

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Biocept, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

8071
(Primary Standard Industrial
Classification Code Number)

80-0943522
(I.R.S. Employer
Identification Number)

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)

Michael W. Nall
Chief Executive Officer and President
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San Diego, CA 92121
(858) 320-8200

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

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, 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(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 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 under the Securities Exchange Act of 1934. (Check one):

Large Accelerated Filer ☐

Accelerated Filer ☐

Non-accelerated Filer ☐

Smaller Reporting Company ☒

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered		Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Shares of common stock, \$0.0001 par value per share		3,774,122 (1)	\$1.45 (2)	\$5,472,477	\$551
(1)	Represents 790,000 shares of common stock currently outstanding and 2,984,122 shares of common stock that are issuable pursuant to a common stock purchase agreement with the selling stockholder named herein. Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this Registration Statement also covers any additional shares of common stock which may become issuable to prevent dilution from stock splits, stock dividends and similar events.				
(2)	Pursuant to Rule 457(c) of the Securities Act of 1933, as amended, calculated on the basis of the average and low prices per share of the registrant's common stock reported on The NASDAQ Capital Market on December 18, 2015.				

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 that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholder 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 the selling stockholder is not soliciting offers to buy these securities, in any state where the offer or sale of these securities is not permitted.

PROSPECTUS, SUBJECT TO COMPLETION, DATED DECEMBER 21, 2015



3,774,122 Shares

Common Stock

This prospectus relates to the sale of up to 3,774,122 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive proceeds of up to \$15 million from the sale of our common stock to the selling stockholder, pursuant to a common stock purchase agreement entered into with the selling stockholder on December 21, 2015, once the registration statement, of which this prospectus is a part, is declared effective.

The selling stockholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholder will be paid by the selling stockholder.

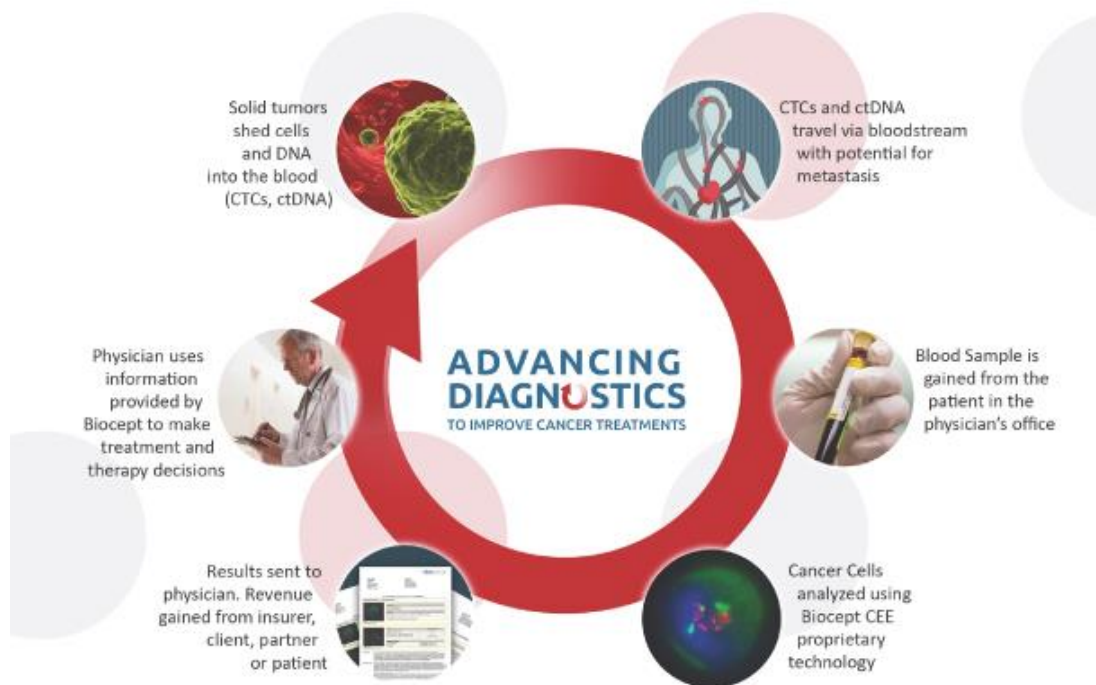
Our common stock is listed on The NASDAQ Capital Market under the ticker symbol “BIOC.” On December 21, 2015, the last reported sale price per share of our common stock was \$1.48 per share.

You should read this prospectus, together with additional information described under the headings “Incorporation of Certain Information by Reference” and “Where You Can Find More Information,” carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See “[Risk Factors](#)” on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is .



The CEE Solution
Personalized Medicine from a Liquid Biopsy

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We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under “Where You Can Find More Information.” You should carefully read this prospectus as well as additional information described under “Incorporation of Certain Information by Reference,” before deciding to invest in our common shares. All references in this prospectus to “Biocept,” “the Company,” “we,” “us” or “our” mean Biocept, Inc., unless we state otherwise or the context otherwise requires.

We are responsible for the information contained in this prospectus. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front of this prospectus.

We use in this prospectus our BIOCEPT logo, for which a United States trademark application has been filed, 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.

