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

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**AMENDMENT NO. 2  
TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**Biocept, Inc.**

(Exact name of registrant as specified in its charter)

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

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

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

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**Michael W. Nall**  
Chief Executive Officer and President  
Biocept, Inc.  
5810 Nancy Ridge Drive  
San Diego, CA 92121  
(858) 320-8200

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

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after 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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act:

Large accelerated filer

☐

Non-accelerated filer

☐ (Do not check if a smaller reporting company)

Accelerated filer

☐

Smaller reporting company

☒

Emerging growth company

☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☒

CALCULATION OF REGISTRATION FEE

Title of Securities being Registered	Proposed Maximum Aggregate Offering Price (1) (2)	Amount of Registration Fee (3)
Shares of common stock, \$0.0001 par value per share	\$12,500,000	\$1,556.25
Series A Warrants to purchase shares of common stock (4)		
Shares of common stock issuable upon exercise of the Series A Warrants	\$9,375,000	\$1,167.19
Series B Warrants to purchase shares of common stock (4)		
Shares of common stock issuable upon exercise of the Series B Warrants	\$3,125,000	\$389.07
Total	\$25,000,000	\$3,112.51

- (1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.
- (2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (3) \$1,245 of which was previously paid.
- (4) No fee is required pursuant to Rule 457(i) under the Securities Act of 1933, as amended.

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. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION, DATED JANUARY 22, 2018



**18,796,992 Shares of Common Stock**  
**Series A Warrants to Purchase Up to 14,097,744 Shares of Common Stock**  
**Series B Warrants to Purchase Up to 4,699,248 Shares of Common Stock**

Biocept, Inc. is offering 18,796,992 shares of our common stock and warrants to purchase shares of our common stock, at an assumed combined offering price of \$0.665 per share of common stock and accompanying warrants (the last reported sale price of our common stock on January 19, 2018). Each share of our common stock is being sold together with 0.75 of a Series A warrant to purchase one share of our common stock and 0.25 of a Series B warrant to purchase one share of our common stock. Each warrant will have an exercise price per share of not less than 100% of the last reported sale price of our common stock on the trading day immediately preceding the pricing of this offering, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date with respect to the Series A warrant and on the six month anniversary of the original issuance date with respect to the Series B warrant. The shares of our common stock and warrants are immediately separable and will be issued separately, but will be purchased together in this offering. This prospectus also relates to the offering of shares of our common stock issuable upon exercise of the warrants.

Our common stock is listed on The NASDAQ Capital Market under the symbol "BIOC." On January 19, 2018, the last reported sale price of our common stock on The NASDAQ Capital Market was \$0.665 per share. There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

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

You should read this prospectus, together with additional information described under the heading "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](#)" beginning on page 5 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

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

	Per Share and Related Warrants	Total (2)
Public offering price	\$	\$
Placement agent fees(1)	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) See "Plan of Distribution" on page 117 for additional disclosure regarding placement agent compensation and reimbursement of expenses.

(2) Assumes maximum offering is completed.

The placement agent expects to deliver the common stock and the warrants to purchasers in this offering on or about , 2018.

Dawson James Securities, Inc.

WestPark Capital, Inc.

The date of this prospectus is .



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

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

For investors outside the United States: We have not, and the placement agent has not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby and the distribution of this prospectus outside the United States.

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

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

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We use in this prospectus our BIOCEPT logo, for which a United States trademark application has been filed. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear (after the first usage) without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

## SUMMARY

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

### Our Company

We are an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or “liquid biopsy.” Our current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring in order to identify specific resistance mechanisms. Often, traditional methodologies such as tissue biopsies are insufficient or unavailable to provide the molecular subtype information necessary for clinical decisions. Our assays have the potential to provide more contemporaneous information on the characteristics of a patient’s disease compared with traditional methodologies such as tissue biopsy and radiographic imaging. Additionally, commencing in October 2017, our pathology program initiative provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results and is available to pathology practices and hospital systems throughout the United States. Further, our proprietary blood collection tubes, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world, are anticipated to be sold to laboratory supply distributor(s) commencing in 2018.

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

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We also performed research and development that led to our current assays, and we also intend to perform research and development for planned assays, at this facility. In addition, we manufacture our microfluidic channels, related equipment and certain reagents. The assays we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations. 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. In addition, we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and adherence to specific quality standards.

### 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 \$189.6 million (as of September 30, 2017);
- we expect to incur net losses in the future, and we may never achieve sustained profitability;
- we need to raise additional capital to continue as a going concern;
- our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a de-listing of our common stock;
- our financial condition may be materially adversely affected in an event of default under our credit facility;
- our sale of our common stock may cause substantial dilution to our existing stockholders and could cause the price of our common stock to decline;
- our business depends upon our ability to increase sales of our current products, assays and services and to develop and commercialize other products, assays and services;

- our business depends on executing on our sales and marketing strategy for our products and diagnostic assays and gaining acceptance of our current products, assays and services and future products, assays and services in the market, for which we expect to continue to incur significant expenses;
- our business depends on our ability to continually develop new products and diagnostic assays and enhance our current products assays and future products, assays and services, for which we expect to continue to incur significant expenses;
- our business depends on our ability to effectively compete with other products and diagnostic assays, methods and services that now exist or may hereafter be developed;
- our business depends on our senior management;
- our business depends on our ability to attract and retain scientists, clinicians, laboratory personnel and sales personnel with extensive experience in diagnostics and/or oncology, who are in short supply;
- our business depends on our ability to enter into agreements with commercialization partners, who may not perform adequately or be locatable, for the sales, marketing and commercialization of our current products, assays and services and our planned future products, assays and services;
- we expect to expand our international business, which would increase our exposure to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States;
- our financial condition may be materially adversely affected by healthcare policy changes, including legislation reforming the United States health care system;
- our business depends on being able to obtain coverage and adequate reimbursement from governmental and other third-party payers for assays and services;
- our business depends on satisfying any applicable United States (including Food and Drug Administration) and international regulatory requirements with respect to products, assays and services, and many of these requirements are new and still evolving; and
- we need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned products, assays and services, and we must avoid infringement of third-party intellectual property.

#### **Company Information**

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

#### **Implications of Being an Emerging Growth Company**

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

- 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 offered by us**

18,796,992 shares (assuming a combined public offering price of \$ 0.665 per share and related warrants, the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018).

### **Warrants offered by us**

Series A Warrants to purchase up to 14,097,744 shares of our common stock (assuming a combined public offering price of \$ 0.665 per share and related warrants, the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018). Each share of our common stock is being sold together with 0.75 of a Series A warrant to purchase one share of our common stock. Each Series A warrant will have an exercise price per share of not less than 100% of the last reported sale price of our common stock on the trading day immediately preceding the pricing of this offering, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date.

Series B Warrants to purchase up to 4,699,248 shares of our common stock (assuming a combined public offering price of \$0.665 per share and related warrants, the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018). Each share of our common stock is being sold together with 0.25 of a Series B warrant to purchase one share of our common stock. Each Series B warrant will have an exercise price per share of not less than 100% of the last reported sale price of our common stock on the trading day immediately preceding the pricing of this offering, will be immediately exercisable and will expire on the six-month anniversary of the original issuance date.

### **Common stock outstanding after this offering**

49,055,735 shares (assuming a combined public offering price of \$ 0.665 per share and related warrants, the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018) (or 67,852,727 shares if the warrants sold in this offering are exercised in full).

### **Use of proceeds**

Based on an assumed combined public offering price of \$ 0.665 per share and related warrants (the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018), we estimate that the net proceeds from our sale of shares of our common stock and warrants in this offering will be approximately \$ 11.2 million, after deducting estimated placement agent fees and estimated offering expenses payable by us. We currently expect to use the net proceeds from this offering for general corporate purposes and to fund ongoing operations and expansion of our business.

For additional information please refer to the section entitled “Use of Proceeds” on page 35 of this prospectus.

### **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.

**Market Symbol and trading**

Our common stock is listed on The Nasdaq Capital Market under the symbol “BIOC.” There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

The number of shares of our common stock to be outstanding after this offering is based on 30,258,743 shares of our common stock outstanding as of September 30, 2017 and excludes as of such date:

- 2,484,286 shares of our common stock issuable upon the exercise of stock options, with a weighted-average exercise price of \$3.93 per share;
- 360,920 shares of our common stock issuable upon the settlement of outstanding restricted stock units;
- 8,402,275 shares of our common stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of \$2.69 per share;
- 246,250 shares of our common stock issuable upon the exercise of outstanding warrants by the placement agent of a registered direct offering of our common stock in December 2017, with an exercise price of \$0.85 per share;
- 4,925,000 shares of our common stock issued in a registered direct offering of our common stock in December 2017; and
- 813,771 other shares of our common stock reserved for future issuance under our 2013 Amended and Restated Equity Incentive Plan.

## RISK FACTORS

*An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained elsewhere in this prospectus, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this prospectus and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.*

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

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

We have historically incurred substantial net losses, including net losses of \$18.4 million for the year-ended December 31, 2016 and \$15.9 million for the nine-month period ended September 30, 2017, and we have never been profitable. At September 30, 2017, our accumulated deficit was approximately \$189.6 million. Before 2008, we were pursuing a business plan relating to fetal genetic disorders and other fields, all of which were unrelated to cancer diagnostics. The portion of our accumulated deficit that relates to the period from inception through December 31, 2007 is approximately \$66.5 million.

We expect our losses to continue as a result of costs relating to our lab operations as well as increased sales and marketing costs and ongoing research and development expenses. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

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

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

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

On April 30, 2014, we borrowed \$5.0 million pursuant to the terms of a credit facility, or the April 2014 Credit Facility, with Oxford Finance LLC, or Oxford. At September 30, 2017, a principal balance of approximately \$1.7 million was outstanding and due within one year under the April 2014 Credit Facility. The April 2014 Credit Facility includes events of default, the occurrence and continuation of which provide Oxford, as collateral agent, with the right to exercise remedies against us and the collateral securing the loans under the April 2014 Credit Facility, including foreclosure against our properties securing the April 2014 Credit Facility, including our cash. These events of default include, among other things, our failure to pay any amounts due under the April 2014 Credit Facility, a breach of covenants under the April 2014 Credit Facility, our insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$250,000, and a final judgment against us in an amount greater than \$250,000.

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

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

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

We currently derive substantially all of our revenues from sales of diagnostic assays. We began offering our assays through our Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified, CAP accredited, and state-licensed laboratory in 2014. Additionally, our proprietary blood collection tubes, or BCTs, which allow for the intact transport of liquid biopsy samples for RUO from regions around the world, are anticipated to be sold to laboratory supply distributor(s) commencing in 2018. We are in varying stages of research and development for other products and diagnostic assays that we may offer. If we are unable to increase sales of our existing products and diagnostic assays or successfully develop and commercialize other products and diagnostic assays, we will not produce sufficient revenues to become profitable.

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

We are an early stage molecular oncology diagnostics company and have engaged in only limited sales and marketing activities for the diagnostic assays we currently offer through our CLIA-certified, CAP accredited, and state-licensed laboratory. To date, our revenue has been insufficient to fund operations.

Although we believe that our current assays and our planned future assays, as well as our BCT product, represent a promising commercial opportunity, our products or assays may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for our products and diagnostic assays and build that market through physician education, awareness programs and the publication of clinical trial results. Gaining acceptance in medical communities requires, among other things, publications in leading peer-reviewed journals of results from studies using our current products, assays and services and/or our planned future products, assays and services. 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 products, assays and services and our planned future products, assays and services.

Our ability to successfully market the products and diagnostic assays that we have developed, and may develop in the future, will depend on numerous factors, including:

- conducting clinical utility studies of such assays in collaboration with key thought leaders to demonstrate their use and value in important medical decisions such as treatment selection;
- whether our current or future partners, vigorously support our offerings;
- the success of our sales force;
- whether healthcare providers believe such diagnostic assays provide clinical utility;
- whether the medical community accepts that such diagnostic assays are sufficiently sensitive and specific to be meaningful in-patient care and treatment decisions;
- our ability to continually source raw materials, BCTs, shipping kits and other products that we sell or consume in our manufacturing process that are of sufficient quality and supply;
- our ability to continue to fund planned sales and marketing activities; and
- whether private health insurers, government health programs and other third-party payers will adopt liquid biopsy-based assays in their guidelines, or cover such diagnostic assays and, if so, whether they will adequately reimburse us.

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

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***If we cannot develop products, assays and services 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 products and diagnostic assays and enhance any existing products, assays and services to keep pace with evolving standards of care. Our current products, assays and services and our planned future products, assays and services 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 products and diagnostic assays 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 products, assays and services and our planned future products, assays and services to new treatments, by incorporating important biomarker analysis, sales of our products, assays and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

***If our current products, assays and services and our planned future products, assays and services 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 products and assay results. We believe that our customers are likely to be particularly sensitive to product or assay defects and errors. As a result, the failure of our current or planned future products or assays to perform as expected, including with respect to our ability to maintain the sensitivity, specificity, concordance or reproducibility of such assays, would significantly impair our reputation and the public image of our products and cancer assays, and we may be subject to legal claims arising from any defects or errors.

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

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

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

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

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

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

Our principal competition comes from mainstream diagnostic methods, used by oncologists, pathologists and other physicians for many years, which focus on tumor tissue analysis. The methods or behavior of oncologists, pathologists and other physicians may be difficult to change regarding the use of our CTC and ctDNA assays, including molecular diagnostic assays, in their practices in conjunction with or instead of tissue biopsies and analysis. In addition, companies offering capital equipment, BCTs, and kits or reagents to local pathology laboratories or laboratory supply distributors represent another source of potential competition. These kits are used directly by the pathologist, which can facilitate adoption. Historically, we have focused our marketing and sales efforts on

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medical oncologists rather than pathologists, although commencing in October 2017, our technical component/technical component offering provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results and is available to pathology practices and hospital systems throughout the United States.

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA assays in various cancers. CTC and ctDNA products, assays and services represent a new area of science and we cannot predict what products or assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the products or assays we develop. Competitors include but are not limited to companies such as Atossa, Qiagen, Roche, Guardant, Cancer Genetics, Alere (Adnagen), Illumina, Grail, Apocell, EPIC Sciences, Clearbridge Biomedics, Biodesix, Thermo Fisher Scientific, Foundation Medicine, Neogenomics, Cynvenio Biosystems, Genomic Health, Fluxion Biosciences, RareCells, ScreenCell, Menarini Silicon Biosystems and Sysmex. Some of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents.

There are a number of companies which are focused on the oncology diagnostic market, such as Agendia and Genoptix, who while not currently offering CTC or ctDNA assays are selling to the medical oncologists and pathologists and could develop or offer CTC or ctDNA assays. Large laboratory services companies such as Quest and LabCorp provide more generalized cancer diagnostic assays and testing but could also offer a CTC or ctDNA assay service. Companies like Abbott, Danaher, Qiagen, Thermo Fisher Scientific and others could develop equipment or reagents in the future as well. Currently, companies like Streck, Roche and Biomatrix offer BCTs, and in the future, companies like Covidien, Beckton Dickinson, Thermo Fisher, and other large medical device companies may develop BCTs as well.

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

We expect that biopharmaceutical companies will increasingly focus attention and resources on the personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. For example, the FDA has approved three such agents: Xalkori® from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc., Zelboraf® from Daiichi-Sankyo/Genentech/Roche along with its companion BRAF kinase V600 mutation test from Roche Molecular Systems, Inc. and Tafenlar® from GlaxoSmithKline along with its companion BRAF kinase V600 mutation test from bioMérieux. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests such as ours would be considered an off-label use and this may limit our access to this market segment.

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

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

In recent years, we have incurred significant costs in connection with the development of our products and diagnostic assays. For the year ended December 31, 2016, our research and development expenses were \$2.7 million, and our sales and marketing expenses were \$5.1 million. For the nine months ended September 30, 2017, our research and development expenses were \$2.5 million, and our sales and marketing expenses were \$4.7 million. We expect our expenses to continue to increase for the foreseeable future as we conduct studies of our current products, assays and services and our planned future products, assays and services, continue to establish our sales and marketing organization, drive adoption of and reimbursement for our products and diagnostic assays and develop new products, assays and services. As a result, we need to generate significant revenues in order to achieve sustained profitability.

