent of the other party hereto, except that each party may disclose the terms of this Agreement that are otherwise made public prior to the date of such disclosure or to the extent such disclosure is permitted under Section 9.3.

**9.5 Press Releases; Public Announcements.** Neither party shall make a press release or public announcement that includes information relating to the Collaboration that has not been previously published without the approval of the other party. At least five days prior to any such press release or public announcement the party proposing to make such press release or public announcement (the "**Publishing Party**") shall provide to the other party a draft copy thereof for its review and approval. The Publishing Party may not publish such press release or public announcement without obtaining the other party's prior written approval. In addition, the Publishing Party shall, at the other party's request, remove therefrom any Confidential Information of such other party. The contribution of each party shall be noted in all publications or presentations by acknowledgment or co-authorship, whichever is appropriate.

## 10. TERM AND TERMINATION

**10.1 Term.** The term of this Agreement will commence on the Effective Date and continue for a period of three (3) years after the Effective Date (the “**Initial Term**”). Thereafter, this Agreement shall be renewable by mutual written agreement of the parties for successive one (1) year periods thereafter (each, a “**Renewal Term**” and together with the Initial Term, the “**Term**”).

### 10.2 Termination.

(a) **Material Breach.** Either party shall have the right to terminate this Agreement before the end of the Term upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (the “**Cure Period**”) after notice from the terminating party requesting cure of the breach. Any such termination shall become effective at the end of such Cure Period unless the breaching party has cured such breach prior to the end of such Cure Period. Any right to terminate under this Section 10.2(a) shall be stayed and the Cure Period tolled in the event that, during any Cure Period, the party alleged to have been in material breach shall have initiated dispute resolution in accordance with Article 12 with respect to the alleged breach, which stay and tolling shall continue until such dispute resolution procedures have been completed in accordance with Article 12. Nothing herein is intended to prevent either party from seeking immediate equitable or injunctive relief.

(b) **Termination for Convenience.** Clariant shall have the right to terminate this Agreement at any time, for any or for no reason, upon one hundred twenty (120) days written notice to Biocept.

### 10.3 Effect of Termination; Surviving Obligations.

(a) Upon any termination or expiration of this Agreement, all licenses granted hereunder shall automatically terminate and revert to the granting party and all other rights and obligations of the parties under this Agreement shall terminate, except as provided elsewhere in Section 10.4.

(b) Upon termination or expiration of this Agreement, each party will use their best efforts to return to the other party or destroy all tangible copies of the other party’s Confidential Information in such party’s possession or control and will erase from its computer systems all electronic copies thereof; provided, however, that each party may retain one archival copy of the other party’s Confidential Information solely for purposes of monitoring compliance with its obligations under Article 9 hereof.

**10.4 Survival.** Expiration or early termination of this Agreement shall not relieve either party of any obligation accruing prior to such expiration or termination. In addition, Sections 3.3(g), 4.3, 5.1, 5.2 (to the extent required by law) 8.1, 8.2, 8.3, 8.5, 10.3 and 10.4, and Articles 1, 7, 9, 11, 12 and 13 will survive any expiration or termination of this Agreement.

## 11. INDEMNIFICATION

**11.1 Indemnification by Clariant.** Clariant hereby agrees to save, defend, indemnify and hold harmless Biocept, its Affiliates and their respective officers, directors, employees, consultants and agents (the “**Biocept Indemnitees**”), from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys’ fees resulting from any claim, demand, action or other proceeding by any Third Party (“**Losses**”) to the extent such Losses arise directly or indirectly out of: (a) the gross negligence or willful misconduct of any Clariant Indemnatee (defined below); (b) the material breach by Clariant of any warranty, representation, covenant or agreement made by it in this Agreement; or (c) the performance by Clariant of the material aspects of the Professional Component of a Diagnostic Test; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Biocept Indemnatee or the material breach by Biocept of any warranty, representation, covenant or agreement made by it in this Agreement.