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 in this prospectus and the documents that we incorporate by reference herein and have been filed as exhibits to the registration statement of which this prospectus is a part. 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.

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 before making an investment decision.

Our Company

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

Our current molecular cancer diagnostics and our planned future diagnostics utilize our CEE technology for the enumeration and analysis of CTCs, and our Target-Selector™ technology for the detection and analysis of ctDNA from plasma, each performed on a standard blood sample. The CEE technology is an internally developed and patented, 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 from a standard blood sample. The Target-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 from ctDNA. We believe the Target-Selector technology could someday be used as a stand-alone test for molecular biomarker screening and monitoring.

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 (“CLIA”) and accredited by the College of American Pathologists (“CAP”). We manufacture our CEE microfluidic channels, related equipment and certain reagents to perform our current assays and our planned future assays at this facility. CLIA certification is required before any clinical laboratory, including ours, may perform testing on human specimens for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of health. The assays we offer and intend to offer are classified as laboratory developed tests under CLIA regulations.

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 \$150.6 million (as of September 30, 2015);
- 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 business depends on executing on our sales and marketing strategy for our cancer diagnostic tests and gaining acceptance of our current tests and future tests in the market;
- our business depends on our ability to continually develop new cancer diagnostic tests and enhance our current tests and future tests;
- our business depends on being able to obtain coverage and 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. 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 December 31, 2019. However, if certain events occur prior to December 31, 2019, 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 such date.

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 being offered by the selling stockholder

3,774,122 shares

Common stock outstanding

18,880,054 (as of December 17, 2015)

Use of proceeds

The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to \$15 million in proceeds from the sale of our common stock to the selling stockholder under the common stock purchase agreement described below. Any proceeds from the selling stockholder that we receive under the purchase agreement are expected to be used for working capital and general corporate purposes.

NASDAQ Capital Market Symbol

BIOC

Risk Factors

Investing in our securities involves a high degree of risk. You should carefully review and consider the “Risk Factors” section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

On December 21, 2015, we entered into a common stock purchase agreement (referred to in this prospectus as the “Purchase Agreement”), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as “Aspire Capital” or the “selling stockholder”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$15 million of our shares of common stock over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 165,000 shares of our common stock as a commitment fee (referred to in this prospectus as the “Commitment Shares”). Upon execution of the Purchase Agreement, the Company agreed to sell to Aspire Capital 625,000 shares of common stock at \$1.60 per share for proceeds of \$1,000,000 (referred to in this prospectus as the “Initial Purchase Shares”). Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital (referred to in this prospectus as the “Registration Rights Agreement”), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 17, 2015, there were 18,880,054 shares of our common stock outstanding (16,480,183 shares held by non-affiliates) excluding the 3,774,122 shares offered that have been issued or may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of such 3,774,122 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 19.99% of the total common stock outstanding or 22.90% of the non-affiliate shares of common stock outstanding as of the date hereof. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 3,774,122 shares of our common stock under the Securities Act, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and 2,984,122 shares of common stock which we may issue to Aspire Capital after this registration statement is declared effective under the Securities Act, such shares together with the Initial Purchase Shares. All 3,774,122 shares of common stock are being offered pursuant to this prospectus.

After the Securities and Exchange Commission has declared effective the registration statement of which this prospectus is a part, on any trading day on which the closing sale price of our common stock exceeds \$0.50, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”), directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per trading day, up to \$15 million of our common stock in the aggregate at a per share price (the “Purchase Price”) calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 100,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than \$0.50 per share of Common Stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “VWAP Purchase Notice”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company’s common stock traded on the Nasdaq

Capital Market on the next trading day (the “VWAP Purchase Date”), subject to a maximum number of shares we may determine (the “VWAP Purchase Share Volume Maximum”) and a minimum trading price (the “VWAP Minimum Price Threshold”) (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice (the “VWAP Purchase Price”) is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than \$0.50 per share (the “Floor Price”). This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

RISK FACTORS

You should carefully consider the following information about risks, together with the other information contained in this prospectus, before making an investment in our common stock. If any of the circumstances or events described below actually arises or occurs, our business, results of operations, cash flows and financial condition could be harmed. In any such case, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating to Our Financial Condition and Capital Requirements

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

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

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

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

We expect to continue to incur losses for the foreseeable future and will have to raise additional capital to fund our planned operations and to meet our long-term business objectives. As a result, there is substantial doubt about our ability to continue as a going concern unless we are able to successfully raise additional capital. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund our operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. Failure to raise additional capital in sufficient amounts would significantly impact our ability to continue as a going concern. The actual amount of funds that we will need and the timing of any such investment will be determined by many factors, some of which are beyond our control.

Risks Relating to Our Business and Strategy

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

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

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

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

Although we believe that our current tests and our planned diagnostic tests represent a promising commercial opportunity, our tests may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for

us. We will need to establish a market for our cancer diagnostic tests and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publication in leading peer-reviewed journals of results from studies using our current tests and/or our planned cancer tests. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals would limit the adoption of our current tests and our planned tests.