***If oncologists, pathologists and other physicians decide not to order our current or planned future assays, or if laboratory supply distributors or their customers decide not to order our current or planned future products, we may be unable to generate sufficient revenue to sustain our business.***

To generate demand for our current products, assays and services and our planned future products, assays and services, we will need to educate oncologists, pathologists, and other health care professionals, as well as laboratory and medical equipment suppliers, on the clinical utility, benefits and value of the products, assays and services 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, pathologists, and other physicians of our ability to obtain and maintain coverage and adequate payment from third-party payers. We need to hire additional commercial, scientific, technical and other personnel to support this process. Unless an adequate number of medical practitioners order our current assays and our planned future assays, or unless an adequate number of laboratory supply distributors order our current and planned future products, 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 payers an assay's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that an assay provides clinically meaningful information and value, commercial adoption of such assay may be slow, which would negatively impact our business.***

Clinical utility studies show when and how to use a clinical test or assay 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 or assay 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 or assay, as well as why they should use it. These publications are also used with payers to obtain coverage for a test or assay, helping to assure there is appropriate reimbursement.

We need to conduct additional studies for our assays, increase assay adoption in the marketplace and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, or should their results not provide clinically meaningful data and value for oncologists, pathologists and other physicians, adoption of our assays could be impaired, and we may not be able to obtain coverage and adequate reimbursement for them.

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

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Michael W. Nall, our Chief Executive Officer and President, Lyle J. Arnold, Ph.D., our Senior Vice-President of Research & Development and Chief Scientific Officer, Veena M. Singh, M.D., our Senior Vice President and Senior Medical Director, Michael Terry, our Senior Vice President Commercial Operations, and Timothy C. Kennedy, our Chief Financial Officer, Senior Vice President of Operations and Secretary. The collective efforts of each of these persons and others working with them as a team are critical to us as we continue to develop our technologies, products, services, assays and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management 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 executive management team each have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of 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 products and diagnostic assays, to expand geographically and to successfully commercialize any other products or assays we may develop.***

To succeed in selling our products and diagnostic assays and any other products or assays 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, as well as laboratory supply distributors. To achieve our marketing and sales goals, we will need to continue to build our sales and commercial infrastructure. 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 products, assays and services 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 products, assays and services, as well as our planned future products, assays and services, and to do so we must enter into agreements with these partners to sell, market or commercialize our products, assays and services. 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 products or assays. These partners may not commit the necessary resources to market and sell our products and diagnostics assays to the level of our expectations, and we may be unable to locate suitable alternatives should we terminate our agreement with such partners or if such partners terminate their agreement with us.

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

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

***We currently rely on third-party suppliers for our BCTs, shipping kits, and critical materials needed to perform our current assays, as well as our planned future products, assays and services, and any problems experienced by them could result in a delay or interruption of their supply to us.***

We currently purchase our BCTs and raw materials for our microfluidic channels and assay 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 BCTs, shipping kits, 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 obtaining BCTs and shipping kits, manufacturing the microfluidic channels, or performing assays while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new BCTs, shipping kits, 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 diagnostic assays in a timely manner and sell our products.



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Some of the components used in our current or planned future products are currently sourced from a supplier for which alternative suppliers exist but we have not validated the products of such alternative suppliers, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by any one of our suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations or product sales. 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 products and current assays, as well our planned future products, assays and services, could lead to the filing of product liability claims against us if someone alleges that our products or assays failed to perform as designed. We may also be subject to liability for errors in the assay 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 products or assays, or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

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

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

As our product and assay volume grows, we will need to increase our assay 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 assays on a larger scale. Examples of challenges we may face include, but are not limited to, maintaining the same validated sensitivity in our assays for both CTC and ctDNA analysis as our assay volume increases. We will also need additional clinical laboratory scientists and other scientific and technical personnel to process these additional assays. Any increases in scale, related improvements and quality assurance may not be successfully implemented and appropriate personnel may not be available. As additional products, assays and services are commercialized, we may need to bring new equipment on line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. Failure to implement or maintain necessary procedures or to hire the necessary personnel could result in a higher cost of processing or an inability to meet market demand. We cannot assure you that we will be able to perform assays on a timely basis, or procure BCTs, shipping kits or other materials we sell, at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of our assay results, or that we will respond successfully to the growing complexity of our operations. If we encounter difficulty meeting market demand or quality standards for our current products, assays and services and our planned future products, assays and services, including with respect to our assays our ability to maintain the sensitivity, specificity, concordance and reproducibility of such assays, 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.

***Billing for our diagnostic assays is complex, and we must dedicate substantial time and resources to the billing process to be paid.***

Billing for clinical laboratory assay services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, including Medicare, insurance companies and patients, all of which have different billing requirements. We generally bill third-party payers for our diagnostic assays and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our assays and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing Medicare;
- risk of government audits related to billing Medicare;
- disputes among payers as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payers, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes and/or coverage policies that apply to our assays;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for our diagnostic assays. These codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our revenues. There can be no assurance that payers will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

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As we introduce new assays, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. These billing complexities, and the related uncertainty in obtaining payment for our assays, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

***We rely on third-party billing provider software, and an in-house billing function, to transmit claims to payers, and any delay in transmitting claims could have an adverse effect on our revenue.***

While we manage the overall processing of claims, we rely on third-party billing provider software to transmit the actual claims to payers based on the specific payer billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payers on a timely basis or are erroneously submitted, or if we are required to switch to a different software provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payers, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

***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 products, assays and services and our planned future products, assays and services 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 assays and generate revenues.

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

Our business strategy is to pursue increased international expansion, including partnering with academic and commercial testing laboratories, and introducing our technology outside the United States as part of IVD test kits and/or testing systems utilizing our technologies. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products or assays and our planned future products or assays in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payer systems, multiple payer-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 products or assays and our planned future products or assays cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

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- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

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

Continuing concerns over United States health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession. If the economic climate deteriorates, our business, including our access to patient samples and the addressable market for products or diagnostic assays that we may successfully develop, as well as the financial condition of our suppliers and our third-party payers, 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 software 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 assay processing, sample tracking, quality control, customer service and support, billing and reimbursement, research and development activities and our general and administrative activities. Information technology and telecommunications systems are

vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from processing assays, providing assay results to oncologists, pathologists, billing payers, 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 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 diagnostic assays or to our products that are currently sold or in development; nevertheless, this could change in the future if either the FDA or the Internal Revenue Service, which regulates the payment of this excise tax, changes its position.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extends coverage to over 30 million previously uninsured people, which may result in an increase in the demand for our current assays and our planned future assays. The mandatory purchase of insurance has been strenuously opposed by a number of state governors, resulting in lawsuits challenging the constitutionality of certain provisions of the ACA. In 2012, the Supreme Court upheld the constitutionality of the ACA, with the exception of certain provisions dealing with the expansion of Medicaid coverage under the law. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Congress may consider other legislation to repeal or replace elements of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly alters the current payment methodology under the CLFS. Under the new law, issued in 2016 and the reporting period beginning in 2017 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. 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 payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2018, the Medicare payment rate for each clinical diagnostic lab test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. The PAMA rate changes to our tests that were impacted did not materially affect our payments beginning in 2018; however, we cannot predict how this may change future payment in coming years. Also, under PAMA, the Centers for Medicare & Medicaid Services, or CMS, is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS was required to publicly report payment for the tests no later than January 1, 2016. Further, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. We cannot determine at this time the full impact of PAMA on our business, financial condition and results of operations.

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

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Some of our laboratory assay 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. 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.

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

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

Oncologists, pathologists and other physicians may not order our current assays and our planned future assays unless third-party payers, such as managed care organizations and government payers (e.g., Medicare and Medicaid), pay a substantial portion of the assay price. Coverage and reimbursement by a third-party payer may depend on a number of factors, including a payer's determination that assays 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 payer 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 payers 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 payer generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic assays, seeking payer approvals is a time-consuming and costly process. We cannot be certain that coverage for our current assays and our planned future assays will be provided in the future by additional third-party payers 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 payers such as Medicare and Medicaid for our current assays, or new assays or assay enhancements that we may develop in the future, our ability to generate revenues could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. Further, we may experience delays and interruptions in the receipt of payments from third-party payers due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, to the extent that our assays are 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.



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

Approximately 40% and 41% of total net revenues during the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively, were associated with Medicare reimbursement. Approximately 11% and 17% of total net revenues during the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively, were associated with Blue Cross Blue Shield reimbursement, and approximately 19% and 12%, respectively, of total net revenues were associated with United Healthcare reimbursement. We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare, Blue Cross Blue Shield, and United Healthcare covered-portions of our current assays and our planned future assays would, without such contracted payer 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 payers may change their coverage policies or cancel future contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our assays altogether, which would reduce our total revenues. Payers 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 payers that currently cover and provide reimbursement for our current assays and our planned future assays may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we are currently considered a “non-contracted provider” by many private payers because we have not entered into a specific contract to provide diagnostic assays to their insured patients at specified rates of reimbursement. Additionally, a significant amount of our non-Medicare business (private payers) has historically not been contracted, and reimbursement for this business has historically not been at “in network” rates and has therefore been inconsistent. We first began to contract private payer networks in 2015, and since then our number of accessions treated as “in network” has increased as we continue to execute additional contracts, and reimbursement is improving. We are currently contracted with nine preferred provider organization networks, three large health plans, and five regional independent physician associations, and expect to continue to gain contracts in order to be considered as an “in-network” provider with additional plans. If we were to become a contracted provider with additional payers in the future, the amount of overall reimbursement we receive would likely decrease because we could be reimbursed less money per assay performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

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

Medicare has coverage policies that can be national or regional in scope. Coverage means that assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC enumeration portion of our assays. Because our laboratory is in California, the regional MAC for California is the relevant MAC for all our assays. The previous MAC for California, Palmetto GBA, LLC, which is contracted with CMS to administer the MolDx program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore, the enumeration portion of our assays is not currently covered, and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Although approximately 84% and 77% of all billable cases received during the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively, relate to our Target-Selector biomarker assays, we continue to receive orders for traditional enumeration testing, which counts disease burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. The CTC enumeration counts disease burden and is a prognostic assay, and although valuable, it does not meet many of the medical necessity requirements of Medicare and the payers. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector assays.

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We cannot assure you that, even if our current assays and our planned future assays are otherwise successful, reimbursement for the currently Medicare, Blue Cross Blue Shield, and United Healthcare-covered portions of our current assays and our planned future assays would, without such contracted payer reimbursement for the capture/enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

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

***Long payment cycles of Medicare, Medicaid and/or other third-party payers, 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 payers 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 assays provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition, our laboratory is located in California and is required by state law to have a California state license; as we expand our geographic focus, we may need to obtain laboratory licenses from additional states. California laws establish standards for operation of our clinical laboratory, including the training and skills required of personnel and quality control. In addition, we hold licenses from the states of Pennsylvania, Florida, Maryland and Rhode Island to test specimens from patients in those states or received from ordering physicians in those states. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York as an out of state laboratory and our products, as LDTs, must be approved by the New York State Department of Health before they are offered in New York. As part of this process, the State of New York requires validation of our assays. 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 assays 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 assays, 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 products or assays and our planned future products or assays, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our assays.***

We provide our assays as LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that final guidance on the oversight of laboratory developed tests would allow for further public discussion. On January 13, 2017 the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA; rather, the document is a method to encourage additional dialogue. The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

FDA review, if required and successfully accomplished, would be expected to have some advantages. Certain health insurance payers have paid higher amounts over LDT prices for FDA approved or cleared tests, recognizing the additional costs of bringing a test through regulatory review. Some payers also accept FDA approval or clearance as a presumptive evidence of an assay's analytic validity and clinical validity, which can reduce the barriers to coverage since the payer can focus its review on clinical utility.

The container we provide for collection and transport of blood samples from a health care provider to our clinical laboratory, as well as our BCTs, may be medical devices subject to the FDA regulation but are 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.

Some of the materials we use for our current products, assays and services and may use in our planned future products, assays and services are labeled for RUO. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational use only, the device would be misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act. Some of the materials and reagents obtained by us from suppliers for use in our current products, assays and services and our planned future products, assays and services are currently labeled as research or investigational use only products. If the FDA were to undertake enforcement actions, some of our suppliers might cease selling research or investigational use products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of materials or reagents used in our current products, assays and services or planned future products, assays and services or delaying, limiting or prohibiting the purchase of materials or reagents necessary to sell our current products or planned future products or to perform our current assays or our planned future assays.

Our BCTs will be marketed for RUO and distributed and sold to end users, some of which will be researchers and institutions while other end users could be labs performing clinical testing that will create their own LDTs utilizing our tubes. Some end users of the BCTs may assert that our BCT caused their assays to perform inadequately or give erroneous results. If that was the case, we could potentially incur additional liabilities.

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

Additionally, CMS has recently issued a proposed decision memo for next generation sequencing, or NGS, for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) for comments ending January 17, 2018 and final decision from CMS on February 28, 2018. This coverage policy ties payment for NGS-based assays in oncology to FDA approval or clearance. If this policy remains limited to coverage for only FDA-approved or cleared assays, we would be required to complete an FDA review to qualify for payment for

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services that we provide for Medicare beneficiaries for NGS-based assays. Currently, only 1 of our 15 CLIA validated assays is NGS-based; however, we plan to offer additional NGS assays in the future, and an FDA review, if required, would result increased costs and delays in the launch timing of these new assays.

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 products or diagnostic assays pending pre-market clearance or approval. If the FDA allows our products or assays to remain on the market but there is uncertainty about our products or assays, if they are labeled investigational by the FDA or if labeling claims the FDA allows us to make are very limited, orders from laboratory supply distributors and physicians, or reimbursement from third-party payers, 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 products or assays may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our products or assays if we determine that doing so would be appropriate.

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

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- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of “designated health services” with whom the physician or a member of the physician’s immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- HIPAA, which established federal crimes for, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- federal false claims and civil monetary penalties laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government;
- the federal Physician Payments 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 payer, including commercial insurers.

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

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

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

The privacy regulations regulate the use and disclosure of Protected Health Information by covered entities engaging in certain electronic transactions or “standard transactions.” They also set forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a covered entity, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. The HIPAA security regulations establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of Protected Health Information in electronic form. These standards apply to covered entities and also to “business associates” or third parties providing services to covered entities involving the use or disclosure of Protected Health Information. The HIPAA privacy and security regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing Protected Health Information. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws.

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

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These laws contain significant fines and other penalties for wrongful use or disclosure of Protected Health Information. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. Adding to the complexity is that our operations are evolving, and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services. 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. The possibility exists that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of diagnostic companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own, or in-license, may fail to result in issued patents with claims that cover our products or services in the United States or in other foreign countries. There is no assurance that all potentially 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 United States Patent and Trademark Office, or USPTO, must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

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

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or 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.

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

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

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

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

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



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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.



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***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 assays. If we cannot successfully negotiate sufficient ownership and commercial rights to any inventions that result from our use of a third-party collaborator's materials, or if disputes arise with respect to the intellectual property developed with the use of a collaborator's samples, or data developed in a collaborator's study, we may be limited in our ability to capitalize on the market potential of these inventions or developments.

### **Risks Relating to Our Common Stock**

***The price of our common stock may be volatile.***

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

- progress, or lack of progress, in performing, developing and commercializing our current assays and our planned future assays;
- favorable or unfavorable decisions about our assays from government regulators, insurance companies or other third-party payers;
- our ability to remain compliant with the terms of our April 2014 Credit Facility;
- our ability to recruit and retain qualified research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described herein; and
- general market and economic conditions.

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

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

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum stockholders' equity requirement, NASDAQ may take steps to de-list our common stock. For example, in May 2016, we received a letter from NASDAQ indicating that we are not in

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compliance with the minimum stockholders' equity requirement of NASDAQ Listing Rule 5550(b)(1), and in both June and November 2016, we received letters from NASDAQ indicating that we are not in compliance with the minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2). Further, our common stock is currently trading below the minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2) that requires that companies listed on The NASDAQ Capital Market maintain a minimum closing bid price of at least \$1.00 per share. If we fail to regain and/or maintain compliance with these, or any other of the continued listing requirements of The NASDAQ Capital Market, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with NASDAQ's listing requirements.

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

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on The NASDAQ Capital Market, and if the price of our common stock is less than \$5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a 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 assays and our planned future assays by healthcare practitioners;
- variations in the level of expenses related to our development programs;
- addition or reduction of resources for sales and marketing;
- addition or termination of clinical utility studies;
- any intellectual property infringement lawsuit in which we may become involved;
- third-party payer determinations affecting our assays; and
- regulatory developments affecting our assays.