**11.2 Indemnification by Biocept.** Biocept hereby agrees to save, defend, indemnify and hold harmless Clariant, its Affiliates and their respective officers, directors, employees, consultants and agents (the “**Clariant Indemnitees**”), from and against any and all Losses to the extent such Losses arise directly or indirectly out of: (a) the gross negligence or willful misconduct of any Biocept Indemnatee; (b) the material breach by Biocept of any warranty, representation, covenant or agreement made by it in this Agreement; or (c) the performance by Biocept of the material aspects of the Technical Component of a Diagnostic Test; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Clariant Indemnatee or the material breach by Clariant of any warranty, representation, covenant or agreement made by it in this Agreement.

**11.3 Procedure.** In the event a party seeks indemnification under Section 11.1 or 11.2, it shall inform the other party (the “**Indemnifying Party**”) of a claim as soon as reasonably practicable after such party (the “**Indemnified Party**”) receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 11.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party; in each case, without the prior written consent of the Indemnified Party.

**11.4 Insurance.** Each party, at its own expense, shall maintain product liability and other appropriate insurance (or self-insure) in an amount consistent with industry standards during the Term and shall name the other party as an additional insured with respect to such insurance. Each party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other party upon request.

## **12. Dispute Resolution**

The parties recognize that disputes as to certain matters may arise from time to time during the Term. The parties shall first submit the dispute to the Joint Steering Committee for resolution in accordance with Section 4.3 hereof. In the event that the Joint Steering Committee is unable to resolve the dispute, the parties shall be entitled to seek relief in a court of competent jurisdiction. Notwithstanding the foregoing, to the full extent allowed by law, either party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect the parties' rights or enforce the parties' obligations under this Agreement pending resolution of any claims related thereto by the Joint Steering Committee.

## **13. GENERAL PROVISIONS**

**13.1 Governing Law.** This Agreement and any disputes, claims, or actions related thereto shall be governed by and construed in accordance with the laws of the State of California, USA, without regard to the conflicts of law provisions thereof.

**13.2 Entire Agreement; Modification.** This Agreement, including the Exhibits hereto, is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. This Agreement may only be amended, modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

**13.3 Relationship Between the Parties.** The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

**13.4 Non-Waiver.** The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

**13.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise

transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

**13.6 No Third Party Beneficiaries.** This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

**13.7 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

**13.8 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earlier of: (a) the date of actual receipt; or (b) if mailed, five calendar days after the date of postmark.

If to Biocept, notices must be addressed to:

Biocept, Inc.  
5810 Nancy Ridge Drive, Suite 150  
San Diego, CA 92121  
Attention: David Hale  
Executive Chairman  
Telephone: (858) 320-8200  
Facsimile: (858) 320-8225

If to Clariant, notices must be addressed to:

Clariant Diagnostic Services, Inc.  
31 Columbia  
Aliso Viejo, CA 92656  
Attention: General Counsel  
Telephone: 949 643-7452  
Facsimile: 949 425-5863



**13.9 Force Majeure.** Each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control, including but not limited to, Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, any strike or labor disturbance. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within five (5) calendar days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute. In the event of a force majeure that persists for thirty (30) days or more, then either party may terminate this Agreement upon written notice to the other party.

**13.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first set forth above.

**BIOCEPT, INC.**

By: /s/ David F. Hale

Name: David Hale

Title: Executive Chairman

**CLARIANT DIAGNOSTIC SERVICES, INC.**

By: /s/ Ron Andrews

Name: Ron Andrews

Title: CEO

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## **Exhibit A**

[Although the agreement calls for an Exhibit A, the issuer's records indicate that no such exhibit was attached to the agreement.]

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## **Exhibit B**

[Although the agreement calls for an Exhibit B, the issuer's records indicate that no such exhibit was attached to the agreement.]