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

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

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

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

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

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

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

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

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

customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

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

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

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

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

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

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

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

There are a number of companies which are focused on the oncology diagnostic market, such as Biodesix, Caris, 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 and other physicians could view as functionally equivalent to our current or planned tests, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more sensitive or specific than ours may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

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

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

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

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

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

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

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

We are undergoing a management transition.

Until August 26, 2013, David F. Hale, our Chairman, served as our principal executive officer. On that date, Michael W. Nall began his employment with us as our Chief Executive Officer and President, with David F. Hale remaining employed as our Executive Chairman until February 10, 2014. Mr. Hale currently serves as non-Executive Chairman of our Board of Directors. We intend to recruit and hire other senior executives, including our recent hiring of Mark Foletta as our interim Chief Financial Officer. Such a

management transition subjects us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge. In addition, Mr. Nall has not previously been the chief executive officer of a public or private company, and therefore his lack of experience may result in some of his time being spent acclimating to his new position and responsibilities. A lack of significant experience in being the chief executive officer of a public company could have an adverse effect on his ability to quickly respond to problems or effectively manage issues surrounding the operation of a public company.

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

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

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

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

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

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

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

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

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

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

Any relationships we form with commercialization partners are subject to change over time. For example, over 75% of our revenue in 2012 was generated through our arrangement with 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. In 2013 and 2014, only 10% and 6%, respectively, of our revenues were generated through our arrangement with Clariant, and we expect that in the future the percentage of our revenue which is generated through our arrangement with Clariant will diminish further. 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 or our third party suppliers terminate their relationship with us, our business may be materially harmed.

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

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

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

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

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

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

Although we believe that our existing product and professional liability insurance is adequate, our insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or

professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation, result in the recall of tests, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

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

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

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

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

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

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

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

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

We currently manufacture our proprietary microfluidic channels at our San Diego facility and intend to continue to do so. We believe we currently have adequate manufacturing capacity for our microfluidic channels. If demand for our current tests and our planned future tests increases significantly, we will need to either expand our manufacturing capabilities or outsource to other

manufacturers. If we or third party manufacturers engaged by us fail to manufacture and deliver our microfluidic channels or certain reagents in a timely manner, our relationships with our customers could be seriously harmed. We cannot assure you that manufacturing or quality control problems will not arise as we attempt to increase the production of our microfluidic channels or reagents or that we can increase our manufacturing capabilities and maintain quality control in a timely manner or at commercially reasonable costs. If we cannot manufacture our microfluidic channels consistently on a timely basis because of these or other factors, it could have a significant negative impact on our ability to perform tests and generate revenues.

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

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

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

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

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

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

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

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

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

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

Regulatory Risks Relating to Our Business

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

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

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

diagnostic test or to our products that are in development; nevertheless, this could change in the future if either the FDA or the Internal Revenue Service, which regulates the payment of this excise tax, changes its position.

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

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

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

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

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

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

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

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

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

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

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

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

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

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare, that a substantial portion of the patients for whom we would expect to perform cancer diagnostic tests will have Medicare as their primary medical insurance. Only in November 2013 did we first directly bill any payor for physician-ordered testing; until May 2013, our commercialization partner 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 tests, 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, and from July to December 2014, we performed an average of 65 physician-ordered tests per month (in addition to the tests which we have been performing since January 2013 for a clinical utility study with investigators at the Dana-Farber Cancer Institute, with an average of 15-30 tests per month performed during the trial's enrollment period through May 2014). Billing for these physician-ordered tests is now handled for us by a non-Clariant billing service provider. Between May 2013 and December 2014, we invoiced, through this service provider, for 239 physician-ordered tests. Of these, 37 tests were billed to Medicare and the remainder were billed to other payors. As of December 31, 2014, we have been paid by private payors for 67 of these tests. As of December 31, 2014, all of our revenue recognized has come from private payors, and processing of the Medicare claims above was delayed due to a new application process relating to a change in our tax identification

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Intellectual Property Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

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

Risks Relating to Our Common Stock

The price of our common stock may be volatile.

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

- progress, or lack of progress, in developing and commercializing our current tests and our planned future cancer diagnostic tests;
- favorable or unfavorable decisions about our tests from government regulators, insurance companies or other third-party payors;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;

- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled “Risk Factors”; and
- general market and economic conditions.

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

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

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

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

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

Our quarterly operating results may fluctuate significantly.

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

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

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

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

Sales of substantial amounts of our common stock, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We had outstanding 18,880,054 shares of common stock as of December 17, 2015, 2,702,534 of which are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended. In addition, as of December 17, 2015, we had outstanding options to purchase 2,012,086 shares of our common stock, 77,265 shares of common stock were issuable upon the settlement of outstanding restricted stock units and we had outstanding warrants to purchase 2,354,325 shares of our common stock. Shares issued upon the exercise of stock options or upon the settlement of outstanding restricted stock units generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

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

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

Claire K. T. Reiss beneficially owned approximately 10.7% of our common stock at December 17, 2015. Mrs. Reiss has significant influence over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Accordingly, this concentration of ownership might harm the market price of our common stock by:

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

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

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

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until

December 31, 2019, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

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

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

Certain provisions of our amended certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. (For example, Delaware law provides that if a corporation has a classified board of directors, stockholders cannot remove any director during his or her term without cause.) These provisions also

could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

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

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

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

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

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

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

We could be subject to securities class action litigation.