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

***If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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

Sales of substantial amounts of our common stock or other securities, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. For example, in May 2015, the SEC declared effective a shelf registration statement filed by us. This shelf registration statement allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as our public float is less than \$75 million. In connection with our offering in March 2017 under this shelf registration statement, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year from the closing date of the March 2017 offering. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under this shelf registration statement may cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this shelf registration statement, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

We had outstanding 35,183,743 shares of common stock as of January 19, 2018, of which no more than 2,008,182 are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of January 19, 2018, we had outstanding options to purchase 2,458,012 shares of our common stock, 360,920 shares of common stock were issuable upon the settlement of outstanding restricted stock units, or RSUs, and 8,648,525 shares of our common stock were issuable upon the exercise of outstanding warrants. Shares issued upon the exercise of stock options or upon the settlement of outstanding RSUs generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common stock.

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

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

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

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

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

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

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

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

***We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our 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 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

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replace or remove members of our Board of Directors. (For example, Delaware law provides that if a corporation has a classified board of directors, stockholders cannot remove any director during his or her term without cause.) These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

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

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

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

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

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

Our ability to utilize our estimated federal net operating loss, carryforwards and federal tax credits may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an “ownership change,” as defined by Section 382 of the Code, occurs. If we have experienced an ownership change at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership (including in connection with future offerings, as well as other changes that may be outside of our control), may trigger an ownership change and, consequently, limitations under Sections 382 and 383 of the Code. As a result, if we earn net taxable income, our ability to use our estimated pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. As of December 31, 2016, we had estimated federal and state net operating loss carryforwards of approximately \$5.3 million and \$8.6 million, respectively, and estimated federal and California research and development credits of approximately \$0.0 million and \$3.4 million, respectively, which could be limited if we have experienced or do experience any “ownership changes.” We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe ownership changes likely occurred in each of 2015, 2016 and 2017. As a result, we have estimated that the use of our net operating loss is limited and the amounts above represent the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future, which remain fully offset by a valuation allowance to reduce the net asset to zero.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted

earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

***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 Relating to This Offering**

***If you purchase our securities in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The combined public offering price per share of our common stock and related warrants will be substantially higher than the net tangible book value per share of our common stock immediately prior to the offering. After giving effect to the assumed sale of shares of our common stock and related warrants in this offering, at an assumed combined public offering price of \$0.665 per share and related warrants (the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018), and after deducting the estimated placement agent fees and estimated offering expenses payable by us and attributing no value to the warrants sold in this offering, purchasers of our common stock in this offering will incur immediate dilution of \$0.355 per share in the net tangible book value of the common stock they acquire. In the event that you exercise your warrants, you will experience additional dilution to the extent that the exercise price of the warrants is higher than the tangible book value per share of our common stock. For a further description of the dilution that investors in this offering will experience, see "Dilution."

In addition, to the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution.

***We have broad discretion in the use of the net proceeds we receive from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

***Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock.***

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If additional capital is raised through the sale of equity or convertible debt securities, or perceptions that those sales could occur, the issuance of these securities could result in further dilution to investors purchasing our common stock in this offering or result in downward pressure on the price of our common stock, and our ability to raise capital in the future.

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### ***Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.***

Until you acquire shares of our common stock upon exercise of your warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of your warrants. Upon exercise of your warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

### ***The warrants may not have any value.***

Each warrant issued to investors in this offering will have an exercise price of not less than 100% of the last reported sale price of our common stock as of the close of the trading day immediately preceding the pricing of this offering and will expire on the fifth anniversary and six-month anniversary of the dates they first become exercisable with respect to the Series A warrant and Series B warrant, respectively. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

### ***There is no public market for the warrants to purchase shares of our common stock being offered in this offering.***

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system, including The NASDAQ Capital Market. Without an active trading market, the liquidity of the warrants will be limited.

### ***We are selling the securities offered in this prospectus on a “best efforts” basis with no minimum offering and may not be able to sell any of the securities offered herein.***

We have engaged Dawson James Securities, Inc. to act as a placement agent in connection with this offering. While the placement agent will use its reasonable best efforts to arrange for the sale of the securities, it is under no obligation to purchase any of the securities. As a result, there are no firm commitments to purchase any of the securities in this offering. Consequently, there is no guarantee that we will be capable of selling all, or any, of the securities being offered hereby. In addition, we have not specified a minimum offering amount, nor will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.



## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements, which reflect our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. Forward-looking statements are identified 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. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the information available to management at this time and which speak only as of this date. Examples of our forward-looking statements include:

- our ability to increase sales of our products, assays and services;
- our ability to continually develop new products, diagnostic assays, services and enhance our current products, assays and services and future products, assays, and services;
- our ability to effectively compete with other products, diagnostic assays, methods and services that now exist or may hereafter be developed;
- our ability to expand our international business;
- our ability to obtain coverage and adequate reimbursement from governmental and other third-party payers for assays and services;
- our expectations regarding the use of our existing cash and the expected net proceeds of this offering;
- our ability to enter into agreements with commercialization partners for the sales, marketing and commercialization of our current products, assays and services, and our planned future products, assays and services;
- our ability to satisfy any applicable United States and international regulatory requirements with respect to products, assays and services; and
- our ability to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned products, assays and services.

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



## **USE OF PROCEEDS**

We estimate that the net proceeds of this offering will be approximately \$11.2 million assuming the sale of 18,796,992 shares of our common stock, Series A warrants to purchase up to 14,097,744 shares of our common stock and Series B warrants to purchase up to 4,699,248 shares of our common stock at an assumed combined public offering price of \$0.665 per share and related warrants (the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018), after deducting the estimated placement agent fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants. However, this is a best efforts offering with no minimum offering amount, and we may not sell all or any of the securities; as a result, we may receive significantly less in net proceeds, and the net proceeds received may not be sufficient to execute our business plan. Each \$0.25 increase (decrease) in the assumed combined public offering price of \$0.665 per share would increase (decrease) the net proceeds to us from this offering by approximately \$4.4 million, assuming the number of shares and warrants offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated placement agent fees and estimated offering expenses payable by us. We may also increase or decrease the number of shares of our common stock and warrants we are offering. An increase (decrease) of 1 million in the number of shares sold in this offering would increase (decrease) the expected net proceeds of the offering to us by approximately \$0.6 million, assuming that the assumed combined public offering price per share and the related warrant coverage remains the same. We currently intend to use the net proceeds of the offering for general corporate purposes and to fund ongoing operations and expansion of our business.

## **DIVIDEND POLICY**

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

## SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of, and for the period ended on, the dates indicated. We have derived the statement of operations data for the years ended December 31, 2015 and 2016 and the balance sheet data as of December 31, 2016 from our audited financial statements appearing elsewhere in this prospectus. We have derived the statements of operations data for the nine months ended September 30, 2016 and 2017 and balance sheet data as of September 30, 2017 from our unaudited financial statements appearing elsewhere in this prospectus. The unaudited financial statements have been prepared on a basis consistent with our audited financial statements included in this prospectus and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, necessary to fairly state our financial position as of September 30, 2017 and results of operations for the nine months ended September 30, 2016 and 2017. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the section in this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of our future results.

	Year ended December 31, 2015	2016	For the nine months ended September 30, 2016 (unaudited)	2017 (unaudited)
(in thousands, except share and per share data)				
<b>Statement of Operations Data:</b>				
Net revenues	\$ 610	\$ 3,223	\$ 1,932	\$ 4,073
Costs and expenses:				
Cost of revenues	4,596	6,920	5,021	6,985
Research and development expenses	2,858	2,713	2,045	2,456
General and administrative expenses	5,687	6,561	4,923	5,539
Sales and marketing expenses	3,880	5,054	3,875	4,701
Total costs and expenses	(17,021)	(21,248)	(15,864)	(19,681)
Loss from operations	(16,411)	(18,025)	(13,932)	(15,608)
Total other income/(expense)	(537)	(372)	(278)	(334)
Loss before income taxes	(16,948)	(18,397)	(14,210)	(15,942)
Income tax expense	(2)	(2)	(2)	(5)
Net loss and comprehensive loss	\$ (16,950)	\$ (18,399)	\$ (14,212)	\$ (15,947)
Weighted-average shares outstanding used in computing net loss per common share:				
Basic	5,512,989	9,578,285	7,549,663	25,816,181
Diluted	5,512,989	9,578,285	7,549,663	25,816,181
Net loss per common share				
Basic	\$ (3.07)	\$ (1.92)	\$ (1.88)	\$ (0.62)
Diluted	\$ (3.07)	\$ (1.92)	\$ (1.88)	\$ (0.62)

	As of December 31, 2016 Actual	As of September 30, 2017 Actual (Unaudited)
<b>Balance Sheet Data (in thousands):</b>		
Cash	\$ 4,609	\$ 5,879
Total assets	\$ 7,578	\$ 11,120
Credit facility, net of discount	\$ 3,058	\$ 1,645
Total liabilities	\$ 6,919	\$ 7,094
Total shareholders’ equity	\$ 659	\$ 4,026

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or "liquid biopsy." Our current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring in order to identify specific resistance mechanisms. Often, traditional methodologies such as tissue biopsies are insufficient or unavailable to provide the molecular subtype information necessary for clinical decisions. Our assays have the potential to provide more contemporaneous information on the characteristics of a patient's disease compared with traditional methodologies such as tissue biopsy and radiographic imaging. Additionally, commencing in October 2017, our pathology program initiative provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results and is available to pathology practices and hospital systems throughout the United States. Further, our proprietary blood collection tubes, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world, are anticipated to be sold to laboratory supply distributor(s) commencing in 2018.

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

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We also performed research and development that led to our current assays, and we also intend to perform research and development for planned assays, at this facility. In addition, we manufacture our microfluidic channels, related equipment and certain reagents. The assays we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations. 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. In addition, we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and adherence to specific quality standards.

Our revenue generating efforts are focused in three areas:

- providing clinical testing that oncologists, pathologists and other physicians use in order to determine the best treatment plan for their patients;
- providing clinical trial, research and development services to biopharmaceutical companies developing drug candidates to treat cancer; and
- licensing and/or selling our proprietary testing and/or technologies to partners in the United States and abroad.

### **Assays, Products and Services**

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

In the case of our breast and gastric cancer offerings, biomarker analysis involves fluorescence in situ hybridization, or FISH, for the detection and quantitation of the human epidermal growth factor receptor 2, or HER2, gene copy number as well as immunocytochemical, or ICC, analysis of estrogen receptor, or ER, protein, progesterone receptor, or PR, protein, and androgen receptor, or AR, protein, which are currently commercially available. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

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Our lung cancer biomarker analysis offering currently includes FISH testing for ALK, ROS1, RET, MET and FGFR1 gene rearrangements, as well as analysis for the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor, or EGFR gene, as well as BRAF, KRAS and NRAS. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are associated with the use of the drugs Tarceva®, Gilotrif® and Iressa®. For lung cancer, we also offer a resistance profile assay consisting of the biomarkers MET, HER2 (both of which we perform using our technology for CTCs), KRAS, and T790M (both of which are performed using ctDNA in plasma). These assays can be used by physicians to identify the mechanism causing disease progression for patients with NSCLC who are being treated with tyrosine kinase inhibitor, or TKI, therapy and therefore may qualify patients for inclusion in a clinical trial. In November 2015, Tagrisso® was approved by the U.S. Food and Drug Administration, or FDA, providing another biomarker-based therapy for the treatment of patients with EGFR-related lung cancer. Tagrisso® is indicated for the treatment of patients with metastatic disease, who have progressed on or after EGFR TKI therapy, and who have acquired a T790M resistance mutation. Recently, the FDA approved the combination of Novartis' Tafenlar® (dabrafenib) and Mekinist® (trametinib) for the treatment of patients with metastatic NSCLC whose tumors express the BRAF V600E mutation, an FDA "breakthrough therapy" designation for patients who have received prior chemotherapy. This combination was approved in Europe for the same indication in March 2017. BRAF mutations, which appear in approximately 1-3% of NSCLC cases globally, are associated with Zelboraf® and Tafenlar® treatment, as these BRAF inhibitors are both approved for the treatment of patients with melanoma.

In September 2017, we launched our assay for mutations of the NRAS oncogene, which can be used to detect and monitor an actionable biomarker associated with multiple cancer types such as metastatic melanoma, colorectal and lung cancer. As a result, we now offer 15 CLIA-certified liquid biopsy tests utilizing our Target-Selector platform to determine the status of key cancer biomarkers listed in the National Comprehensive Cancer Network Guidelines®. Our NRAS assay combines our proprietary switch blocker technology for improved mutation detection with next generation sequencing, resulting in ultra-high sensitivity.

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

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

We plan to release additional blood-based biomarker assays, such as those that test for ESR1, to our current menu of liquid biopsy assays using blood samples. In addition, we plan to complete the development and offer multiplexed biomarker tests, which will allow the detection and quantitative monitoring of multiple biomarkers in a single assay.

In August 2017, we announced that we had executed a distribution agreement for our proprietary blood collection tubes with VWR International, LLC which can preserve intact cells (such as CTCs) for up to 96 hours and ctDNA for up to 8 days, allowing for the intact transport of RUO liquid biopsy samples from regions around the world.

In October 2017, we launched our pathology partnership initiative, expanding access of our proprietary liquid biopsy testing to community pathologists and hospitals throughout the United States. The aim of this program is to incorporate community pathologists into the review of biomarkers found in liquid biopsy for patients diagnosed with cancer. Pathologists are now enabled to interpret our liquid biopsy results locally, while patient specimens will continue to be sent to us for processing in our CLIA-certified, CAP-accredited high complexity laboratory.

### ***Pharmaceutical and Research Collaborations***

We continue to execute on our strategies intended to expand our business globally, as well as to engage with pharmaceutical companies on clinical trials and assay development. We have preferred provider agreements in place in Mexico with Quest Diagnostics to support testing for a large pharmaceutical company partner. In addition, we have distribution agreements in place in Mexico, Uruguay, Turkey, the Czech Republic, the Philippines, Lebanon, Columbia, Israel and Canada.

During 2016, we announced three pharmaceutical collaborations. The first agreement provides testing for a clinical trial that includes patients who have leptomeningeal disease or metastatic lung cancer in the brain. In this exploratory trial, we are testing both cerebral spinal fluid and blood for molecular alterations that could be impacted by treatment. The second agreement is a milestone-based assay

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development project focused on hepatocellular carcinoma, or liver cancer, whereby we intend to develop assays utilizing both our CTC and ctDNA technologies for clinical trials. The third collaboration involves a study presented at the European Society for Medical Oncology, or ESMO, Annual Congress in October 2016, evaluating the detection of EGFR alterations (del19, L858R and T790M) by our Target-Selector liquid biopsy. Subsequent to this study, we have earned business in both Mexico and Columbia for EGFR testing in blood to qualify patients for the pharmaceutical company's targeted therapy.

In April 2017, we announced our entry into a preferred provider collaboration and services agreement with Oregon Health & Sciences University on behalf of the OHSU Knight Cancer Institute, or collectively OHSU. The multiphase agreement grants OHSU the rights to commercially offer our Target-Selector liquid biopsy testing services exclusively throughout the state of Oregon. Additionally, we and OHSU plan to engage in technology transfer, whereby OHSU will have the ability to use Target-Selector assays in-house, and act as a secondary laboratory for our research and testing activities. We and OHSU also plan to co-develop additional liquid biopsy assay technologies and platform capabilities including highly sensitive, multiplexed assay panels for molecular biomarker detection and assessment. Additional research and development and commercial pilot projects are anticipated under the agreement.

In May 2017, we announced jointly with the Addario Lung Cancer Medical Institute, or ALCMI, entry into a clinical collaboration and initiation of the ALCMI-009 liquid biopsy clinical trial. This large-scale trial was developed, and will be conducted, by ALCMI and its consortium of leading U.S. and international oncology centers. The prospective, multi-center study, which plans to enroll 400 patients, will utilize our Target-Selector testing platform and services to detect and assess cancer biomarkers found in both CTCs and ctDNA from the blood of patients with lung cancer. We expect this study to commence in the first half of 2018.

In May 2017, we entered into a clinical study agreement with the University of Texas Southwestern Medical Center. Led by recognized oncologist and ALK alteration researcher, Dr. Saad Khan, the study is designed to evaluate the clinical utility of our Target-Selector platform for patients diagnosed with ALK-positive NSCLC and treated with ALK-inhibitor therapy. A second arm of the study will evaluate patients with rare cancers such as anaplastic thyroid cancer to determine if driver mutations such as ALK rearrangements can be identified and treated with targeted therapy to improve patient outcomes.

In October 2017, we entered into a promotion and marketing agreement with Miraca Life Sciences, Inc., or Miraca Life Sciences, to market our Target-Selector liquid biopsy tests and services to community-based oncologists and hematologists in specified sales territories in the United States. Based on the agreement, Miraca Life Sciences' sales professionals will promote our liquid biopsy tests to both their existing and new clinician clients in designated sales territories, with the potential to expand the agreement to additional territories in the future. All tests will be performed in our CLIA-certified CAP-accredited laboratory.