## Exhibit C

<u>Test ID</u>	<u>CPT</u>	<u>Description</u>	<u>2011 Medicare Allowable (Per Unit)</u>	<u>2008 Medicare Allowable (Per Unit)</u>	<u>Unit</u>
Enumeration					
Capture	88346-TC	Immunofluorescent study, each Ab, direct	\$ 77.12	\$ 69.92	10
DAPI	88313	Special stains, Group II	\$ 96.64	\$ 85.35	1
	88313-TC	Special stains, Group II	\$ 84.04	\$ 72.93	
	88313-26	Special stains, Group II	\$ 12.61	\$ 12.42	
CK, CD45	88360	Morphometric analysis, each Ab, manual*	\$147.37	\$135.43	2
	88360-TC	Morphometric analysis, each Ab, manual*	\$ 90.07	\$ 77.56	
	88360-26	Morphometric analysis, each Ab, manual*	\$ 57.29	\$ 57.87	
HER2					
	88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$267.47	\$228.67	2
	88368-TC	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$200.19	\$157.70	
	88368-26	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative) each probe; manual	\$ 67.27	\$ 70.97	
	Aggregated Pricing				
	88342		\$124.72	\$113.35	
	88342-TC		\$ 79.71	\$ 68.96	
	88342-26		\$ 45.01	\$ 44.39	
	88346		\$122.41	\$114.70	
	88346-TC		\$ 77.12	\$ 69.92	
	88346-26		\$ 45.29	\$ 44.78	

[\*\*] Confidential portions omitted and filed separately with the Securities and Exchange Commission.

## ASSIGNMENT AND EXCLUSIVE CROSS-LICENSE AGREEMENT

THIS ASSIGNMENT AND EXCLUSIVE CROSS-LICENSE AGREEMENT (the “**Agreement**”) is entered into as of June 2, 2012 (the “**Effective Date**”) by and between AEGEA BIOTECHNOLOGIES, a California corporation, with an address of 15638 Boulder Mountain Road, Poway, California 92064 (“**Aegea**”), and BIOCEPT, INC., a Delaware corporation, with an address of 5810 Nancy Ridge Drive, San Diego, California 92121 (“**Biocept**”).

WHEREAS, Aegea, Biocept and Dr. Lyle Arnold (the “**Inventor**”) are parties to that certain binding letter of intent dated May 2, 2012 (the “**LOI**”), pursuant to which, among other things:

- (a) each of Aegea and Biocept assigned to the other party an undivided joint ownership interest in and to specified inventions and related patent rights;
- (b) the parties agreed to file specified patent applications claiming such inventions; and
- (c) the parties granted exclusive cross-licenses to each other with respect to the foregoing; and

WHEREAS, as contemplated by the LOI, the parties now wish to enter into a definitive agreement memorializing the terms of the LOI and setting forth other reasonable and customary terms and conditions.

NOW THEREFORE, in consideration of the foregoing and the covenants and premises contained in this Agreement, the parties agree as follows:

### 1. DEFINITIONS

**1.1 “Aegea Field”** shall mean all applications, including all research use applications, and sample types outside of the Biocept Field.

**1.2 “Aegea Inventions”** shall mean the inventions described in the Inventor’s invention disclosures identified in Exhibit A hereto.

**1.3 “Affiliate”** shall mean, as to any person or entity, any other person or entity which directly or indirectly controls, is controlled by, or is under common control with such person or entity. For purposes of the preceding definition, “control” shall mean beneficial ownership of more than 50% of the outstanding shares or securities or the ability otherwise to elect a majority of the board of directors or other managing authority.

**1.4 “Biocept Field”** shall mean (a) oncology clinical testing and oncology diagnostics (including both laboratory developed tests and *in vitro* diagnostic tests as applied to the oncology field), and (b) oncology basic and clinical research that is performed (i) internally by Biocept, (ii) as a service offered by Biocept, or (iii) in a *bona fide* collaboration between Biocept and one or more third parties (each, a “**Collaborator**”), provided that such collaboration is not solely or primarily directed to providing research reagents or research technologies to such Collaborator(s), and does not involve the sale or re-sale of research reagents covered by the Joint Patents, or the licensing of technologies for research applications covered by the Joint Patents, by any Collaborator to third parties; in each case, where the sample types tested are tissue, whole blood, bone marrow, CSF or derivatives of any of the foregoing.

**1.5 “Biocept Inventions”** shall mean the inventions claimed or disclosed in the Biocept Provisional Application.

**1.6 “Biocept Provisional Application”** shall mean U.S. provisional patent application no. 61/482,576.

**1.7 “Group A Application”** shall mean PCT patent application no. PCT/US2012/036678, titled “Methods for Detecting Nucleic Acid Sequence Variants,” filed May 4, 2012.

**1.8 “Group A Inventions”** shall mean, collectively: (a) the Biocept Inventions; and (b) those Aegea Inventions described in the Inventor’s invention disclosures identified in items 4, 6 and 7 of **Exhibit A** hereto.