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

Risks Related to This Offering

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

We will need to raise substantial additional capital in the future to fund our operations. The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. See “The Aspire Capital Transaction” section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than \$0.50 per share. Even if we are able to access the full \$15 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We are registering for sale the Commitment Shares and Initial Purchase Shares that we have issued and 2,984,122 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all, some or none of the \$15 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. However, we have the right under the Purchase Agreement to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to \$15 million under the Purchase Agreement with Aspire Capital. The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. This anticipated use of net proceeds from the sale of shares our common stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions.

THE ASPIRE CAPITAL TRANSACTION

General

On December 21, 2015, we entered into the Purchase Agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$15 million of our shares of common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company agreed to sell to Aspire Capital 625,000 Initial Purchase Shares for proceeds of \$1,000,000. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 165,000 Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 17, 2015, there were 18,880,054 shares of our common stock outstanding (16,480,183 shares held by non-affiliates) excluding the 3,774,122 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of such 3,774,122 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 19.99% of the total common stock outstanding or 22.90% of the non-affiliate shares of common stock outstanding as of the date hereof. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 3,774,122 shares of our common stock under the Securities Act, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and 2,984,122 shares of common stock which we may issue to Aspire Capital after this registration statement is declared effective under the Securities Act. All 3,774,122 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 3,774,122 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 3,774,122 shares of common stock offered hereby.

After the Securities and Exchange Commission has declared effective the registration statement of which this prospectus is a part, on any trading day on which the closing sale price of our common stock is not less than \$0.50 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 100,000 shares of our common stock per business day, up to \$15 million of our common stock in the aggregate over the term of the Purchase Agreement, at a Purchase Price calculated by reference to the prevailing market price of our common stock over the preceding 10-business day period (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 100,000 Purchase Shares and the closing price of our common stock is not less than \$0.50 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than the Floor Price. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Purchase Of Shares Under The Common Stock Purchase Agreement

Under the common stock Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds \$0.50 per share, we may direct Aspire Capital to purchase up to 100,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 100,000 shares and on which the closing price of our common stock exceeds \$0.50 per share, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the our common stock traded on the Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of the Company's common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the Closing Sale Price on the VWAP Purchase Date; or
- 97% of the volume-weighted average price for our common stock traded on the Nasdaq Capital Market:
 - o on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or
 - o during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the Nasdaq Capital Market exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the Company's common stock falls below the VWAP Minimum Price Threshold.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than \$0.50 per share.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following, among other, events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC such lapse or unavailability may continue for a period of no more than 30 consecutive business days;
- the suspension from trading or failure of our common stock to be listed on our principal market for a period of three consecutive business days;
- the delisting of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Select Market, the Nasdaq Global Market, the OTB Bulletin Board or the OTCQB marketplace or OTCQX marketplace of the OTC Markets Group;

- our transfer agent's failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;
- any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;
- if we become insolvent or are generally unable to pay our debts as they become due; or
- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 3,774,122 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 2,984,122 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to \$15 million of our shares of common stock. However, we estimate that we will sell no more than 2,984,122 shares to Aspire Capital under the Purchase Agreement (exclusive of the 165,000 Commitment Shares and the 625,000 Initial Purchase Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 3,774,122 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 3,774,122 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price (1)	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (2)
\$0.50	\$2,482,061	3,589,122	16.6%
\$1.00	\$3,964,122	3,589,122	16.6%
\$1.50	\$5,446,183	3,589,122	16.6%
\$2.00	\$6,928,244	3,589,122	16.6%
\$5.00	\$15,000,000	3,425,000	16.0%
\$10.00	\$15,000,000	2,025,000	10.4%

(1) Excludes 165,000 Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital.

(2) The denominator is based on 18,880,054 shares outstanding as of December 17, 2015, which includes the 790,000 shares previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to

Aspire Capital. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed purchase price set forth in the adjacent column.

SELLING STOCKHOLDER

The selling stockholder may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the “selling stockholder” in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholder’s interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling stockholder for whom we are registering shares for sale to the public, the number of shares of common stock beneficially owned by the selling stockholder prior to this offering, the total number of shares of common stock that the selling stockholder may offer pursuant to this prospectus and the number of shares of common stock that the selling stockholder will beneficially own after this offering. Except as noted below, the selling stockholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling stockholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling stockholder, assuming that the selling stockholder sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling stockholder will not own any shares other than those appearing in the column entitled “Beneficial Ownership After This Offering.” We cannot advise you as to whether the selling stockholder will in fact sell any or all of such shares of common stock. In addition, the selling stockholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act of 1933 after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering (1)	
Name	Shares of Common Stock Owned Prior to this Offering	Shares of Common Stock Being Offered	Number of Shares	% (2)
Aspire Capital Fund, LLC (3)	790,000 (4)	2,984,122	—	—
<p>* Represents less than 1% of outstanding shares.</p> <p>(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholder is under no obligation known to us to sell any shares of common stock at this time.</p> <p>(2) Based on 18,880,054 shares of common stock outstanding on December 17, 2015.</p> <p>(3) Aspire Capital Partners LLC (“Aspire Partners”) is the Managing Member of Aspire Capital Fund LLC (“Aspire Fund”). SGM Holdings Corp (“SGM”) is the Managing Member of Aspire Partners. Mr. Steven G. Martin (“Mr. Martin”) is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown (“Mr. Brown”) is the president and sole shareholder of Red Cedar Capital Corp (“Red Cedar”), which is a principal of Aspire Partners. Mr. Christos Komissopoulos (“Mr. Komissopoulos”) is president and sole shareholder of Chrisko Investors Inc (“Chrisko”), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Fund. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial ownership of the common stock held by Aspire Fund.</p> <p>(4) As of the date hereof, 790,000 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of shares we issued to Aspire Capital as a commitment fee and the Initial Purchase Shares sold to Aspire Capital. We may elect in our sole discretion to sell to Aspire Capital up to an additional 2,984,122 shares under the Purchase Agreement but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.</p>				