### ***Provider Agreements***

In January 2017, we announced that we had secured an in-network provider agreement with Blue Cross Blue Shield of Texas, the largest provider of health benefits in Texas. In addition, we entered into a national master business agreement with the Blue Cross Blue Shield Association, a not-for-profit trade association that provides multiple services for its 38-member Blue Cross and Blue Shield health plan companies across the U.S., including forming national strategic vendor partnerships. We were selected by the Blue Cross Blue Shield Association based on a rigorous request-for-proposal process. This agreement establishes pricing for our Target-Selector liquid biopsy testing service through the Blue Cross Blue Shield Association's group purchasing organization, CareSourcing Workgroup. The pricing offered by the CareSourcing Workgroup group purchasing organization is available to those Blue Cross and Blue Shield member health plans that have, or may seek, in-network agreements with us.

In June 2017, we entered into a participating provider agreement with MediNcrease Health Plans, LLC and a preferred provider agreement with Scripps Health Plan Services, Inc., both establishing pricing for our Target-Selector liquid biopsy testing service.

In December 2017, we signed an agreement with Wellmark, Inc., the largest health insurer in Iowa and South Dakota. The agreement marks our third Blue Cross Blue Shield contract and enables patients diagnosed with cancer the ability to access our proprietary testing services in-network under their Wellmark health plan.

We are currently contracted with nine preferred provider organization networks, three large health plans, and five regional independent physician associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans.

### ***Patents and Technology***

We have issued patents with broad claims covering our blood collection tube, antibody cocktail approach, microchannel, and CTC detection methodologies. In addition to issuance of patents in the U.S., we have patents for our proprietary microchannel in China, Korea, Europe, Hong Kong, and Japan, and for our antibody cocktail in Australia, Europe, and Japan. Our patent estate continues to

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evolve, and in addition to the broad patent estate around our CTC platform, we expect issuances of multiple patents for our novel switch blocker technology in the near future, solidifying our proprietary enrichment methodology for detecting ctDNA with very high sensitivity. Our CTC platform patents were filed from 2005 through 2012, and we expect to have patent protection into the 2030s. Our patents and applications cover not only cancer as a target, but also prenatal and other rare cells of interest. Recently allowed patents in the U.S. cover the capture of “any target of interest on any solid surface” using our antibody capture approach. The patent for our proprietary specimen collection tubes expire in 2031.

As of December 31, 2017, we owned 25 issued patents and 23 patents pending related to our current technologies. Of these, 8 are issued and 5 are pending patents in the U.S., while 17 are issued and 18 are pending patents in non-U.S. territories. Separately, we also own 7 issued patents related to our earlier microarray and cell analysis technology.

## Results of Operations

### Three Months Ended September 30, 2016 and 2017

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

	Three months ended September 30,		Change	
	2016	2017	\$	%
<i>(dollars in thousands)</i>				
Net revenues	\$ 1,047	\$ 1,111	\$ 64	6%
Cost of revenues	1,876	2,487	611	33%
Research and development expenses	601	857	256	43%
General and administrative expenses	1,919	1,834	(85)	(4%)
Sales and marketing expenses	1,278	1,676	398	31%
<b>Loss from operations</b>	<b>(4,627)</b>	<b>(5,743)</b>	<b>(1,116)</b>	<b>24%</b>
Interest expense	(154)	(88)	66	(43%)
Other income	38	13	(25)	(66%)
<b>Loss before income taxes</b>	<b>(4,743)</b>	<b>(5,818)</b>	<b>(1,075)</b>	<b>23%</b>
Income tax expense	—	(3)	(3)	—
<b>Net loss</b>	<b>\$ (4,743)</b>	<b>\$ (5,821)</b>	<b>\$ (1,078)</b>	<b>23%</b>

### Net Revenues

Net revenues were approximately \$1,111,000 for the three months ended September 30, 2017, compared with approximately \$1,047,000 for the same period in 2016, an increase of \$64,000, or 6%. Of the \$1,111,000 of revenues recognized during the three months ended September 30, 2017, \$1,009,000 related to revenues recognized on an accrual basis, while \$102,000 related to revenues recognized upon the receipt of cash, as compared to the same period in 2016 when \$72,000 of revenues were recognized on an accrual basis and \$975,000 of revenues were recognized upon the receipt of cash. During the three months ended March 31, 2017, we converted from cash-based revenue recognition for our commercial revenues to accrual-based revenue recognition. As a result of the change to accrual-based revenue recognition, we recognized incremental revenue of \$125,000 during the three months ended September 30, 2017, which represents the total amount of net revenue recorded in excess of the amount of commercial cash collections. Cash collections on commercial cases increased \$119,000 during the three months ended September 30, 2017 compared to the same period in 2016, after considering an estimated \$175,000 in collections received during the three months ended September 30, 2016 that had been delayed until improvements in billing and collection timeliness and effectiveness were implemented, whereby total cash collections on commercial cases were \$919,000 during the three months ended September 30, 2017 as compared to \$975,000 during the same period in 2016, a net decrease of \$56,000. Additionally, there was a \$5,000 decrease in development services revenues during the three months ended September 30, 2017 as compared to the same period in 2016.

These results reflect the impact on sales and volume from the hurricanes in Texas and Florida, as well as the earthquake in Mexico City, all of which occurred during the three months ended September 30, 2017. In addition, there were 2 less sales days in three months ended September 30, 2017 as compared to the same period in 2016. We believe these factors negatively impacted our reported volume during the three months ended September 30, 2017 by approximately 15 to 20%. The net estimated revenue per commercial accession delivered was approximately \$945 during the three months ended September 30, 2017, based on 997 commercial accessions delivered and approximately \$942,000 in corresponding commercial accrual-based revenues during that period. The following table sets forth certain information regarding commercial accessions received during the three months ended September 30, 2016 and 2017:

	Three months ended September 30,		Change	
	2016	2017	# / \$	%
# Commercial accessions received	1,023	1,009	(14)	(1%)
\$ Value estimated per commercial accession received	\$ 1,012	\$ 1,035	\$ 23	2%

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The following table sets forth certain information regarding development services accessions delivered during the three months ended September 30, 2016 and 2017:

	Three months ended September 30,		Change	
	2016	2017	#	%
# Development services cases delivered	155	178	23	15%
\$ Value estimated per development services accession delivered	\$ 463	\$ 379	\$(84)	(18%)

### **Costs and Expenses**

**Cost of Revenues.** Cost of revenues was approximately \$2,487,000 for the three months ended September 30, 2017, compared with approximately \$1,876,000 for the three months ended September 30, 2016, an increase of \$611,000, or 33%. The increase was primarily attributable to an increase of \$446,000 in personnel and travel costs mainly related to higher assay volume as the average number of full-time laboratory and manufacturing employees increased from an average of 25 full-time employees during the three months ended September 30, 2016 to 41 full-time employees during the same period in 2017, as we created excess laboratory accession throughput capacity of approximately 31% as of September 30, 2017 in advance of an anticipated increase in accession volumes resulting from our expanded sales force and pathology partnership initiative. Additionally, there was an increase of \$177,000 in depreciation expense, computer equipment, software amortization, and allocated information technology and facility charges as we implemented our pathology partnership initiative, invest in upgrading our laboratory equipment and information system and maintaining our facility, as well as an increase of \$55,000 in consulting and other third-party service provider costs associated with higher assay volume, were partially offset by a decrease associated with greater laboratory costs charged to research and development of approximately \$64,000.

**Research and Development Expenses.** Research and development expenses were approximately \$857,000 for the three months ended September 30, 2017, compared with approximately \$601,000 for the three months ended September 30, 2016, an increase of \$256,000, or 43%. The increase was primarily attributable to an increase of \$136,000 in higher personnel and travel costs as the average headcount in our research and development function increased to 13 full-time employees during the three months ended September 30, 2017 from 10 full-time employees during the same period in 2016, as we focus on the development and deployment of next generation sequencing, support and implementation of data-intensive laboratory processes, and new product validations. Additionally, there was a \$64,000 increase associated with greater laboratory costs charged to research and development during the three months ended September 30, 2017 as compared to the same period in 2016, \$32,000 in materials and other costs associated with research and development activities, and \$24,000 in computer equipment, software and laboratory equipment preventative maintenance costs.

**General and Administrative Expenses.** General and administrative expenses were approximately \$1,834,000 for the three months ended September 30, 2017, compared with approximately \$1,919,000 for the three months ended September 30, 2016, a decrease of \$85,000, or 4%. The decrease was primarily due to a decrease of \$98,000 in third-party billing provider costs resulting from bringing our billing function in-house in April 2017, as well as decreases of \$46,000 in stock-based compensation expense, \$44,000 in legal patent costs, \$29,000 in allocated facilities costs, and \$23,000 in directors and officers insurance premiums. These decreases were partially offset by an increase of \$92,000 in non-stock-based compensation personnel and travel costs as the average headcount included in the general and administrative function rose from 9 full-time employees during the three months ended September 30, 2016 to 14 full-time employees during the same period in 2017, primarily resulting from bringing our billing function in-house in April 2017, as well as an increase of \$70,000 in consulting and other third-party service provider costs supporting expanded commercial and strategic activities.

**Sales and Marketing Expenses.** Sales and marketing expenses were approximately \$1,676,000 for the three months ended September 30, 2017, compared with approximately \$1,278,000 for the three months ended September 30, 2016, an increase of \$398,000, or 31%. The increase was primarily attributable to an increase of \$454,000 in personnel and travel costs as the average headcount included in the sales and marketing function rose from 15 full-time employees during the three months ended September 30, 2016 to 25 full-time employees during the same period in 2017 as we expanded our sales force, as well as increases associated with expanded commercial activities of \$18,000 in marketing materials, trade show and conference costs and \$15,000 in computer equipment and other office expenses, partially offset by a decrease of \$90,000 in third-party service provider and consulting costs.



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### **Income Taxes**

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

We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe ownership changes likely occurred during each of 2015, 2016 and 2017. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

### **Nine Months Ended September 30, 2016 and 2017**

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

(dollars in thousands)	Nine months ended September 30,		Change	
	2016	2017	\$	%
Net revenues	\$ 1,932	\$ 4,073	\$ 2,141	111%
Cost of revenues	5,021	6,985	1,964	39%
Research and development expenses	2,045	2,456	411	20%
General and administrative expenses	4,923	5,539	616	13%
Sales and marketing expenses	3,875	4,701	826	21%
<b>Loss from operations</b>	(13,932)	(15,608)	(1,676)	12%
Interest expense	(393)	(385)	8	(2%)
Other income	115	51	(64)	(56%)
<b>Loss before income taxes</b>	(14,210)	(15,942)	(1,732)	12%
Income tax expense	(2)	(5)	(3)	2
<b>Net loss</b>	\$ (14,212)	\$ (15,947)	\$ (1,735)	12%

### **Net Revenues**

Net revenues were approximately \$4,073,000 for the nine months ended September 30, 2017, compared with approximately \$1,932,000 for the same period in 2016, an increase of \$2,141,000, or 111%. Of the \$4,073,000 of revenues recognized during the nine months ended September 30, 2017, \$2,915,000 related to revenues recognized on an accrual basis, while \$1,158,000 related to revenues recognized upon the receipt of cash, as compared to the same period in 2016 when \$170,000 of revenues were recognized on an accrual basis and \$1,762,000 of revenues were recognized upon the receipt of cash. During the three months ended March 31, 2017, we converted from cash-based revenue recognition for our commercial revenues to accrual-based revenue recognition. As a result of the change to accrual-based revenue recognition, we recognized total nonrecurring revenue of \$839,000 during the nine months ended September 30, 2017, which represents the estimated value of net accounts receivable at December 31, 2016 that was recognized as revenue in the current period presented, and the incremental revenue recorded as a result of the change was \$1,042,000, which represents the total amount of net revenue recorded in excess of the amount of commercial cash collections.

Total cash collections for commercial cases were \$2,820,000 during the nine months ended September 30, 2017 as compared to \$1,762,000 during the same period in 2016, an increase of \$1,058,000 owed primarily to improvements in billing and collection timeliness and effectiveness, as well as increases in accession volume and the expected value per accession received prior to and during the nine months ended September 30, 2017 as compared to the same period in 2016. The net estimated revenue per commercial accession delivered since converting from cash-based revenue recognition to accrual-based revenue recognition on March 31, 2017 and through September 30, 2017 was approximately \$990, based on 1,998 commercial accessions delivered and approximately \$1,978,000 in corresponding commercial accrual-based revenues during that period. The \$1,042,000 in incremental net revenue

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recognized was primarily related to an increase in the expected value per accession received prior to and during the nine months ended September 30, 2017 as compared to the same period in 2016, as well as the increasing commercial case volumes received, as follows:

	Nine months ended September 30,		Change	
	2016	2017	# / \$	%
# Commercial accessions received	2,727	2,947	220	8%
\$ Value estimated per commercial accession received	\$ 962	\$ 1,098	\$136	14%

Additionally, there was a \$41,000 increase in development services revenues during the nine months ended September 30, 2017 as compared to the same period in 2016, which was primarily related to increasing development services case volumes delivered, as follows:

	Nine months ended September 30,		Change	
	2016	2017	# / \$	%
# Development services cases delivered	378	575	197	52%
\$ Value estimated per development services accession delivered	\$ 450	\$ 368	\$ (82)	(18%)

## **Costs and Expenses**

**Cost of Revenues.** Cost of revenues was approximately \$6,985,000 for the nine months ended September 30, 2017, compared with approximately \$5,021,000 for the nine months ended September 30, 2016, an increase of \$1,964,000, or 39%. The increase was primarily attributable to an increase of \$1,287,000 in personnel and travel costs mainly related to higher assay volume as the average number of full-time laboratory and manufacturing employees increased from 24 full-time employees during the nine months ended September 30, 2016 to 39 full-time employees during the same period in 2017, as we created excess laboratory accession throughput capacity of approximately 31% as of September 30, 2017 in advance of an anticipated increase in accession volumes resulting from our expanded sales force and pathology partnership initiative. Additionally, there was an increase of \$436,000 in depreciation expense, computer equipment, software amortization, and allocated information technology and facility charges as we implemented our pathology partnership initiative, invest in upgrading our laboratory equipment and information system and maintaining our facility, as well as increases of \$147,000 in materials, shipping and other direct costs and \$105,000 in third-party service provider and consulting costs associated with higher assay volume.

**Research and Development Expenses.** Research and development expenses were approximately \$2,456,000 for the nine months ended September 30, 2017, compared with approximately \$2,045,000 for the nine months ended September 30, 2016, an increase of \$411,000, or 20%. The increase was primarily attributable to an increase of \$245,000 in higher personnel and travel costs as the average headcount in our research and development function increased to 12 full-time employees during the nine months ended September 30, 2017 from 10 full-time employees during the same period in 2016, as we focus on the development and deployment of next generation sequencing, support and implementation of data-intensive laboratory processes, and new product validations. Additionally, there were increases of \$93,000 in materials and other costs associated with research and development activities during the three months ended September 30, 2017 as compared to the same period in 2016, \$40,000 in computer equipment, software and laboratory equipment preventative maintenance costs, and \$23,000 in allocated facilities charges.

**General and Administrative Expenses.** General and administrative expenses were approximately \$5,539,000 for the nine months ended September 30, 2017, compared with approximately \$4,923,000 for the nine months ended September 30, 2016, an increase of \$616,000, or 13%. The increase was primarily due to an increase of \$628,000 in non-stock-based compensation personnel costs and travel expenses as the average headcount included in the general and administrative function rose from 8 full-time employees during the nine months ended September 30, 2016 to 12 full-time employees during the same period in 2017, primarily resulting from bringing our billing function in-house in April 2017. Additionally, there was an increase of \$226,000 in third-party service provider and consulting fees associated with increased commercial and strategic activities and our expanded investor relations function during the nine months ended September 30, 2017, an increase of \$64,000 in computer equipment, office expenses, and other general and administrative costs associated with increased commercial and strategic activities, as well as an increase of \$40,000 in legal and independent accountant and audit fees, which were partially offset by decreases of \$148,000 in stock-based compensation expense, \$134,000 in directors and officers insurance costs, and \$52,000 in third-party billing provider costs resulting from bringing our billing function in-house in April 2017.

**Sales and Marketing Expenses.** Sales and marketing expenses were approximately \$4,701,000 for the nine months ended September 30, 2017, compared with approximately \$3,875,000 for the nine months ended September 30, 2016, an increase of \$826,000, or 21%.