**1.9 “Group A Patents”** shall mean: (a) the Biocept Provisional Application; (b) the Group A Application; and (c) all Patents that claim priority to the Biocept Provisional Application or the Group A Application or that claim or disclose any Group A Invention(s), whether now existing or hereafter filed.

**1.10 “Group B Application”** shall have the meaning provided in Section 4.1(b).

**1.11 “Group B Inventions”** shall mean, collectively, those Aegea Inventions described in the Inventor’s invention disclosures identified in items 1, 2, 3 and 5 of **Exhibit A** hereto.

**1.12 “Group B Patents”** shall mean: (a) the Group B Application; and (b) all Patents that claim priority to the Group B Application or that claim or disclose any Group B Invention(s), whether now existing or hereafter filed.

**1.13 “Inventions”** shall mean, collectively, the Group A Inventions and the Group B Inventions.

**1.14 “Joint Patents”** shall mean the Group A Patents and the Group B Patents.

**1.15 “Patents”** shall mean patents and patent applications, including provisional applications, continuations, continuations-in-part, continued prosecution applications, divisionals, substitutions, reissues, additions, renewals, reexaminations, extensions, term restorations, confirmations, registrations, revalidations, revisions, priority rights, requests for continued examination and supplementary protection certificates granted in relation thereto, as well as utility models, innovation patents, petty patents, patents of addition, inventor’s certificates, and equivalents in any country or jurisdiction.

**1.16 “Third Party”** shall mean any entity other than Biocept or Aegea or an Affiliate of Biocept or Aegea.

**1.17 “Valid Claim”** shall mean (a) a claim of an issued and unexpired patent within the Joint Patents, or a supplementary protection certificate thereof, which has not been held permanently revoked, unenforceable or invalid by a decision of a court, patent office or other

forum of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) a claim of a pending patent application within the Joint Patents that has not been abandoned, finally rejected or expired without the possibility of appeal or re-filing.

## 2. ASSIGNMENTS

**2.1 Confirmation of Assignments.** The parties confirm their agreement under the LOI that Aegea and Biocept shall jointly own, in undivided shares, the Joint Patents and the Inventions, and reaffirm the following assignments made pursuant to the LOI and effective as of May 2, 2012:

(a) the Inventor assigned to Aegea all of the Inventor's right, title and interest in and to the Aegea Inventions, including, without limitation, all Patents and other intellectual property rights therein;

(b) Aegea assigned to Biocept an undivided joint ownership interest in and to the Aegea Inventions, including, without limitation, all Patents and other intellectual property rights therein; and

(c) Biocept assigned to Aegea an undivided joint ownership interest in and to the Biocept Provisional Application and the Biocept Inventions, including, without limitation, all Patent and other intellectual property rights therein.

**2.2 Further Actions.** Each of the parties agrees to execute, verify and deliver such assignments or other instruments, and to take such actions, as are necessary to effect, perfect or record the foregoing assignments or Aegea's and Biocept's joint ownership, in equal undivided shares, of the Inventions and the Joint Patents.

## 3. CROSS-LICENSES

**3.1 License Grant by Biocept to Aegea.** Subject to the terms and conditions of this Agreement, Biocept hereby grants to Aegea an exclusive (even as to Biocept), worldwide, royalty-free, fully-paid, irrevocable and perpetual license, including the right to sublicense through multiple tiers, under Biocept's interest in the Joint Patents and the Inventions for all applications in the Aegea Field, including to make, have made, use, sell, have sold, offer for sale, and import products in the Aegea Field and to develop, sell, have sold, offer for sale, perform and provide services in the Aegea Field. Aegea shall be free to grant sublicenses under the foregoing license, and to grant licenses under Aegea's interest in the Joint Patents, throughout the world, in each case without Biocept's consent and without accounting to Biocept.