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Aspire Capital, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an "underwriter" within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in

the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. Aspire Capital is being represented by Morrison & Foerster LLP, Washington, D.C.

EXPERTS

The financial statements of Biocept, Inc. as of December 31, 2014 and 2013 and for each of the years in the two-year period ended December 31, 2014, have been incorporated by reference herein and in the registration statement in reliance upon the report of Mayer Hoffman McCann P.C., independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm 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 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 5810 Nancy Ridge Drive, San Diego, California 92121 or telephoning us at (858) 320-8200.

We are subject to the information and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at <http://www.biocept.com>. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference in, and is not part of, this prospectus.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus. We are incorporating by reference the documents listed below, which we have already filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2014;
- our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015;
- the information specifically incorporated by reference into our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 from our definitive proxy statement on Schedule 14A (other than information furnished rather than filed) filed with the SEC on April 30, 2015;
- our Current Reports on Form 8-K filed with the SEC on June 17, 2015, August 21, 2015 and December 21, 2015 (in each case, except for information contained therein which is furnished rather than filed); and
- the description of our common stock, which is registered under Section 12 of the Exchange Act, in our registration statement on Form 8-A, filed with the SEC on January 28, 2014, including any amendments or reports filed for the purpose of updating such description.

Upon request, we will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered a copy of the documents incorporated by reference into this prospectus. You may request a copy of these filings, and any exhibits we have specifically incorporated by reference as an exhibit in this prospectus, at no cost by writing or telephoning us at the following address:

Biocept, Inc.
5810 Nancy Ridge Drive
San Diego, California 92121
Telephone: (858) 320-8200

You also may access these filings on our Internet site at <http://biocept.com>. Our web site and the information contained on that site, or connected to that site, are not incorporated into this prospectus or the Registration Statement on Form S-1.

This prospectus is part of a registration statement we filed with the SEC. We have incorporated exhibits into this registration statement. You should read the exhibits carefully for provisions that may be important to you.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus or in the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

3,774,122 Shares



Common Stock

PROSPECTUS

, 2015

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 by Biocept, Inc., or the Registrant, in connection with the sale and distribution of the securities being registered. All amounts are estimated except the SEC registration fee and the NASDAQ listing fee.

Item	Amount
SEC registration fee	\$ 551
Legal fees and expenses	50,000
Accounting fees and expenses	5,000
Printing and engraving expenses	15,000
Transfer agent and registrar fees and expenses	2,000
Miscellaneous fees and expenses	2,449
Total	\$ 75,000

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 Registrant'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 Registrant'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 Registrant has entered into indemnification agreements with each of its current directors and executive officers. These agreements will require the Registrant to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Registrant and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified. The Registrant also intends to enter into indemnification agreements with its future directors and executive officers.

Item 15. Recent Sales of Unregistered Securities.

Since January 1, 2011, the Registrant made sales of the unregistered securities discussed below. 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.

Aspire Transaction

On December 21, 2015, concurrently with the execution of the Purchase Agreement, the Registrant issued to Aspire Capital 165,000 shares of common stock as a commitment fee and sold to Aspire Capital 625,000 shares of common stock at \$1.60 per share for proceeds of \$1,000,000.

Note and Warrant Financings

In 30 closings from February 2011 to November 2012, the Registrant sold secured convertible promissory notes with an aggregate principal amount of \$12,336,247, together with warrants that subsequently became exercisable for 108,786 shares of its common stock at an exercise price of \$10.00 per share, to 11 accredited investors, for aggregate gross proceeds of \$12,336,247.

In 21 closings from January 2012 to December 2012, the Registrant sold promissory notes with an aggregate principal amount of \$5,960,000, together with warrants that subsequently became exercisable for 52,557 shares of the Registrant's common stock to five accredited investors at an exercise price of \$10.00 per share, for aggregate gross proceeds of \$5,960,000. These promissory notes were converted into shares of the Registrant's common stock upon the closing of its initial public offering.

In 56 closings from December 2012 through January 2014, the Registrant sold promissory notes with an aggregate principal amount of \$5,165,000, together with warrants that subsequently became exercisable for 258,249 shares of the Registrant's common stock at an exercise price of \$10.00 per share, to 14 accredited investors, for aggregate gross proceeds of \$5,165,000.