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The increase was primarily attributable to an increase of \$807,000 in personnel and travel costs as the average headcount included in the sales and marketing function rose from 15 full-time employees during the nine months ended September 30, 2016 to 21 full-time employees during the same period in 2017 as we expanded our sales force, an increase of \$72,000 in computer equipment, allocated information technology costs, shipping and other office expenses associated with expanded commercial activities, as well as an increase of \$43,000 in marketing materials, trade show and conference costs, which were partially offset by a decrease of \$96,000 in third-party service provider and consulting fees.

### **Income Taxes**

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

We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe ownership changes likely occurred during each of 2015, 2016 and 2017. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

### **Years Ended December 31, 2015 and 2016**

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

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

### **Revenues**

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

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

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

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

During the years ended December 31, 2015 and 2016, approximately \$69,000 and \$221,000 or 11% and 7%, respectively, of our total annual revenues were billed to clinical partners. The clinical laboratory industry is highly competitive, and our relationships and our partners’ relationships with decision-makers at hospitals, cancer centers or physician offices is a critical component of securing their business. Consequently, our ability to establish and manage partnerships with groups that have sales and marketing capabilities in our target markets and attract and maintain productive sales personnel that have and can grow these relationships will largely determine our ability to grow our clinical services revenue.

### **Costs and Expenses**

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

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

*General and Administrative Expenses.* General and administrative expenses were approximately \$6,561,000 for the year ended December 31, 2016, compared with approximately \$5,687,000 for the year ended December 31, 2015, an increase of \$874,000, or 15%. The increase was primarily due to an increase of approximately \$237,000 in third-party billing fees associated with increased cash collections, an increase of approximately \$227,000 in consulting and other third-party service provider costs mainly related to expanded commercial activities, an increase of approximately \$229,000 in personnel costs related to an increase in the average number of employees included in the general and administrative function from 7 employees during the year ended December 31, 2015 to 9 employees during the same period in 2016, an increase of approximately \$87,000 due to increased allocated facility costs and depreciation, as well as an increase of approximately \$81,000 in legal fees.

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

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### **Income Tax Expense**

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

We have not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation, due to the complexity and cost associated with such a study, and the fact that there may be additional ownership changes in the future, however, we believe ownership changes likely occurred during both 2015 and 2016. As a result, we have estimated that the use of our net operating loss is limited and the remaining net operating loss carryforwards and research and development credits we estimate can be used in the future remain fully offset by a valuation allowance to reduce the net asset to zero.

### **Inflation**

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

### **Liquidity and Capital Resources**

#### **Cash Flows**

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

(dollars in thousands)	Nine months ended September 30,	
	2016	2017
Cash provided by/ (used in):		
Operating activities	\$ (11,257)	\$ (13,897)
Investing activities	(391)	(1,055)
Financing activities	3,506	16,222
Net increase/ (decrease) in cash	\$ (8,142)	\$ 1,270

**Cash Used in Operating Activities.** Net cash used in operating activities was \$13.9 million for the nine months ended September 30, 2017, compared to net cash used in operating activities of \$11.3 million for nine months ended September 30, 2016. The net increase of \$2.6 million in cash used was primarily related to an increase of \$1.7 million in cash used to fund our net loss, as well as a net decrease of \$1.1 million in cash provided by operating assets and liabilities, partially offset by a \$0.2 million increase in non-cash depreciation and amortization, inventory reserve, interest and stock-based compensation expenses.

**Cash Used in Investing Activities.** Net cash used in investing activities of approximately \$1,055,000 and \$391,000 during the nine months ended September 30, 2017 and 2016, respectively, was related to purchases of fixed assets.

**Cash Provided by Financing Activities.** Net cash provided by financing activities was \$16.2 million for the nine months ended September 30, 2017, compared to net cash provided by financing activities of \$3.5 million for the nine months ended September 30, 2016. Our primary sources of cash from financing activities during the nine months ended September 30, 2017 consisted of \$8.6 million and \$2.0 million in net proceeds from our offerings in March 2017 and August 2017, respectively, as well as proceeds of \$7.5 million from the exercise of common stock warrants sold in our offering in October 2016, which were partially offset by \$1.9 million of principal payments made on indebtedness. Our primary sources of cash from financing activities during the nine months ended September 30, 2016 related to \$4.3 million in net proceeds from our offering in May 2016 as well as \$0.5 million in net proceeds received from the sale of common stock to Aspire Capital, which were partially offset by \$1.3 million of principal payments made on indebtedness.

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

(dollars in thousands)	For the year ended December 31,	
	2015	2016
Cash provided by/(used in):		
Operating activities	\$ (15,155)	\$ (15,697)
Investing activities	(165)	(451)
Financing activities	18,777	11,936
Net increase/(decrease) in cash	<u>\$ 3,457</u>	<u>\$ (4,212)</u>

**Cash Used in Operating Activities.** Net cash used in operating activities was \$15.7 million for the year ended December 31, 2016, compared to net cash used in operating activities of \$15.2 million for the year ended December 31, 2015. The net increase of \$0.5 million in cash used in operating activities for the year ended December 31, 2016 as compared to the same period in 2015 was primarily related to an increase of \$1.4 million in cash used to fund our net loss, partially offset by an increase of approximately \$0.7 million in cash provided by operating assets and liabilities, as well as an increase of \$0.2 million in adjustments to reconcile net loss to net cash used in operating activities primarily related to stock compensation expense, depreciation expense, and non-cash interest expense.

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

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

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

We expect to continue to incur substantial operating losses in the future. It may take several years to achieve positive operational cash flow, or we may not ever achieve positive operational cash flow. We expect that we will use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our assays, acquire equipment, implement automation and scale our capabilities to prepare for significant assay volume, for general corporate purposes and to fund ongoing operations and the expansion of our business, including the increased costs associated with expanded commercial activities. We may also use the net proceeds from our sale of equity securities, if any, cash received from the licensing of our technology, if any, and our revenues from operations to acquire or invest in businesses, technologies, services or products, although we do not have any current plans to do so.

As of September 30, 2017, our cash totaled \$5.9 million, and our outstanding net indebtedness totaled \$3.3 million. While we currently are in the commercialization stage of operations, we have not yet achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. Management expects that we will need additional financing to execute on our current or future business strategies beyond February 2018.

Subsequent to the closing of a follow-on offering in February 2015, cash proceeds of approximately \$9.8 million have been received from the exercise of warrants sold in that offering, while approximately \$2.7 million in gross warrant proceeds remain outstanding and available to be exercised at \$4.68 per share until their expiration in February 2020.

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



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exclusive placement agent agreement dated March 28, 2017 between us and Roth Capital Partners, LLC as lead placement agent, and WestPark Capital and Chardan Capital as co-placement agents, a securities purchase agreement for an offering of 4,320,000 shares of our common stock was effected under this registration statement at a per share price of \$2.15. In a concurrent private placement, we sold unregistered warrants to purchase up to an aggregate of 2,160,000 shares of our common stock that closed concurrently with the offering common stock sold pursuant to this shelf registration statement, of which none have been subsequently exercised. All warrants sold in this offering have a per share exercise price of \$2.50 and expire on October 1, 2022. The closing of the sale of these securities to the purchasers occurred on March 31, 2017, when we received approximately \$8.6 million of net cash proceeds. In connection with the closing of this offering, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year following the closing of this offering, with certain exceptions. Pursuant to an exclusive placement agent agreement dated December 5, 2017 between us and Dawson James Securities, Inc. as lead placement agent, and WestPark Capital as co-placement agent, a securities purchase agreement for a registered direct offering of 4,925,000 shares of our common stock was effected under this registration statement at a per share price of \$0.68. The placement agent was issued a warrant to purchase 246,250 shares of common stock at an exercise price of \$0.85 per share, which is first exercisable on June 5, 2018 and expires on December 5, 2022. The closing of the sale of these securities occurred on December 8, 2017, when we received approximately \$3.0 million of net cash proceeds. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

On October 19, 2016, we received net cash proceeds of approximately \$9.0 million as a result of the closing of a follow-on public offering. Subsequent to the closing of this offering on October 19, 2016, the offering's underwriters exercised their overallotment option to purchase 627,131 option warrants for total proceeds of \$564. Subsequent to the closing of this offering, approximately \$7.5 million of additional cash proceeds had been received from the exercise of warrants sold in this offering, with approximately \$3.2 million in gross warrant proceeds remaining outstanding and available to be exercised at \$1.10 per share until their expiration in October 2021.

Pursuant to a common stock and warrant purchase agreement dated August 9, 2017, we received net cash proceeds of approximately \$2.0 million as a result of the sale of our common stock and warrants. Subsequent to the closing of this offering, no additional cash proceeds had been received from the exercise of warrants sold in this offering, with approximately \$2.2 million in gross warrant proceeds remaining outstanding and available to be exercised at \$1.50 per share until their expiration in August 2022.

We expect that we will need additional financing to execute on our current or future business strategies. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time, subject to certain restrictions that apply for so long as our public float is less than \$75 million. In connection with our offering in March 2017, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year, subject to certain exceptions. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. If we are unable to raise a sufficient amount of financing in a timely manner, we would likely need to scale back our general and administrative activities and certain of our research and development activities. Our forecast pertaining to our current financial resources and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

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

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- our ability to collect revenues; and
- other risks discussed in our other filings with the SEC.

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

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

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

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

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

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

- revenue recognition; and
- stock-based compensation.

### **Revenue Recognition and Related Reserves**

Our commercial revenues are generated from diagnostic services provided to physicians and billed to third-party insurance payers such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. We recognize revenue in accordance with the provision of ASC 954-605, Health Care Entities—Revenue Recognition, which requires that four basic criteria must be met prior to recognition of revenue: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. Commencing on March 31, 2017, we recognize commercial revenue related to billings for assays delivered and billed to Medicare and other third-party payers on an accrual basis when amounts that will ultimately be realized can be estimated upon delivery, whereby prior to March 31, 2017, we recognized revenues for our commercial diagnostic services on a cash basis as collected because the amounts ultimately expected to be received could not be estimated upon delivery due to insufficient collection history experience.

We bill third-party payers on a fee-for-service basis at our list price and third-party commercial revenue is recorded net of contractual discounts, payer-specific allowances and other reserves. Our development services revenues are supported by contractual agreements and generated from assay development services provided to entities, as well as certain other diagnostic services provided to physicians. Diagnostic services are completed upon the delivery of assay results to the prescribing physician, at which time we bill for the service.

Our gross commercial revenues billed are subject to estimated deductions for such contractual discounts, payer-specific allowances and other reserves to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected. These third-party payer discounts and sales allowances are estimated based on a number of assumptions and factors, including historical payment trends, seasonality associated with the annual reset of patient deductible limits on January 1 of each year, and current and estimated future payments. Specifically, we maintain four such reserves: the reserve for

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contractual discounts, the reserve for aged non-patient receivables, the reserve for estimated patient receivables, and the reserve for other payer-specific sales allowances. The reserve for contractual discounts relates to discounts to gross amounts billed to Medicare and contracted third-party payers to arrive at the deemed “allowed expense” amount covered by that payer. Our contracted third-party commercial sales are recorded using an actual or contracted fee schedule at the time of sale, while estimated fee schedules are maintained for each non-contracted payer separately as part of other payer-specific sales allowances. Contractual discounts are recorded at the transaction level at the time of sale based on a fee schedule that is maintained for each contracted third-party payer. We periodically adjust fee schedules for both contracted and non-contracted third-party payers based upon historical payment trends. The reserve for aged non-patient receivables reduces gross amounts billed to non-contracted third-party payers for amounts estimated to be collected according to the age of the outstanding balance. The reserve for estimated patient receivables reduces gross amounts billed to third-party payers for amounts estimated to be collected directly from individual patients, such as copayments, deductibles, or amounts otherwise designated as patient responsibility. The reserve for other payer-specific sales allowances relates to the amounts billed to non-contracted third-party payers that are estimated to not be covered by that specific payer’s coverage policies, as well as estimated necessary adjustments to gross amounts billed based on historical collection experience for a particular third-party payer unrelated to the age of outstanding balances.

The estimates of amounts that will ultimately be realized from commercial diagnostic services require significant judgment by management. Patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that they have not met their annual deductible limit under their insurance policy, if any, or if their insurance otherwise declines to reimburse us. Adjustments to the estimated payment amounts are recorded at the time of final collection and settlement of each transaction as an adjustment to commercial revenue. The estimation process used to determine third-party payer discounts and sales allowance has been applied on a consistent basis since March 31, 2017, and no significant subsequent adjustments have been necessary to increase or decrease these discounts and allowances as a result of changes in underlying estimates.

### **Stock-Based Compensation**

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

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

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

## BUSINESS

We are an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or “liquid biopsy.” Our current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring in order to identify specific resistance mechanisms. Often, traditional methodologies such as tissue biopsies are insufficient or unavailable to provide the molecular subtype information necessary for clinical decisions. Our assays have the potential to provide more contemporaneous information on the characteristics of a patient’s disease compared with traditional methodologies such as tissue biopsy and radiographic imaging. Additionally, commencing in October 2017, our pathology program initiative provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results and is available to pathology practices and hospital systems throughout the United States. Further, our proprietary blood collection tubes, or BCTs, which allow for the intact transport of liquid biopsy samples for research use only, or RUO, from regions around the world, are anticipated to be sold to laboratory supply distributor(s) commencing in 2018.

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

At our corporate headquarters facility located in San Diego, California, we operate a clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologists, or CAP. We also performed research and development that led to our current assays, and we also intend to perform research and development for planned assays, at this facility. In addition, we manufacture our microfluidic channels, related equipment and certain reagents. The assays we offer and intend to offer are classified as laboratory developed tests, or LDTs, under CLIA regulations. 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. In addition, we participate in and have received CAP accreditation, which includes rigorous bi-annual laboratory inspections and adherence to specific quality standards.

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

Our revenue generating efforts are focused in three areas:

- providing clinical testing that oncologists, pathologists and other physicians use in order to determine the best treatment plan for their patients;
- providing clinical trial, research and development services to biopharmaceutical companies developing drug candidates to treat cancer; and
- licensing and/or selling our proprietary testing and/or technologies to partners in the United States and abroad.

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

## Market Overview

### Cancer Market Overview

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. According to the World Cancer Report 2014, cancers figure among the leading causes of morbidity and mortality worldwide, and according to the World Health Organization, there were approximately 14 million new cases and 8.8 million cancer related deaths in 2015. The number of new cases is also expected to rise by approximately 70% over the next two decades. According to the World Health Organization, the most common causes of cancer death are cancers of the lung (21%), liver (10%), colon (9%), stomach (9%), and breast (7%). The incidence of, and deaths caused by, the major cancers are staggering. According to the National Cancer Institute, there were approximately 249,000 new cases of breast cancer and approximately 224,000 new cases of lung cancer diagnosed in the United States in 2016, with over 3.5 million patients who have had a diagnosis of these cancers and are either living with these diseases and are undergoing treatment or are being monitored. For example, in breast cancer, many women have been deemed cancer-free, but continue to undergo periodic monitoring to assure there has been no disease recurrence. Our commercialized assays and our other planned future assays only require a readily accessible standard blood sample and thus may be used to help manage these patients, including supporting the selection of appropriate treatment, at multiple time points during the course of their disease. Because our assays require only a standard blood sample, they can be particularly useful when there is no currently available biopsy or surgical material, as is often the case in lung cancer, even at the time of initial evaluation. For example, up to 25% of patients with stage I non-small cell lung cancer, or NSCLC, are not surgically treated for various reasons, including patient status (consensus statement from the American College of Chest Physicians and the Society of Thoracic Surgeons; *Chest*, Dec. 2012). This is also the case with breast and lung cancers once surgical resection of the tumor has taken place and treatment has been initiated. Patients with breast and lung cancer must often undergo surgical resection of their primary tumor as part of their treatment. Therefore, at the time of progression or recurrence there may be no ability to obtain a tissue biopsy. Additionally, many studies have shown that most tumors mutate during treatment and as the disease progresses, so information from the initial tumor tissue may not be relevant. Again, a significant benefit of our technology is that it allows physicians to assess the current status of the tumors on a real-time basis utilizing a standard blood sample or liquid biopsy.