**3.2 License Grant by Aegea to Biocept.** Subject to the terms and conditions of this Agreement, Aegea hereby grants to Biocept an exclusive (even as to Aegea), worldwide, royalty-free, fully-paid, irrevocable and perpetual license, including the right to sublicense through multiple tiers, under Aegea's interest in the Joint Patents and the Inventions for all applications in the Biocept Field, including to make, have made, use, sell, have sold, offer for sale, and import products in the Biocept Field and to develop, sell, have sold, offer for sale, perform and provide services in the Biocept Field. Biocept shall be free to grant sublicenses under the foregoing license, and to grant licenses under Biocept's interest in the Joint Patents, throughout the world, in each case without Aegea's consent and without accounting to Aegea.



**3.3 Section 365(n) of Bankruptcy Code.** The licenses granted by the parties pursuant to Sections 3.1 and 3.2 are, and will be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a party under the U.S. Bankruptcy Code, the other party, as a licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code.

**3.4 No Implied Licenses.** No rights or licenses with respect to any intellectual property of either party are granted or deemed granted hereunder or in connection herewith, other than those rights and licenses expressly granted in this Agreement.

## **4. INTELLECTUAL PROPERTY**

### **4.1 Patent Prosecution and Maintenance.**

**(a) Group A Patents.** Biocept shall have primary responsibility for preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the Group A Patents, using outside patent counsel mutually acceptable to the parties.

**(b) Group B Patents.** Prior to March 15, 2013, as appropriate, the parties shall file or cause to be filed one or more U.S. non-provisional patent applications, PCT patent applications, U.S. provisional patent applications and/or utility patent applications (as agreed by the parties) claiming the Group B Inventions (the “**Group B Application**”). Aegea shall have primary responsibility for preparation, filing, prosecution (including any interferences, reissue proceedings and reexaminations) and maintenance of the Group B Patents, using outside patent counsel mutually acceptable to the parties.

**(c) Generally.** Aegea and Biocept shall share equally (50%/50%) the reasonable and documented fees and costs of preparation, filing, prosecution and maintenance of the Joint Patents, including any interferences, reissue proceedings and re-examinations. The calculation of the fees and costs incurred by each party and the determination of the amount one party may owe the other shall occur annually by January 15<sup>th</sup> of each year for the preceding year, starting on January 15, 2014. Each party shall keep the other party reasonably informed of progress with regard to the preparation, filing, prosecution and maintenance of Joint Patents for which such party (the “**First Party**”) has primary responsibility, and shall consult with, and consider in good faith the requests and suggestions of, the other party (the “**Second Party**”) with respect to strategies for filing and prosecuting Joint Patents worldwide. Neither party shall abandon or cease prosecution or maintenance of any Joint Patent in the United States, the European Patent Organization, Canada, Australia, Japan and China, except by specific written notice of such intent to the other party. Further, if the First Party desires to abandon or cease prosecution or maintenance of any Joint Patent in any country, the First Party shall provide reasonable prior written notice to the Second Party of such intention to abandon (which notice shall, to the extent possible, be given no later than 30 days prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, the Second Party may, in its sole discretion, elect to continue prosecution or maintenance of such Joint Patent, at its sole expense, and the First Party shall assign its rights to that Joint Patent to the Second Party. Similarly, if the Second Party desires to cease paying its 50% share of prosecution and maintenance costs for any Joint Patent in any country, the Second Party shall provide 30 days’ prior written notice thereof to the First Party. In such case,

the Second Party shall remain responsible for its 50% share of prosecution and maintenance incurred during such 30-day notice period and shall assign its rights to that Joint Patent to the First Party.

**4.2 Cooperation.** Each party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of Joint Patents under Section 4.1 and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect thereto. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to effectuate the ownership of Inventions and Joint Patents set forth in Section 2.1, and to enable the other party to apply for and to prosecute patent applications within the Joint Patents in any country as provided in Section 4.1; and (b) promptly informing the other party of any matters coming to such party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

#### **4.3 Patent Enforcement.**

**(a) Notice.** In the event that either Biocept or Aegea becomes aware of any infringement or threatened infringement by a Third Party of any Joint Patent, it shall promptly notify the other party in writing to that effect.

**(b) Biocept Field.** Subject to Section 4.3(d), Biocept shall have the sole right to bring and control any action or proceeding with respect to infringement of any Joint Patent in the Biocept Field, at its own expense and by counsel of its own choice.

**(c) Aegea Field.** Subject to Section 4.3(d), Aegea shall have the sole right to bring and control any action or proceeding with respect to infringement of any Joint Patent in the Aegea Field, at its own expense and by counsel of its own choice.