Compensatory Issuances

In 2011 the Company issued 36,260 common stock options (at a \$4.62 weighted average exercise price per share) and 23,874 preferred stock restricted stock units (number of common stock equivalents) to service providers.

In 2012 the Registrant issued 330 common stock options (at a \$4.62 weighted average exercise price per share) and 32,769 common stock restricted stock units to service providers.

In 2013, the Registrant issued 300,438 common stock options (at a \$5.18 weighted average exercise price per share) and 101,202 common stock restricted stock units to service providers.

In 2014, the Registrant issued 647,298 common stock options (at a \$6.71 weighted average exercise price per share) and 44,496 common stock restricted stock units to service providers. Upon the completion of the Registrant's initial public offering in February 2014, a total of 73,151 preferred stock restricted stock units (number of common stock equivalents) vested in accordance with underlying agreements, including the 23,874 preferred stock restricted stock units (number of common stock equivalents) issued in 2011.

In the nine months ended September 30, 2015, the Registrant issued 1,194,871 common stock options (at a \$2.07 weighted average exercise price per share) to service providers.

Inducement Warrants

In September 2012, the Registrant 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. The Series A preferred stock warrants are exercisable for 1,587 shares of the Registrant's common stock at an exercise price of \$25.20 per share.

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

In July 2013 through January 2014, the Registrant issued common stock warrants which became exercisable upon the completion of the Registrant's initial public offering in February 2014 for an aggregate 128,903 shares of the Registrant's common stock, at an exercise price of \$10.00 per share, to five guarantors in connection with their guaranties of its UBS Bank USA revolving line of credit.

In September 2013, the Registrant 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. Upon the completion of the Registrant's initial public offering in February 2014, the exercise price of the common stock warrants issued to its landlord was fixed at \$10.00 per share for an aggregate 50,260 shares of the Registrant's common stock.

Recapitalization

In November 2011, the Registrant effected a recapitalization in which all outstanding shares of, and warrants to purchase and restricted stock units to obtain, the Registrant'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 Registrant effected the 1-for-3 reverse split of its common stock.

Conversions and Exercises

In November 2011, the Registrant's Executive Chairman exercised 10,204 common stock options, paying an aggregate exercise price of \$47,183.

In October 2011, a major stockholder 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 stock options for 85 shares of common stock, 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 \$2,581,000 voluntarily converted such principal and interest into 42,245,834 shares of the Registrant's Series A preferred stock. Such shares of Series A preferred stock were subsequently converted into 1,652,851 shares of the Registrant's common stock upon completion of the Registrant's initial public offering in February 2014.

In the fourth quarter of 2013, four employees exercised 3,936 common stock options, paying an aggregate exercise price of \$19,710.

In February 2014:

- The \$1,400,000 principal amount of and the \$233,982 accrued interest on the Registrant's 2008 convertible note held by a trust affiliated with the Registrant's majority stockholder, Claire K. T. Reiss, were converted at \$10.00 per share into a total of 163,399 shares of common stock.
- The \$5,165,000 principal amount of and the \$313,017 accrued interest on our "2013" convertible notes held by various persons, including several insiders, were converted at \$10.00 per share into a total of 547,801 shares of common stock. The following persons received the following numbers of such shares:
 - o Affiliates of Claire K. T. Reiss, majority stockholder—270,484
 - o Affiliate of David F. Hale, Chairman—47,181
 - o Affiliate of Edward Neff, Director—108,140
 - o Marsha Chandler, Director—5,078
 - o M. Faye Wilson, Director—2,650
 - o Bruce E. Gerhardt, Director—1,055
- Warrants for an aggregate 95,000 shares of the Registrant's common stock were issued to the underwriters of the Registrant's initial public offering and are exercisable at a price of \$12.50 per share.
- Common stock options for an aggregate 285,000 shares of the Registrant's common stock were issued to the underwriters of the Registrant's initial public offering and were exercisable through March 21, 2014 at an exercise price of \$9.30 per share to cover over-allotments, which was not exercised.

In February 2015:

- Warrants for an aggregate 8,000,000 shares of the Registrant's common stock were issued to participants, including several insiders, of the Registrant's secondary public offering and are exercisable at a price of \$1.56 per share, with total proceeds of \$9,760,060 received from the exercises of such warrants from February 13, 2015 through December 17, 2015. Each of the members of the Registrant's Board of Directors participated in the Registrant's secondary public offering, purchasing an aggregate 142,000 shares of the Registrant's common stock and warrants to purchase up to an aggregate of 142,000 shares of the Registrant's common stock for a total purchase price of \$177,500. The following persons received the following numbers of such warrants:
 - o Affiliate of David F. Hale, Chairman—40,000
 - o Affiliate of Edward Neff, Director —40,000
 - o Bruce A. Huebner, Director—12,000
 - o Bruce E. Gerhardt, Director—20,000
 - o Marsha A. Chandler, Director—2,000
 - o Michael W. Nall, President and CEO, Director—12,000
 - o M. Faye Wilson, Director—4,000
 - o Retirement account of Ivor Royston, M.D., Director—12,000
- Common stock options for an aggregate 1,200,000 shares of the Registrant's common stock at an exercise price of \$1.25 per share and/or additional warrants for an aggregate 1,200,000 shares of the Registrant's common stock at an

exercise price of \$0.0001 per warrant were issued to the underwriters of the Registrant's secondary public offering to cover overallocments, which were exercisable through March 30, 2015 and were not exercised.