The following data published by the National Cancer Institute shows estimated new cases and deaths for 2017, and prevalence in 2013, in the United States for the major solid cancers types:

Cancer Type	Est. Incidence (New Cases/Year-2017)	Est. Mortality (Deaths/Year-2017)	Est. Prevalence (Diagnosed and Alive as of 2013)**
Bladder	79,030	16,870	587,426
Breast*	252,710	40,610	3,069,231
Cervical	12,820	4,210	248,920
Colorectal*	95,520	50,260	1,177,556
Endometrial	61,380	10,920	***
Gastric*	28,000	10,960	79,843
Kidney	63,990	14,000	394,336
Lung*	222,500	155,870	415,707
Melanoma*	87,110	9,730	1,034,460
Ovarian	22,440	14,080	195,767
Pancreatic	53,670	43,090	46,620
Prostate*	161,360	26,730	2,850,139
Thyroid	56,870	2,010	637,115

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

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

\*\*\* National Cancer Institute data is unavailable for 2013. 2010 data indicates an estimated prevalence of 600,346.

In addition to the human toll, the financial cost of cancer is overwhelming. An independent study published in 2010 and conducted jointly by the American Cancer Society and LIVESTRONG ranked cancer as the most economically devastating cause of death in the world - estimated to be as high as \$1.4 trillion globally. According to an article in the Journal of the National Cancer Institute, the direct cost of cancer deaths in the United States in 2000 was over \$115 billion, and forecasted to rise to over \$157 billion by 2020.

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

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

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

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

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

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

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

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

CTCs are cancer cells that have detached from the tumor matrix and entered the patient's blood or other bodily fluids. These cells are representative of the tumor and its metastases and can function as their surrogates. Testing CTCs can complement pathologic information drawn from a biopsy or resected tissue sample, helping to ensure that the analysis is comprehensive and not biased by tumor heterogeneity and sampling issues. They can also provide critical data when a biopsy is not possible. Clinical studies have demonstrated that the presence and number of CTCs provides information on the likely course of certain types of disease for the cancer patient, or in other words they are considered "prognostic." Since CTCs are representative of the tumor, they can also be used for biomarker analysis, such as helping to guide therapy selection. Such analyses are "predictive" in that they offer insight into the



likely responsiveness or resistance to particular therapies. After surgery and during any subsequent therapy or monitoring period, blood samples can periodically be drawn in a standard manner and analyzed to evaluate a therapy's continuing effectiveness, as well as to detect other biomarkers such as new genetic mutations that may arise as a result of selection pressure by a particular therapy or by chance. Physicians can use this information to determine which therapy is most likely to benefit their patients at particular times through the course of their disease. Treatment decisions based on patient-specific information are the foundation of personalized medicine, and assays that guide a physician in the selection of individualized therapy for a patient are termed "predictive assays."

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

Given the incidence of cancer in the United States, with an estimated 1,260,000 new cases in 2016 for the major solid tumors targeted by our planned future assay products, the markets for our current and planned future cancer diagnostic assays are very large. Furthermore, these market opportunities are even greater due to the benefits of CTC and ctDNA testing, including not only the ability to offer physicians a simple way to augment an initial tumor biopsy analysis but also to provide a means for relatively frequent monitoring of the tumor's molecular status, utilizing a standard blood sample as a "liquid biopsy." The latter application enables the physician to determine if or how a tumor is changing over time or is responding to therapy and what the next treatment should be. For example, in the United States, the incidence of new cases of breast cancer alone is estimated to be over 232,000 in 2016, and the prevalence of this disease is over 2.8 million (the number of women with a history of breast cancer in the United States, including women being treated and women who have finished treatment), with an estimated 330,000 lumpectomies performed annually in the United States. Of these lumpectomies, 20% need to be repeated because on pathological examination it is shown the procedure did not result in "clean margins," thus suggesting the entire tumor was not removed, according to a Johns Hopkins report. If a CTC assay were performed at the time of initial diagnosis, at the time of surgery, or in lieu of, or as an adjunct to, a PET/CT scan (as a CTC assay has the potential to identify a single tumor cell in a blood sample, while a scan requires a tumor mass of millions of cells to be detectable), to monitor disease progression or test for recurrence, thousands of assays, in breast cancer alone, could be performed per year with still relatively low market penetration.

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

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

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



## Our Business Strategy

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

Our approach is to develop and commercialize CTC and ctDNA assays and services that enable us to offer standard blood sample based, real-time testing solutions for a range of solid tumor types to oncologists that improve patient treatment with better prognostic and predictive tools. To achieve this, we intend to:

- Develop and commercialize a portfolio of proprietary CTC and ctDNA assays and services, to enable physicians to develop personalized treatment plans. We intend to continue the development of additional prognostic and predictive assays and services to provide information that is essential to personalized cancer treatment. By including predictive information on biomarkers associated with specific therapies in our analysis in addition to CTC enumeration, our assays are designed to provide a more complete profile of a patient's disease than existing CTC tests. The biomarker information will assist physicians in selecting appropriate therapies for individual patients. Our ctDNA assays are expected to offer enhanced sensitivity and specificity based on the Target-Selector technology, enabling earlier detection of therapy-associated mutation targets or resistance markers, again supporting treatment decisions. We have launched our Target-Selector offering in a number of key indications such as breast cancer, lung cancer, gastric cancer, colorectal cancer, prostate cancer, and melanoma, which are performed in our CLIA-accredited testing facility. We plan to perform the necessary validation studies to allow us to commercialize these assays through our clinical laboratory.
- Scale our internal sales and marketing capabilities. Our direct sales force with specialized experience in cancer diagnostic testing focuses on key identified territories in order to provide geographic coverage throughout the United States. At December 31, 2017, we had 14 sales representatives, and depending on our assay volume, we expect to increase this group to 20-25 within two years and potentially 30-35 within five years. This team will educate physicians directly on the benefits of our assays and the clinical data supporting them, as well as provide support to and serve as technical specialists for our partners. In addition to our internal efforts, we are actively seeking commercial partnerships that can increase our market reach.
- Develop and expand our collaborations with leading university hospitals and research centers. We collaborate with key thought leaders, physicians and clinical researchers, including those at Sarah Cannon Research Institute, University of Colorado, the University of California, San Diego, the University of Minnesota, the John Wayne Cancer Institute, Columbia University, Johns Hopkins Medical Institute, Vanderbilt University, University of Texas Southwestern Medical Center, St. Josephs of Orange, St. Luke's Cancer Center, and Georgetown University. Our collaborations enable us to test new technologies, validate the effectiveness and utility of our planned future assays in a clinical setting and provide us access to clinically well-characterized and highly annotated patient data. These samples and data accelerate our validation process and facilitate the testing and refinement of our planned new assays.
- Enhance our efforts in reaching and educating oncologists, pathologists and other physicians about CTC and ctDNA assays. According to the State of Cancer Care in America 2014 Report, published in the Journal of Oncology Practice in March 2014, there were approximately 13,400 medical oncologists in the United States or 16,500 if gynecologic and pediatric oncologists are included. With the support of our key thought leader collaborators, we intend to focus on oncologists, pathologists and other physicians who treat cancer patients by targeting our sales and marketing efforts on this important customer segment. We believe this will expand and optimize the oncology testing services and personalization of cancer treatment provided by oncologists, pathologists and other physicians so that they can better serve their cancer patients.
- Increase our efforts to provide biopharmaceutical companies and clinical research organizations with our current and planned CTC and ctDNA assays and services. Oncology drugs have the potential to be among the most personalized of therapeutics, yet oncology drugs have one of the worst approval rates, at 13.4% for leading indications and 8.2% for secondary indications of cancer drug compounds from first administration in humans to approval (2013, Clinical Pharmacology and Therapeutics). In an effort to improve the outcome of clinical trials for oncology drugs, and more rapidly advance targeted therapeutics, pharmaceutical and biopharmaceutical companies are increasingly looking to companies that have cancer diagnostic assays that specifically address their needs, including the ability to characterize and monitor a patient's tumor over time using CTC and ctDNA assays to analyze biomarkers of interest. There are over 5,000 active trials in the United States in breast, lung, colorectal, prostate and gastric cancers and melanoma according to clinicaltrials.gov. We expect to increase our sales and marketing focus in this business as well as seek additional collaborations and partnerships with diagnostic, pharmaceutical and biopharmaceutical companies.

- Become an enabling technology to cancer targeted therapies. Biopharmaceutical companies will increasingly focus on the personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. As targeted therapies move into their next phase, the market is beginning to see next generation of drugs such as Astra Zeneca's Tagrisso (Osimertinib) that work after a patient on targeted therapy begin to progress and show a resistance mechanism that is identifiable / targetable, in this case a mutation in EGFR known as T790M. With these drugs, the original biopsy tissue would not show the resistance mechanism, so the patient must either undergo a re-biopsy procedure. In many cases re-biopsy is not medically feasible and liquid biopsy offers a more cost effective and safer alternative in this application. Another area of interest for the pharmaceutical industry is in immuno-oncology. This is the challenge of helping the body to counter the cancer cell's ability to evade the immune system. Several protein-based tests are being developed in tissue to work as complimentary or companion diagnostics to these new and promising drugs, but the use of these tests will be limited as a result of limitations of tissue biopsies. Another solution would be to test for these proteins with a liquid biopsy-based CTC test rather than relying on tissue biopsies.
- Conduct additional clinical studies with our current CTC and ctDNA assays and assays we plan to introduce in various cancer types. Clinical utility and validation studies for our planned ctDNA assays may rely on archived plasma or blood samples from clinical trials in which patient outcomes are already available, in a retrospective-prospective design that significantly shortens the length of such studies.
- Continue to enhance our current and planned future CTC and ctDNA assays and reduce the costs associated with providing them through internal research and development and partnering with leading technology developers and reagent suppliers. We intend to work closely with select key technology developers and suppliers to further automate the optical interpretation of our current assays and our planned additional CTC assays, including enumeration, immunocytochemical biomarker staining and FISH. We also intend to reduce the costs associated with key material components of these assays, including FISH probes. We have and currently utilize an automation system that significantly reduces the hands-on time of our cytogenetic technologists for microfluidic channel analysis while increasing the uniformity of the data we generate. This system is also expected to provide the ability to evaluate multiple fluorescent signals of different wavelengths simultaneously for multiplexed analysis, further enhancing efficiency.

### **Our Competitive Advantages**

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

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

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

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

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

*Collaborative relationships with physicians at Sarah Cannon Research Institute, University of Colorado, the University of California, San Diego, the University of Minnesota, the John Wayne Cancer Institute, Columbia University, Johns Hopkins Medical Institute, Vanderbilt University, University of Texas Southwestern Medical Center, St. Josephs of Orange, St. Luke's Cancer Center, and Georgetown University.* We have worked closely with a number of physicians at institutions on various collaborative projects in different cancer types including breast, NSCLC, prostate, colorectal, ovarian, bladder, renal and endometrial. These projects provide us access to leading researchers, clinicians and key thought leaders, access to valuable patient samples and insight into clinical applications for our assays. Some of these projects have resulted in publications in leading journals, such as Cancer Discovery and Cancer Medicine, which enhances our standing in the oncology community and supports our marketing efforts.

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

## **Our Assays, Products and Services**

### ***Assays, Products and Services***

We currently offer and conduct our commercialized diagnostic assays and offer our clinical trial services at our CLIA-certified, CAP-accredited and state-licensed laboratory. We have commercialized our Target-Selector assays for a number of solid tumor indications such as: breast cancer, NSCLC, gastric cancer, colorectal cancer, prostate cancer, melanoma, pancreaticobiliary cancer, and ovarian cancer. These assays utilize our dual CTC and ctDNA technology platforms and provide biomarker analysis from a patient's blood sample.

Our current assays and our planned near-term cancer diagnostic assays and clinical trial services include:

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

In the case of our breast and gastric cancer offerings, biomarker analysis involves fluorescence in situ hybridization, or FISH, for the detection and quantitation of the human epidermal growth factor receptor 2, or HER2, gene copy number as well as immunocytochemical, or ICC, analysis of estrogen receptor, or ER, protein, progesterone receptor, or PR, protein, and androgen receptor, or AR, protein, which are currently commercially available. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

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Our lung cancer biomarker analysis offering currently includes FISH testing for ALK, ROS1, RET, MET and FGFR1 gene rearrangements, as well as analysis for the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor, or EGFR gene, as well as BRAF, KRAS and NRAS. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are associated with the use of the drugs Tarceva®, Gilotrif® and Iressa®. For lung cancer, we also offer a resistance profile assay consisting of the biomarkers MET, HER2 (both of which we perform using our technology for CTCs), KRAS, and T790M (both of which are performed using ctDNA in plasma). These assays can be used by physicians to identify the mechanism causing disease progression for patients with NSCLC who are being treated with tyrosine kinase inhibitor, or TKI, therapy and therefore may qualify patients for inclusion in a clinical trial. In November 2015, Tagrisso® was approved by the FDA, providing another biomarker-based therapy for the treatment of patients with EGFR-related lung cancer. Tagrisso® is indicated for the treatment of patients with metastatic disease, who have progressed on or after EGFR TKI therapy, and who have acquired a T790M resistance mutation. Recently, the FDA approved the combination of Novartis' Tafenlar® (dabrafenib) and Mekinist® (trametinib) for the treatment of patients with metastatic NSCLC whose tumors express the BRAF V600E mutation, an FDA "breakthrough therapy" designation for patients who have received prior chemotherapy. This combination was approved in Europe for the same indication in March 2017. BRAF mutations, which appear in approximately 1-3% of NSCLC cases globally, are associated with Zelboraf® and Tafenlar® treatment, as these BRAF inhibitors are both approved for the treatment of patients with melanoma.

In September 2017, we launched our assay for mutations of the NRAS oncogene, which can be used to detect and monitor an actionable biomarker associated with multiple cancer types such as metastatic melanoma, colorectal and lung cancer. As a result, we now offer 15 CLIA-certified liquid biopsy tests utilizing our Target-Selector platform to determine the status of key cancer biomarkers listed in the National Comprehensive Cancer Network Guidelines®. Our NRAS assay combines our proprietary switch blocker technology for improved mutation detection with next generation sequencing, resulting in ultra-high sensitivity.

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

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

We plan to release additional blood-based biomarker assays, such as those that test for ESR1, to our current menu of liquid biopsy assays using blood samples. In addition, we plan to complete the development and offer multiplexed biomarker tests, which will allow the detection and quantitative monitoring of multiple biomarkers in a single assay.

In August 2017, we announced that we had executed a distribution agreement for our proprietary blood collection tubes with VWR International, LLC which can preserve intact cells (such as CTCs) for up to 96 hours and ctDNA for up to 8 days, allowing for the intact transport of RUO liquid biopsy samples from regions around the world.

In October 2017, we launched our pathology partnership initiative, expanding access of our proprietary liquid biopsy testing to community pathologists and hospitals throughout the United States. The aim of this program is to incorporate community pathologists into the review of biomarkers found in liquid biopsy for patients diagnosed with cancer. Pathologists are now enabled to interpret our liquid biopsy results locally, while patient specimens will continue to be sent to us for processing in our CLIA-certified, CAP-accredited high complexity laboratory.

We intend to continue to commercialize cancer diagnostic assays in the United States as LDTs performed in our CLIA-certified, CAP-accredited, and state-licensed laboratory. We plan to evaluate potential opportunities for the commercialization of our products in other countries. We believe the Target-Selector technology can someday be used as a stand-alone test for molecular biomarker screening, marked as IVD test kits. Additionally, we plan to evaluate opportunities for licensing of our products and proprietary technologies to partners in the United States and abroad.

### ***Pharmaceutical and Research Collaborations and Studies***

We continue to execute on our strategies intended to expand our business globally, as well as to engage with pharmaceutical companies on clinical trials and assay development. We have preferred provider agreements in place in Mexico with Quest Diagnostics to support testing for a large pharmaceutical company partner. In addition, we have distribution agreements in place in Mexico, Uruguay, Turkey, the Czech Republic, the Philippines, Lebanon, Columbia, Israel and Canada.

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We completed a study, published in *Cancer Medicine* in March 2013, utilizing our assay, and a version of this assay adapted for use with bone marrow samples, with a group at The University of Texas MD Anderson Cancer Center comprised of breast cancer surgeons, pathologists and basic researchers. In this study, we demonstrated the ability to identify HER2 positive CTCs and disseminated tumor cells, or DTCs, seen in bone marrow in patients that had been previously classified as HER2 negative by analysis of their tumor tissue. A HER2 positive result in a patient with breast cancer provides an indication to the physician that there is likely to be a survival benefit from treatment with Herceptin®, which has been demonstrated in a number of large clinical studies.