**(d) Both Fields.** With respect to infringing activity(ies) by a Third Party in both the Biocept Field and the Aegea Field, each party shall have the sole right to bring and control any action or proceeding to enforce the applicable Joint Patent(s) against such Third Party in its respective Field as set forth in Sections 4.3(b) and 4.3(c). Alternatively, the parties may agree to work together, determining who shall bring and control any action or proceeding on behalf of the parties, how expenses and recoveries shall be shared, and which counsel shall be used to represent the parties, taking into account the magnitude of harm suffered by each party.

**(e) Cooperation; Award.** In the event a party brings an infringement action in accordance with this Section 4.3, the other party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party. Neither party shall enter into any settlement or compromise of any action under this Section 4.3 which would in any manner alter, diminish, or be in derogation of the other party's rights under this Agreement without the prior written consent of such other party, which shall not be unreasonably withheld. Except as otherwise agreed by the parties as part of any cost-sharing arrangement, any recovery realized by a party as a result of any action or proceeding pursuant to this Section 4.3, whether by way of settlement or otherwise, after reimbursement of any litigation expenses of the parties, shall be retained by the party that brought and controlled such action for purposes of this Agreement.

**4.4 Third Party Infringement Claims.** Each party shall promptly notify the other in writing of any allegation by a Third Party that the practice of the Inventions infringes or may infringe the intellectual property rights of such Third Party. A party shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by such party's activities at its own expense and by counsel of its own choice. Neither party shall have the right to settle any patent infringement litigation under this Section 4.4 relating to the Joint Patents in a manner that diminishes the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld).

## **5. CONFIDENTIALITY**

**5.1 Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, each party agrees that, during the Term and for five years thereafter, such party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose, other than as expressly provided for in this Agreement, any information relating to the Inventions or the Joint Patents (collectively, "**Confidential Information**"). Each party may use Confidential Information only to the extent required to accomplish the purposes of this Agreement. Each party shall use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its, and its Affiliates', employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. Each party shall promptly notify the other party upon discovery of any unauthorized use or disclosure of the Confidential Information.

**5.2 Exceptions.** Confidential Information shall not include any information which is now, or hereafter becomes, through no breach of this Agreement by either party, generally known or available.

**5.3 Authorized Disclosure.** Each party may disclose Confidential Information of the other party as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

- (a) filing or prosecuting Joint Patents as permitted by this Agreement;
- (b) exercising the license granted to such party hereunder;
- (c) enforcing such party's rights under this Agreement;
- (d) prosecuting or defending litigation as permitted by this Agreement;
- (e) complying with applicable court orders or governmental regulations;

(f) disclosure to Affiliates, licensees and sublicensees, potential licensees and sublicensees, contractors, employees and consultants, in each case, only as necessary for such party to exercise its rights or perform its obligations under this Agreement and on the condition that any such Third Parties agree to be bound by confidentiality and non-use obligations that are no less stringent than the terms of this Agreement; and

(g) disclosure to Third Parties in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Third Party agrees to be bound by reasonable confidentiality and non-use obligations.

Notwithstanding the foregoing, in the event a party is required to make a disclosure of the other party's Confidential Information pursuant to Section 5.3(d) or Section 5.3(e), it shall give reasonable advance notice to the other party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

## 6. REPRESENTATIONS AND WARRANTIES

**6.1 Mutual Representations and Warranties.** Each party hereby represents and warrants to the other party that: (a) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder; (b) this Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; and (c) the execution, delivery and performance of this Agreement do not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

**6.2 Disclaimer.** Except as expressly set forth herein, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS," AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

**6.3 Limitation of Liability.** Except in the case of breach of Article 5, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however,* that this Section 6.3 shall not be construed to limit either party's indemnification obligations under Article 7.

## 7. INDEMNIFICATION

**7.1 Indemnification by Aegea.** Aegea hereby agrees to save, defend, indemnify and hold harmless Biocept, its Affiliates and their respective officers, directors, employees, consultants and agents (the "**Biocept Indemnitees**") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("**Losses**"), to which any Biocept Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Aegea Indemnitee (defined below); (b) the breach by Aegea of any warranty, representation, covenant or agreement made by Aegea in this Agreement; or (c) the practice by Aegea, its Affiliates, licensees or sublicensees of the license granted to Aegea hereunder; in each case, except to the extent such Losses result from the gross negligence or willful misconduct of any Biocept Indemnitee or the breach by Biocept of any warranty, representation, covenant or agreement made by Biocept in this Agreement.