Debt financing warrant

In April 2014, the Registrant issued Oxford Finance LLC a warrant to purchase up to 52,966 shares of the Registrant's common stock, at an exercise price of \$4.72 per share. The warrant was issued in connection with a loan and security agreement between the Registrant and Oxford Finance LLC dated April 30, 2014.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial Statement Schedules

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission 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 the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant 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, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in San Diego, California, on the 21st day of December, 2015.

BIOCEPT, INC.

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

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Michael W. Nall and Mark G. Foletta, and each and either of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
<u>/s/ Michael W. Nall</u> Michael W. Nall	Chief Executive Officer, President and Director (Principal Executive Officer)	December 21, 2015
<u>/s/ Mark G. Foletta</u> Mark G. Foletta	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 21, 2015
<u>/s/ David F. Hale</u> David F. Hale	Chairman and Director	December 21, 2015
<u>/s/ Marsha A. Chandler</u> Marsha A. Chandler	Director	December 21, 2015
<u>/s/ Bruce E. Gerhardt</u> Bruce E. Gerhardt	Director	December 21, 2015
<u>/s/ Bruce A. Huebner</u> Bruce A. Huebner	Director	December 21, 2015
<u>/s/ Edward Neff</u> Edward Neff	Director	December 21, 2015
<u>/s/ Ivor Royston</u> Ivor Royston	Director	December 21, 2015
<u>/s/ M. Faye Wilson</u> M. Faye Wilson	Director	December 21, 2015

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
3.1	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
4.3	Form of Representative's Warrant, dated February 10, 2014 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
4.4	Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
4.5	Registration Rights Agreement, dated as of December 21, 2015 between the Registrant and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2015).
5.1	Opinion of Cooley LLP.
10.1+	2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.2+	Form of Stock Option Grant Notice and Option Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.3+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2007 Equity Incentive Plan (incorporated by reference to Exhibit 10.1.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.4+	2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 20, 2013)
10.5+	Form of Notice of Stock Option Grant under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.6+	Form of Stock Option Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.7+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (incorporated by reference to Exhibit 10.2.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.8+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for senior officers: as used August 8, 2013) (incorporated by reference to Exhibit 10.2.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.9+	Form of Restricted Stock Unit Agreement under 2013 Equity Incentive Plan (for non-employee directors: as used August 8, 2013) (incorporated by reference to Exhibit 10.2.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.10+	Restricted Stock Unit Grant Notice / Agreement with David F. Hale, dated as of March 10, 2011 ("Performance-Based") (incorporated by reference to Exhibit 99.3 of the Registrant's Registration Statement on Form S-8 (File No. 333-194930), filed with the SEC on March 31, 2014).
10.11+	Restricted Stock Unit Grant Notice / Agreement with David F. Hale, dated as of March 10, 2011 ("Time-Based") (incorporated by reference to Exhibit 99.4 of the Registrant's Registration Statement on Form S-8 (File No. 333-194930), filed with the SEC on March 31, 2014).

Exhibit No.	Description of Exhibit
10.12+	Restricted Stock Unit Grant Notice / Agreement with Ivor Royston, dated as of November 8, 2010, as amended on February 15, 2012 (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the Commission on September 23, 2013).
10.13+	2014 Annual Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 8, 2014).
10.14+	Form of Indemnification Agreement between the Registrant and its officers and directors (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.15+	Form of Indemnity Agreement between Biocept, Inc., a California corporation, and its officers and directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.16+	Employment Agreement, between the Registrant and Lyle J. Arnold, dated April 30, 2011(incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.17+	Employment Agreement, between the Registrant and Raaj Trivedi, dated March 1, 2014 (incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on January 9, 2015).
10.18	Lease, between the Registrant and Nexus Equity VIII LLC, dated March 31, 2004 (incorporated by reference to Exhibit 10.1.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
10.19	First Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated November 1, 2011(incorporated by reference to Exhibit 10.11.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.20	Second Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated September 10, 2012 (incorporated by reference to Exhibit 10.11.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.21	Third Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated as of January 31, 2013, and effective as of January 1, 2013 (incorporated by reference to Exhibit 10.11.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.22	Fourth Amendment to Lease, between the Registrant and ARE-SD Region No. 18, LLC, dated as of September 10, 2013, and effective as of August 1, 2013 (incorporated by reference to Exhibit 10.11.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.23	Warrant to Purchase Preferred Stock, dated September 10, 2012, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.24	Warrant to Purchase Common Stock, dated September 10, 2013, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.25	Amended and Restated Investor Rights Agreement, dated as of October 31, 2011, among the Registrant and certain investors named therein (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.26*	Collaboration Agreement dated as of November 2, 2012 between the Registrant and Life Technologies Corporation (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 30, 2014).
10.27	Collaboration Agreement dated as of August 17, 2011 between the Registrant and Clariant Diagnostic Services, Inc. (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 8, 2014).
10.28	Warrant to Purchase Preferred Stock dated as of January 21, 2009, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.29	Warrant to Purchase Common Stock dated as of July 31, 2013, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).