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

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

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

During 2016, we announced three pharmaceutical collaborations. The first agreement provides testing for a clinical trial that includes patients who have leptomeningeal disease or metastatic lung cancer in the brain. In this exploratory trial, we are testing both cerebral spinal fluid and blood for molecular alterations that could be impacted by treatment. The second agreement is a milestone-based assay development project focused on hepatocellular carcinoma, or liver cancer, whereby we intend to develop assays utilizing both our CTC and ctDNA technologies for clinical trials. The third collaboration involves a study presented at the European Society for Medical Oncology, or ESMO, Annual Congress in October 2016, evaluating the detection of EGFR alterations (del19, L858R and T790M) by our Target-Selector liquid biopsy. Subsequent to this study, we have earned business in both Mexico and Columbia for EGFR testing in blood to qualify patients for the pharmaceutical company's targeted therapy.

In April 2017, we announced our entry into a preferred provider collaboration and services agreement with Oregon Health & Sciences University on behalf of the OHSU Knight Cancer Institute, or collectively OHSU. The multiphase agreement grants OHSU the rights to commercially offer our Target-Selector liquid biopsy testing services exclusively throughout the state of Oregon. Additionally, we and OHSU plan to engage in technology transfer, whereby OHSU will have the ability to use Target-Selector assays in-house, and act as a secondary laboratory for our research and testing activities. We and OHSU also plan to co-develop additional liquid biopsy assay technologies and platform capabilities including highly sensitive, multiplexed assay panels for molecular biomarker detection and assessment. Additional research and development and commercial pilot projects are anticipated under the agreement.

In May 2017, we announced jointly with the Addario Lung Cancer Medical Institute, or ALCMI, entry into a clinical collaboration and initiation of the ALCMI-009 liquid biopsy clinical trial. This large-scale trial was developed, and will be conducted, by ALCMI and its consortium of leading U.S. and international oncology centers. The prospective, multi-center study, which plans to enroll 400 patients, will utilize our Target-Selector testing platform and services to detect and assess cancer biomarkers found in both CTCs and ctDNA from the blood of patients with lung cancer. We expect this study to commence in the first half of 2018.

In May 2017, we entered into a clinical study agreement with the University of Texas Southwestern Medical Center. Led by recognized oncologist and ALK alteration researcher, Dr. Saad Khan, the study is designed to evaluate the clinical utility of our Target-Selector platform for patients diagnosed with ALK-positive NSCLC and treated with ALK-inhibitor therapy. A second arm of the study will evaluate patients with rare cancers such as anaplastic thyroid cancer to determine if driver mutations such as ALK rearrangements can be identified and treated with targeted therapy to improve patient outcomes.

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In October 2017, we entered into a promotion and marketing agreement with Miraca Life Sciences, Inc., or Miraca Life Sciences, to market our Target-Selector liquid biopsy tests and services to community-based oncologists and hematologists in specified sales territories in the United States. Based on the agreement, Miraca Life Sciences' sales professionals will promote our liquid biopsy tests to both their existing and new clinician clients in designated sales territories, with the potential to expand the agreement to additional territories in the future. All tests will be performed in our CLIA-certified CAP-accredited laboratory.

### ***Provider Agreements***

In January 2017, we announced that we had secured an in-network provider agreement with Blue Cross Blue Shield of Texas, the largest provider of health benefits in Texas. In addition, we entered into a national master business agreement with the Blue Cross Blue Shield Association, a not-for-profit trade association that provides multiple services for its 38-member Blue Cross and Blue Shield health plan companies across the U.S., including forming national strategic vendor partnerships. We were selected by the Blue Cross Blue Shield Association based on a rigorous request-for-proposal process. This agreement establishes pricing for our Target-Selector liquid biopsy testing service through the Blue Cross Blue Shield Association's group purchasing organization, CareSourcing Workgroup. The pricing offered by the CareSourcing Workgroup group purchasing organization is available to those Blue Cross and Blue Shield member health plans that have, or may seek, in-network agreements with us.

In June 2017, we entered into a participating provider agreement with MediNcrease Health Plans, LLC and a preferred provider agreement with Scripps Health Plan Services, Inc., both establishing pricing for our Target-Selector liquid biopsy testing service.

In December 2017, we signed an agreement with Wellmark, Inc., the largest health insurer in Iowa and South Dakota. The agreement marks our third Blue Cross Blue Shield contract and enables patients diagnosed with cancer the ability to access our proprietary testing services in-network under their Wellmark health plan.

We are currently contracted with nine preferred provider organization networks, three large health plans, and five regional independent physician associations, and expect to continue to gain contracts in order to be considered as an "in-network" provider with additional plans.

### **Laboratory Testing**

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

### **Clinical Trial Services**

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



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

### Assay Development Process

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

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

We currently offer 15 assays that are available for clinical use that have completed all four stages of the development protocol. Other assays for both CTCs and ctDNA are in earlier stages of development. Markers for such assays include, but are not limited to, ESR1 and a multiplexed assay.

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

If the FDA finalizes its current draft guidance on a risk-based framework for regulation of LDTs, our process would also need to allow for obtaining FDA review, clearance or approval, as applicable, which would add delay, expense and risk to our current assay development process. In November 2016, the FDA put the process to review and issue this guidance on hold and has not yet provided further information as to when the process will move forward.

### Research and Development

We incurred research and development expenses of \$2.7 million and \$2.5 million for the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively, which represented 84% and 60% of our net revenues, respectively. Research and development expenses represented 13% and 12% of our total costs and expenses for the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively. Major components of research and development expenses were direct personnel costs, laboratory equipment, consumables and overhead expenses.



### ***Technology Development***

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

- **Improve Ability to Capture CTCs**

Continued modification and optimization of our microfluidic channel as a way to further enhance CTC capture efficiency. Capture efficiency directly impacts sensitivity, informative rate, and the ability to perform accurate and reliable biomarker analyses on the CTCs, all of which increase the value of our offering. We are utilizing some of our early research experience to improve CTC capture rates and reduce background contamination from normal white blood cells.

- **Automation of Our Assay Process**

Development of automation throughout the assay process, but particularly at the visual evaluation steps, which include enumeration, any ICC for biomarkers beyond those used to identify CTCs, for example protein biomarkers, and FISH analysis, is a way to drive efficiencies, reduce costs, speed up turnaround time, and generate more reliable, uniform, and in some cases more sensitive data. We have implemented an automation solution for the visual analysis, which has been validated and implemented in our CLIA laboratory. We have also adapted a semi-automated system for the separation, processing and washing steps before running a sample on the microfluidic channel, which has also been validated and implemented in the CLIA laboratory. These measures will reduce costs and time as well as allow for higher-throughput as sample volumes increase.

- **Development of Second Generation Platform for CTC Testing**

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

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

The ctDNA technology should enable us to multiplex mutation testing such that larger panels of genes can be analyzed in a single step and interfaced with genetic sequencing. This should position us for the analysis at the molecular level of whole signaling pathways or enzyme cascades. We plan to take advantage of the sensitivity and specificity of the ctDNA technology and leverage interest in the clinical research community for detecting any actionable biomarker in a particular tumor, as opposed to only those that are known to occur at relatively higher frequencies in that type of tumor. Such multiplexed mutation assays, relying on our ctDNA technology, could provide a more global evaluation of a tumor through analysis of either CTCs or ctDNA. This would offer a broader range of potential treatment options as well as enable the monitoring of the effectiveness of those treatments over time.

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

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

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

In the course of our research and validation studies, we have processed and analyzed thousands of normal control and cancer patient samples. Our initial focus has been on breast cancer, where validation studies for our CTC assay, including enumeration of CTCs on the Biocept platform compared to the CellSearch® system, and HER2 FISH performed on CTCs and compared with HER2 analysis performed on tumor tissue from the same patients, involved over 120 patient samples. The results of our validation studies, and the demonstration of a reliable and reproducible method for CTC capture and analysis using our platform were published in a paper

entitled “Novel Platform for the Detection of Cytokeratin Positive (CK+) and Cytokeratin Negative (CK-) CTCs” appearing in the December 2011 issue of *Cancer Discovery* and a paper entitled “Efficient capture of circulating tumor cells with a novel immunocytochemical microfluidic device” appearing in the September 2011 issue of *BioMicrofluidics*.

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

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

In a collaboration with physicians and researchers at The University of Texas MD Anderson Cancer Center, we evaluated matched samples of tumor tissue, blood for CTCs and bone marrow for DTCs in recently diagnosed breast cancer patients for evidence of HER2 amplification. Positive HER2 status would indicate eligibility for HER2-targeted therapies like Herceptin®, a potentially life-saving treatment. These results were presented at both the 2011 and 2012 annual meetings of the American Society of Clinical Oncology. In a study published in *Cancer Medicine* (2013, 2(2) 226-233) involving 95 patients, HER2 positive CTCs and/or DTCs were identified in 18.9% of cases in which the primary tumor was HER2 negative. In the same cohort of patients, only 12.6% were HER2 positive in their primary tumor. In other words, beyond the 12 (of the 95) which traditional tumor tissue analysis had indicated could benefit from Herceptin-based therapy, the Target-Selector assay detected 18 (of the 95 patients) who (despite the fact they were identified as being HER2 negative by primary-tumor testing) could benefit from Herceptin-based therapy. Patients classified as HER2 negative based on tumor tissue and found to have HER2 positive CTCs and/or DTCs will continue to be followed by our collaborators at The University of Texas MD Anderson Cancer Center to assess their overall and progression-free survival. Tumor heterogeneity is one likely cause of the discordance for HER2 status between tumor tissue and our assay performed on blood and bone marrow samples. Tumor heterogeneity indicates an important clinical application for the CTC analysis with the Target-Selector assay. Our technology can use a standard blood sample to confirm and crosscheck tissue analysis performed by the pathologist at the time of biopsy or surgery, especially if HER2 negative.

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

We have also developed proprietary and robust technology to detect and quantify mutant ctDNA in plasma originating from the same blood sample that is used for the previously described CTC analyses. In collaboration between Mexico’s Instituto Nacional de Cancerología and AstraZeneca, a clinical evaluation of blood-based liquid biopsy mutational profiling using our service was performed on 60 advanced-stage non-small cell lung cancer patients. This poster discussion presentation at the European Society for Molecular Oncology in October 2016 demonstrated EGFR mutation detection (exon 19 deletions, L858R, and T790) by Target-Selector with 90% sensitivity, 100% specificity, 100% positive predictive value and 90.9% negative predictive value. The same cohort

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was then presented by the authors of the study at the World Lung Congress in October 2017. Target-Selector assays are highly sensitive with the ability to detect EGFR mutations down to one mutant copy per milliliter of plasma. The high concordance of ctDNA versus tissue exhibited in this work highlights Target-Selector plasma ctDNA assays as a viable and practical means to detect EGFR activating and acquired resistance mutations relevant for guiding targeted therapy decisions.

Clinical utility studies, which demonstrate the specific clinical setting in which a particular CTC or ctDNA assay is used, and how to use the information generated for medical, specifically treatment-related, decision making is a key part of our strategy and research and development plan. Data resulting from such studies is critical not only in the sales and marketing process, but also for reimbursement, as many health plans and government payers now ask for peer-reviewed publications describing such studies and results before agreeing to coverage of a specific assay. We are involved in and plan to become involved in numerous studies to further demonstrate the clinical utility of our assays.

### **Sales and Marketing**

At December 31, 2017, our sales organization consisted of 14 sales representatives placed in strategic locations around the country that have high concentrations of cancer patients, and we may, depending on assay volume, potentially grow this number to 20-25 sales representatives within two years and to 30-35 within five years. We have defined sales territories and have hired sales professionals with extensive successful experience in clinical oncology sales or oncology diagnostic testing sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We plan on growing this specialized, oncology-focused sales force and supporting it with clinical specialists who bring significant technical knowledge in the use of CTC and ctDNA assays. We have also invested in sales headcount focusing on biopharma clinical trial opportunities.

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

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

- Work with oncologists, other physicians and group practices at community hospitals and cancer centers to educate them on the advantages and opportunities that CTC and ctDNA assays provide for better information, allowing them to select the most appropriate therapy for their patients, and how and when these assays are most effectively used;
- build relationships with key thought leaders in oncology, specifically in the cancer types for which we are offering or plan to offer assays, to educate and support community oncologists;
- collaborate with leading research universities and institutions that enable the validation of our new assays, as well as the generation of clinical utility data;
- partner with pharmaceutical companies for clinical trial work focusing on CTC and ctDNA testing and analysis; and
- add value for the payer community by delivering clinically actionable information and providing a cost-effective alternative to access clinically actionable information through the use of a simple blood test.

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

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

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

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

## Competition

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

- Our ability to utilize standard blood samples, enabling frequent testing of patients through the course of their disease in addition to, or without a biopsy, thereby reducing cost and trauma, saving time, and providing real-time information on the current status of the tumor;
- our ability to include biomarker information in our analysis, in addition to CTC enumeration, thereby providing a more complete profile of a patient's disease than existing CTC tests. This clinically actionable information can assist physicians in selecting more personalized treatment plans for individual patients;
- our current and planned future CTC assays' ability to capture and detect a broader range of CTC phenotypes than existing tests, and potentially at earlier stages of disease, resulting in fewer non-informative cases and more information for physicians. For example, our antibody capture cocktail targets not only EpCAM but also other epithelial antigens as well as mesenchymal and cancer stem cell antigens, indicative of cells having undergone the epithelial-to-mesenchymal transition. These cells may be more relevant for metastasis;
- our ability to rapidly integrate new biomarkers, either validated in academic laboratories or of interest to pharmaceutical and biopharmaceutical companies in the context of their new therapies, into our current and planned future assays, facilitating the expansion of actionable information for oncologists, pathologists and other physicians;
- our research and clinical collaborations with key academic and clinical study groups, which enhance our research and development resources and, by enhancing our standing in the oncology community, support our marketing efforts; and
- our planned ctDNA assays based on our technology, which are expected to offer enhanced sensitivity and specificity in detecting mutation targets or resistance markers, again supporting treatment decisions.

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

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

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

We also face competition from companies that offer products or are conducting research to develop products for CTC or ctDNA testing in various cancers. CTC and ctDNA testing is a new area of science and we cannot predict what assays others will develop that may compete with or provide results similar or superior to the results we are able to achieve with the assays we develop. Competitors include but are not limited to companies such as Atossa, Qiagen, Roche, Guardant Health, Menarini Silicon Biosystems (now owns Janssen Diagnostics), Alere (Adnagen), Illumina, Apocell, EPIC Sciences, Clearbridge Biomedics, Biodesix, Thermo Fisher Scientific, Foundation Medicine, Neogenomics, Cynvenio Biosystems, Genomic Health, Fluxion Biosciences, RareCells, ScreenCell, and Sysmex. Some of these groups, in addition to operating research and development laboratories, are establishing CLIA-certified testing laboratories while others are focused on selling equipment and reagents.

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

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

We expect that biopharmaceutical companies will increasingly focus attention and resources on the personalized cancer diagnostic sector as the potential and prevalence of molecularly targeted oncology therapies approved by the FDA along with companion diagnostics increases. For example, the FDA has approved three such agents—Xalkori® from Pfizer Inc. along with its companion anaplastic lymphoma kinase FISH test from Abbott Laboratories, Inc., Zelboraf® from Daiichi-Sankyo/Genentech/Roche along with its companion B-RAF kinase V600 mutation test from Roche Molecular Systems, Inc. and Tafenlar® from GlaxoSmithKline along with its companion B-RAF kinase V600 mutation test from bioMerieux. Since companion diagnostic tests are part of FDA labeling, non-FDA cleared tests such as ours would be considered an off-label use and this may limit our access to this market segment.

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

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

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

## Patents and Technology

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

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

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

Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, see the section entitled “Risk Factors – Intellectual Property Risks Related to Our Business.”

As of December 31, 2017, we owned 25 issued patents and 23 patents pending related to our current technologies. Of these, 8 are issued and 5 are pending patents in the U.S., while 17 are issued and 18 are pending patents in non-U.S. territories. Separately, we also own 7 issued patents related to our earlier microarray and cell analysis technology.

*Microfluidic Channels.* We have 4 issued U.S. patents that are related to our current business, and in 2016 and 2017 we received an additional issued patent on our microfluidic channel in each of China and Hong Kong, respectively, in addition to our earlier allowances in Japan, Hong Kong, Europe, China, and South Korea, which cover our microfluidic channel technology. Further U.S. and foreign patent application are pending.

*Blood Collection Tubes.* In 2015, we received a U.S. patent related to our blood collection tubes, which contain reagents designed to prevent clumping of blood cells and CTCs that could clog the microfluidic channels and disrupt our assays.

*Antibody Enrichment Cocktail.* We have 1 issued and 1 pending U.S. patent application, and 2 broadly issued European patents, as well as other corresponding foreign patent applications directed to our antibody capture cocktail technology. This technology includes using antibodies to a number of tumor-associated antigens from cancer cells of both epithelial and mesenchymal phenotype, as well as cancer stem cells.