**7.2 Indemnification by Biocept.** Biocept hereby agrees to save, defend, indemnify and hold harmless Aegea, its Affiliates and their respective officers, directors, employees, consultants and agents (the “**Aegea Indemnitees**”) from and against any and all Losses to which any Aegea Indemnatee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Biocept Indemnatee; (b) the breach by Biocept of any warranty, representation, covenant or agreement made by Biocept in this Agreement; or (c) the practice by Biocept, its Affiliates, licensees or sublicensees of the license granted to Biocept hereunder; in each case except to the extent such Losses result from the gross negligence or willful misconduct of any Aegea Indemnatee or the breach by Aegea of any warranty, representation, covenant or agreement made by Aegea in this Agreement.

**7.3 Control of Defense.** In the event a party seeks indemnification under Section 7.1 or 7.2, it shall inform the other party (the “**Indemnifying Party**”) of a claim as soon as reasonably practicable after such party (the “**Indemnified Party**”) receives notice of the claim (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a claim as provided in this Section 7.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice), shall permit the Indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party; in each case, without the prior written consent of the Indemnified Party.

**7.4 Insurance.** Each party, at its own expense, shall maintain: (a) comprehensive general liability insurance, including broad form and contractual liability; (b) and product liability and completed operations/clinical trial and other appropriate insurance, in commercially reasonable amounts in light of such party’s activities at a particular time under this Agreement during the Term. Each party shall provide a certificate of insurance evidencing such coverage to the other party upon request.

## **8. TERM**

This Agreement shall continue in full force and effect until the expiration of the last-to-expire Valid Claim of the Joint Patents.

## **9. DISPUTE RESOLUTION**

**9.1 Dispute Resolution.** Any dispute arising under or relating to the parties’ rights and obligations under this Agreement shall be referred to the Chief Executive Officers of Aegea and Biocept for resolution. In the event such individuals are unable to resolve such dispute within 30 days of such dispute being referred to them, then, upon the written request of either party to the other party, the dispute shall be subject to arbitration in accordance with Section 9.2, except as set forth in Section 9.3 below.

**9.2 Arbitration.** Subject to Section 9.3 below, any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement that is not resolved under Section 9.1 within the specified 30-day period shall be resolved by final and binding arbitration administered by JAMS (the “**Administrator**”) in accordance with its then-effective Comprehensive Arbitration Rules and Procedures (the “**Rules**”), except to the extent any such Rule conflicts with the express provisions of this Section 9.2. The arbitration shall be conducted by one neutral arbitrator selected in accordance with the Rules. The arbitration shall be held in San Diego, California. The arbitrator’s award shall include a written statement describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The arbitrator shall, in rendering his or her decision, apply the substantive laws of the State of California, without giving effect to its conflicts of laws principles, and without giving effect to any rules or laws relating to arbitration. The arbitrator’s authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 6.3. The award rendered by the arbitrator shall be final, binding and non-appealable, and judgment may be entered upon it in any court of competent jurisdiction. Each party shall bear its own attorney’s fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Administrator and the arbitrator; provided, however, that the arbitrator shall be authorized to determine whether a party is the prevailing party, and if so, to award to that prevailing party reimbursement for any or all of its reasonable attorneys’ fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the Administrator and the arbitrator.

**9.3 Court Actions.** Nothing contained in this Agreement shall deny either party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the parties or any ongoing arbitration proceeding. In addition, either party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 9.2.

## **10. MISCELLANEOUS PROVISIONS**

**10.1 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of California, USA, without regard to the conflicts of law provisions thereof.

**10.2 Entire Agreement; Modification.** This Agreement, including the Exhibit hereto, is both a final expression of the parties’ agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein, including the LOI. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

**10.3 Relationship Between the Parties.** The parties’ relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

**10.4 Non-Waiver.** The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.

**10.5 Assignment.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); *provided, however*, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent: (a) in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise; or (b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties, and the name of a party appearing herein shall be deemed to include the name of such party's successors and permitted assigns to the extent necessary to carry out the intent of this section. Any assignment not in accordance with this Agreement shall be void.