Exhibit No.	Description of Exhibit
10.30	Form of Warrant to Purchase Preferred Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012 (incorporated by reference to Exhibit 10.19.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.31	Form of Amendment of Warrant to Purchase Preferred Stock, dated as of September 13, 2013 (incorporated by reference to Exhibit 10.19.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.32	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013 (incorporated by reference to Exhibit 10.20.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.33	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various guarantors under the Reimbursement Agreement dated as of July 11, 2013 (incorporated by reference to Exhibit 10.21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.34	Assignment and Exclusive Cross-License Agreement between the Registrant and Aegea Biotechnologies, Inc. dated June 2, 2012 (incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on January 30, 2014).
10.35*	Master Laboratory Research Support and Services Agreement dated as of July 9, 2012 between the Registrant and Dana Farber Partners Cancer Care, Inc. (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
10.36	Laboratory Services Agreement dated July 29, 2013, effective as of May 1, 2013, between the Registrant and Clariant Diagnostic Services, Inc. (incorporated by reference to Exhibit 10.14.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
10.37	Loan and Security Agreement by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC, dated as of April 30, 2014 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
10.38	Separation Agreement between the Registrant and William G. Kachioff, dated August 17, 2015 (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-36284), filed with the SEC on August 21, 2015).
10.39+	Employment Agreement between the Registrant and Mark G. Foletta, dated August 18, 2015 (incorporated by reference to Exhibit 99.3 to the Registrant's Current Report on Form 8-K (File No. 001-36284), filed with the SEC on August 21, 2015).
10.40+	Employment Agreement Amendment between the Registrant and Michael W. Nall, dated November 6, 2015 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-36284), filed with the SEC on November 9, 2015).
10.41	Biocept, Inc. 2013 Amended and Restated Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement and Restricted Stock Unit Agreement for use thereunder (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-36284), filed with the SEC on June 17, 2015).
10.42	Common Stock Purchase Agreement, dated as of December 21, 2015 between the Registrant and Aspire Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2015).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013) .
23.1	Consent of Mayer Hoffman McCann P.C.
23.2	Consent of Cooley LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page hereto).

+ Indicates management contract or compensatory plan.

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

Charles J. Bair
T: +1 858 550 6142
cbair@cooley.com

December 21, 2015

Biocept, Inc.
5810 Nancy Ridge Drive, Suite 150
San Diego, CA 92121

RE: Biocept, Inc.

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the filing by Biocept, Inc., a Delaware corporation (the “**Company**”), of a Registration Statement on Form S-1 (the “**Registration Statement**”) with the Securities and Exchange Commission, covering the registration for resale of (i) 790,000 shares (the “**Shares**”) of the Company's common stock, par value \$0.0001, issued to Aspire Capital Fund, LLC (“**Aspire**”), and (ii) up to 2,984,122 shares of the Company's common stock, par value \$0.0001 (the “**Agreement Shares**”) that may be issued from time to time pursuant to a common stock purchase agreement dated December 21, 2015 (the “**Common Stock Purchase Agreement**”), between the Company and Aspire.

In connection with this opinion, we have examined and relied upon the Registration Statement and related prospectus, the Company's Certificate of Incorporation, as amended, and its Amended and Restated Bylaws, each as currently in effect, the Common Stock Purchase Agreement and the originals or copies certified to our satisfaction of such other records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below.

We have assumed the genuineness and authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies thereof and the due execution and delivery of all documents where due execution and delivery are a prerequisite to the effectiveness thereof. As to certain factual matters, including without limitation the receipt by the Company of the purchase price for the Shares as provided in the Common Stock Purchase Agreement, we have relied upon a certificate of an officer of the Company and have not sought independently to verify such matters.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion as to whether the laws of any particular jurisdiction are applicable to the subject matter hereof. We are not rendering any opinion as to compliance with any federal or state antifraud law, rule or regulation relating to securities, or to the sale or issuance thereof.

With regard to our opinion in clause (ii) below concerning the Agreement Shares, we have assumed that all Agreement Shares issuable pursuant to the Common Stock Purchase Agreement are issued on the date hereof (notwithstanding any conditions or limitations restricting such exercise or issuance set forth in the Common Stock Purchase Agreement).

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Shares are validly issued, fully paid and non-assessable and (ii) upon issuance and delivery of the Agreement Shares by the Company in accordance with the terms of the Common Stock Purchase Agreement, including, without limitation, the payment in full of the applicable consideration therefor, the Agreement Shares will be validly issued, fully paid and non-assessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Registration Statement and in the related prospectus and to the filing of this opinion as an exhibit to the Registration Statement.

Sincerely,

Cooley LLP

By: /s/ Charles J. Bair
Charles J. Bair

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

As independent registered public accountants, we hereby consent to the incorporation by reference of our report dated March 10, 2015, relating to the financial statements of Biocept, Inc., as of and for the years ended December 31, 2014 and 2013, in this Registration Statement on Form S-1. We also consent to the reference to our Firm under the caption “Experts” in the Prospectus, which is part of said Registration Statement.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
December 21, 2015