**10.6 No Third Party Beneficiaries.** This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

**10.7 Severability.** If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

**10.8 Notices.** Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier, to the party to be notified at its address given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five days after the date of postmark; or (c) if delivered by express courier, the next business day the courier regularly makes deliveries in the country of the recipient.

If to Aegea: Aegea Biotechnologies  
15638 Boulder Mountain Road  
Poway, CA 92064  
Attention: Lyle Arnold, Ph.D.

If to Biocept: Biocept, Inc.  
5810 Nancy Ridge Road  
San Diego, CA 92121  
Attention: Corporate Development

**10.9 Interpretation.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. All references in this Agreement to the singular shall include the plural where applicable. Unless otherwise specified, references in this Agreement to any Article shall include all Sections, subsections and paragraphs in such Article, references to any Section shall include all subsections and paragraphs in such Section, and references in this Agreement to any subsection shall include all paragraphs in such subsection. All references to days in this Agreement shall mean calendar days, unless otherwise specified. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist.

**10.10 Counterparts.** This Agreement may be executed in counterparts, including by transmission of facsimile or PDF copies of signature pages to the parties or their representative legal counsel, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

**IN WITNESS WHEREOF,** the parties have executed this Agreement in duplicate originals by their duly authorized officers as of the Effective Date.

**AEGEA BIOTECHNOLOGIES**

**BIOCEPT, INC.**

By: /s/ Lyle Arnold

By: /s/ David F. Hale

Name: LYLE ARNOLD

Name: David F. Hale

Title: Founder & CEO

Title: Executive Chairman



**Exhibit A**  
**AEGEA INVENTIONS**

<u>Item</u>	<u>Title of Invention Disclosure</u>	<u>Date of Disclosure</u>	<u>Description of Invention</u>
1	Whole Genome Amplification	11/09 12/09	Arnold IP. Uses random primers with unique nucleic analog tails to conduct a two-step whole genome amplification. [**]
2	Whole Transcriptome Amplification	11/09 12/09	Arnold IP. Uses random primers with unique nucleic analog tails to conduct a two-step whole transcriptome amplification. [**]
3	Whole Genome Using Random Priming and T7 Amplification	12/09	Arnold IP. Combines random priming (6-9mers typically) with T7 tail sequences. In a first step amplification is driven by random priming. In a second step amplification is effectuated by T7 mediated amplification.
4	Primer Switch Amplification	10/10	Arnold IP. Expands an earlier switch concept wherein an amplification primer can “switch” between two positions. In one position amplification occurs, in the other position amplification does not occur. The position of the switch is dependent on the target strand sequence down to single base resolution. [**]
5	Improved Whole Genome/Whole Transcriptome Amplification	11/10	Arnold IP. As a further improvement to the Whole Genome and Whole Transcriptome Amplification method described previously in this list (11/09, 12/09) process steps are simplified using by selectively binding the engrafted “tail” sequences. [**]
6	Loop Blocker and Primer Combination for Amplification Reactions	11/10	Arnold IP. A combination of an amplification primer and a blocker, wherein the blocker is directly connected through a linker to the primer. Additionally, the blocker portion is designed to be highly sensitive to the target sequence, down to single nucleotide resolution. [**]
7	Switch Blockers for Selective Amplification and Detection	12/10	Arnold IP. Amplification blockers are used that contain hybridization, bridging, and switch regions. [**] Alternatively labels may be incorporated such that the blocker may also serve as a detection probe. The switch is sensitive down to single base changes and may be used for detecting SNPs as well as more significant target alterations.

[\*\*] Confidential portions omitted and filed separately with the Commission.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the use in this Registration Statement on Form S-1/A and related Prospectus of our report dated August 16, 2013 (except as to Note 17, as to which the date is January 8, 2014), relating to the financial statements of Biocept, Inc., (which report includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern) and to the reference to us under the caption "Experts" which is contained in this Prospectus.

/s/ Mayer Hoffman McCann P.C.

San Diego, California

January 8, 2014