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

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

## Operations and Production Facilities

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



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

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

### **Quality Management Program**

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

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

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

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

### **Third-Party Payer Reimbursement**

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

- Third-party payers that provide coverage to the patient, such as an insurance company, a managed care organization or a governmental payer program;
- physicians or other authorized parties, such as hospitals or independent laboratories, that order the testing service or otherwise refer the services to us;



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- patients in cases where the patient has no insurance, has insurance that partially covers the testing, or owes a co-payment, co-insurance or deductible amount;
- collaboration partners; or
- biopharmaceutical companies, universities or researchers for clinical trial work.

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

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

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

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

Medicare has coverage policies that can be national or regional in scope. Coverage means that assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service. There is currently no national coverage policy regarding the CTC enumeration portion of our testing. Because our laboratory is in California, the regional Medicare Administrative Contractor, or MAC, for California is the relevant MAC for all our testing. The previous MAC for California, Palmetto GBA, LLC, which is contracted with CMS to administer the MolDx program that sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays, adopted a negative coverage policy for CTC enumeration. The current MAC for California, Noridian Healthcare Solutions, LLC, is adopting the coverage policies from Palmetto GBA. Therefore, the enumeration portion of our testing is not currently covered, and we will receive no payment from Medicare for this portion of the service unless and until the coverage policy is changed. Although approximately 84% and 77% of all billable cases received during the year ended December 31, 2016 and the nine-month period ended September 30, 2017, respectively, relate to our Target-Selector biomarker assays, we continue to receive orders for our traditional enumeration testing, which counts disease burden, and therefore the enumeration testing receives no payment from Medicare based upon the existing coverage decision. The CTC enumeration counts disease burden and is a prognostic test, and although oncologists find the information valuable, it does not currently meet many of the medical necessity requirements of Medicare and the payers. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector assays.

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

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

CPT codes are the main billing code set used by physicians, hospitals, laboratories and other health care professionals to report separately-payable clinical laboratory and pathology services for reimbursement purposes. The CPT coding system is maintained and updated on an annual basis by the American Medical Association. We believe there are existing codes that describe nearly all of the steps in our testing process. We currently use a combination of codes to bill for our testing and analysis.

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

We are moving forward with plans to obtain reimbursement coverage for the capture components of our assays. For other tests, we are able to utilize existing CPT codes from the Medicare Physician Fee Schedule and Clinical Laboratory Fee Schedule. For these established CPT codes (for example, the codes for molecular testing, FISH and ICC), positive coverage determinations have been adopted as part of national Medicare policy or under applicable Local Coverage Determinations. Specific codes for our assays, however, do not assure an adequate coverage policy or reimbursement rate. Please see the section entitled “Legislative and Regulatory Changes Impacting Clinical Laboratory Tests” for further discussion of certain legislative and regulatory changes to these billing codes and the anticipated impact on our business.

## **Coverage and Reimbursement for our Current Assays and our Planned Future Assays**

Our Medicare Administrative Contractor has issued a negative coverage determination for the enumeration component of all CTC assays. We have received reimbursement for the enumeration component of our assays from some private payers, including major private third-party payers, based on submission of standard CPT codes. FISH, ICC and Molecular Testing CPT codes are the subject of positive coverage national or local Medicare determinations. We believe these codes can be used to bill for the analysis components of our current and planned future CTC assays, however, CMS, Palmetto or Noridian could adopt specific negative coverage policies for CTCs or ctDNA analysis in the future.

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

Additionally, CMS has recently issued a proposed decision memo for next generation sequencing, or NGS, for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) for comments ending January 17, 2018 and final decision from CMS on February 28, 2018. This coverage policy ties payment for NGS-based assays in oncology to FDA approval or clearance. If this policy remains limited to coverage for only FDA-approved or cleared assays, we would be required to complete an FDA review to qualify for payment for services that we provide for Medicare beneficiaries for NGS-based assays. Currently, only 1 of our 15 CLIA validated assays is NGS-based; however, we plan to offer additional NGS assays in the future, and an FDA review, if required, would result increased costs and delays in the launch timing of these new assays.

We believe, based on research showing that approximately 54% of new cancers occur in persons age 65 and older and that almost all Americans age 65 and older are enrolled in Medicare that a substantial portion of the patients for whom we would expect to perform cancer diagnostic assays will have Medicare as their primary medical insurance. We cannot assure you that, even if our current and our planned future assays are otherwise successful, reimbursement for the currently Medicare-covered portions of our current and our planned future assays would, without Medicare reimbursement for the enumeration portion, produce sufficient revenues to enable us to reach profitability and achieve our other commercial objectives.

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

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

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

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

In accordance with Section 1833 (h)(2)(A)(i) of the Social Security Act, the annual update to the CLFS for calendar year 2018 is 1.10% (see 42 CFR405.509(b)(1)). With respect to our diagnostic services for which we expect to be reimbursed under PFS, CMS issues a Final Rule on an annual basis. Since 2015, the PFS Final Rules have included both increases and decreases in certain relative value units and geographic adjustment factors used to determine reimbursement for a number of codes used in our current assays and our planned future assays. These codes describe services that we must perform in connection with our assays and we bill for these codes in connection with the services that we provide.

In addition, other legislative changes have been proposed and adopted since the Patient Protection and Affordable Care Act, or ACA, was enacted in March 2010. The Protecting Access to Medicare Act of 2014, or PAMA, was signed to law, which, among other things, significantly alters the current payment methodology under the CLFS. Under the new law, issued in 2016 and the reporting period beginning in 2017 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. 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 payer (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Beginning in 2018, the Medicare payment rate for each clinical diagnostic lab test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. The PAMA rate changes to our tests that were impacted did not materially affect our payments beginning in 2018; however, we cannot predict how this may change future payment in coming years. Also, under PAMA, the Centers for Medicare & Medicaid Services, or CMS, is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS was required to publicly report payment for the tests no later than January 1, 2016. Further, 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.

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

Some of our Medicare claims may be subject to policies issued by Palmetto GBA and Noridian Healthcare Solutions, our former and current MACs for California, respectively. Palmetto GBA is contracted with CMS to administer the MolDx program, which sets guidelines for coding, coverage and reimbursement of molecular diagnostic assays. Palmetto GBA has issued a Local Coverage Determination, whereby Palmetto GBA will not cover many molecular diagnostic assays, such as the enumeration component of our current assays, unless the test is expressly included in a National Coverage Determination issued by CMS or a Local Coverage Determination or coverage article issued by Palmetto GBA. Currently, laboratories may submit coverage determination requests to Palmetto GBA for consideration and apply for a unique billing code for each assay (which is a separate process from the coverage determination). In the event that a non-coverage determination is issued, the laboratory must wait six months following the determination to submit a new request. Palmetto GBA currently has a negative coverage determination for the enumeration component of CTC assays, but there is no such negative coverage determination for the analysis component of such CTC assays. Denial (or continuation of denial) of coverage for the enumeration component of our current and anticipated CTC assays by Palmetto GBA or its successor MAC, Noridian Healthcare Solutions, which adopts coverage policies set by the MolDx program, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our current assays and our

planned future assays. Noridian Healthcare Solutions intends to follow, for CTC assays, the positive or negative coverage determinations which from time to time Palmetto GBA makes as well as any coverage policy changes set by the MolDx program. On November 27, 2013, Palmetto GBA denied our request for coverage for the enumeration/detection portion of our testing. We have not received any other indications to suggest that the negative coverage determination will be reversed. The CTC enumeration counts disease burden and is a prognostic test, and although oncologists find this information valuable, it does not meet many of the medical necessity requirements of Medicare and the payers. We intend to pursue payment for the capture portion of our CTC technology that allows us to run our diagnostic testing for some of our Target-Selector assays.

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

## **Governmental Regulations**

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

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

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

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

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

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

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

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

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

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

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

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

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

### ***Physician Referral Prohibitions***

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

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

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

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

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

### ***Physician Licensure***

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

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

### ***California State Laboratory Licensure***

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

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

### ***Other States’ Laboratory Licensure***

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

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



## ***U.S. Food and Drug Administration***

We provide our assays as LDTs. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that final guidance on the oversight of laboratory developed tests would allow for further public discussion. On January 13, 2017 the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA; rather, the document is a method to encourage additional dialogue. The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in consistent with the schedule set forth in the guidance. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time. LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be first to occur.

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

## ***Other Regulatory Requirements***

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

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

## ***Segment and Geographical Information***

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

## ***Employees***

As of December 31, 2017, we had a total of 95 full-time employees, 8 of whom hold doctorate degrees and 14 of whom are engaged in full-time research and development activities, as well as one part-time employee. We plan to expand production, sales and marketing and our research and development programs, and we plan to hire additional staff as these initiatives are implemented. None of our employees is represented by a labor union.

## ***Available Information***

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



**Company Information**

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

## MANAGEMENT

### Executive Officers and Directors

The following table sets forth the name, age and position of each of our directors and executive officers as of December 31, 2017.

Name	Age	Position	Served as an Officer or Director Since
David F. Hale	68	Non-executive Chairman of the Board of Directors	2011
Marsha A. Chandler, Ph. D. <sup>(3)</sup> (4)	72	Director	2013
Bruce E. Gerhardt, CPA <sup>(1)(2)</sup>	66	Director	2010
Bruce A. Huebner <sup>(1)(2)(4)</sup>	67	Director	2013
Michael W. Nall	55	Director, Chief Executive Officer and President	2013
Ivor Royston, M.D. <sup>(3)(4)</sup>	72	Director	2010
M. Faye Wilson, CPA, MBA <sup>(1)(2)(3)</sup>	80	Lead Independent Director	2009
Lyle J. Arnold, Ph. D.	71	Senior Vice-President of Research & Development, Chief Scientific Officer	2011
Timothy C. Kennedy	60	Chief Financial Officer, Senior Vice President of Operations and Corporate Secretary	2016
Veena Singh, M.D.	43	Senior Vice President and Senior Medical Director	2014
Michael Terry	63	Senior Vice President Commercial Operations	2017

- (1) Audit Committee
- (2) Compensation Committee
- (3) Nominating and Corporate Governance Committee
- (4) Science, Technology and Clinical Affairs Committee

Our board of directors is classified into three classes of one or three directors each, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are “staggered.” The director in Class I is Mr. Gerhardt. The next election of Class I directors by stockholders will be at our 2020 annual meeting of stockholders, with the elected candidate(s) to then serve until our 2023 annual meeting of stockholders. The directors in Class II are Dr. Chandler, Mr. Huebner and Dr. Royston. The next election of Class II directors by stockholders will be at our 2018 annual meeting of stockholders, with the elected candidates to then serve until our 2021 annual meeting of stockholders. The directors in Class III are Mr. Hale, Mr. Nall and Ms. Wilson. The next election of Class III directors by stockholders will be at our 2019 annual meeting of stockholders, with the elected candidates to then serve until our 2022 annual meeting of stockholders.

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

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

Mr. Hale was appointed as our Executive Chairman in March 2011. As of and in connection with the closing of our initial public offering on February 10, 2014, Mr. Hale now serves as non-executive Chairman. He is the Chairman and CEO of Hale BioPharma Ventures LLC, a private company focused on the formation and development of biotechnology, specialty pharma, diagnostic and medical device companies. Mr. Hale is a serial entrepreneur who has been involved in the founding and/or development of a number of life sciences companies. He served as the Chairman of Santarus, Inc., a specialty biopharmaceutical company, since 2004 and a member of Santarus’ board since 2000, prior to its acquisition by Salix Pharmaceuticals, Ltd. in 2014. He also serves as Chairman of Conatus Pharmaceuticals, Inc, a public company. He was previously President and CEO of CancerVax Corporation from October 1999 through its merger in May 2006 with Micromet, Inc., when he became Chairman of the combined companies. He is a co-founder and served as Chairman of Somaxon Pharmaceuticals, Inc. before its acquisition by Pernix Therapeutics Holdings, Inc., and as Chairman of SkinMedica, Inc., before its acquisition by Allergan, Inc. He also serves as Chairman of Adigica Health, Inc., Clarify Medical, Inc., MDRejuvena, Inc., Neurana Pharmaceuticals, Inc., Neurelis, Inc. and Recros Medica, Inc. In 1982, after joining Hybritech, Inc., the first monoclonal antibody company, he served as COO, President and then Chief Executive Officer, when Hybritech was acquired by Eli Lilly and Co. in 1986. From 1987 until 1997 he was Chairman, President and CEO of Gensia, Inc., which merged with SICOR to become Gensia Sicor, Inc., which was later acquired by Teva Pharmaceuticals. He was a co-founder and Chairman of Viagene, Inc. from 1987 to 1995, when Viagene was acquired by Chiron, Inc. He was President and CEO of Women First HealthCare, Inc. from late 1997 to June 2000, before joining CancerVax in October 1999. Prior to joining Hybritech, Mr. Hale was Vice President and General Manager of BBL Microbiology Systems, a diagnostics division of Becton, Dickinson & Co. and from 1971 to 1980, held various marketing and sales management positions with Ortho Pharmaceutical Corporation, a division of Johnson & Johnson, Inc.

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

### ***Marsha A. Chandler, Ph. D.***

Dr. Chandler currently serves as Senior Policy Fellow at the Global Policy School (GPS) at the University of California, San Diego (UCSD). She served as the Executive Vice-President/Chief Operating Officer of the Salk Institute for Biological Studies from 2007 to 2015, where she managed approximately 1,000 scientific and administrative personnel and oversaw all institutional fiscal, administrative and fund-raising activities. From 1997 to 2007 she was the Senior Vice Chancellor for Academic Affairs at UCSD, where she was the chief academic officer responsible for the policies and decisions relating to all academic programs and faculty appointments and performance. She was the Acting Chancellor from 2003-04 and holds an appointment as Professor of Political Science in the Graduate School of International Relations and Pacific Studies at UCSD.

Dr. Chandler is a Fellow of the Royal Society of Canada, the highest academic honor bestowed in that country. She received her Ph.D. from The University of North Carolina at Chapel Hill. In 2004, she completed the Advanced Management Program at Harvard Business School.

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

### ***Bruce E. Gerhardt, CPA***

Mr. Gerhardt has been self-employed, practicing as a Certified Public Accountant, since 1986. He is also a tax and business advisor providing tax compliance for small businesses and upper income individuals. Prior to 1986, he was a financial vice-president with several companies and a senior accountant with Peat Marwick Mitchell, now KPMG, one of the “Big Four” accounting firms. He earned his Bachelor of Arts Degree from the University of Southern California in 1973 and is a member of the American Institute of Certified Public Accountants.

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

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

Mr. Huebner was a managing director of LynxCom Partners LLC, a healthcare consulting firm, from 2004 through 2016 where his focus was primarily on cancer diagnostics and personalized medicine. In June of 2011, he joined the board of Vermillion, Inc., an ovarian cancer diagnostics company. He assumed the role of Interim Chief Executive Officer and President of Vermillion from November 2012 to March 2013 and then served as Chairman of the Board from March through December 2013. From October 2009 to June 2010, Mr. Huebner served as President and Chief Executive Officer of TrovaGene, Inc., a developer of molecular diagnostics products. From June of 2005 through June of 2008, Mr. Huebner served as President of Osmetech Molecular Diagnostics, a molecular diagnostic microarray products company. From 2002 to 2004, Mr. Huebner was President and Chief Operating Officer of Nanogen, Inc., a publicly held nanotechnology/microarray company. From 1996 to 2002, Mr. Huebner was Executive Vice-President and Chief Operating Officer of Gen-Probe Incorporated, a leader in the development of nucleic acid tests for infectious diseases. Mr. Huebner received his Bachelor of Science degree in Chemistry from the University of Wisconsin-La Crosse and completed a Senior Executive Graduate School program at Columbia University.

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

***Michael W. Nall***

Mr. Nall has over 30 years of healthcare sales and marketing experience, serving as our CEO and President since 2013. Before joining Biocept, Mr. Nall served at Clariant Diagnostic Services, Inc. in positions of increasing responsibility from 2002 through August 2013, with his last position being General Manager, North American Sales and Marketing. While at Clariant, Mr. Nall was also responsible for leading the team assimilating Clariant into GE Healthcare after Clariant was acquired in 2010.

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

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

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

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

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

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

### ***M. Faye Wilson, MBA***

Ms. Wilson is CEO of Wilson Boyles and Company, a business consulting firm specializing in the development and implementation of successful business strategies. Prior to co-founding Wilson Boyles in 2003, she served as Senior Vice-President, Value Initiatives and Risk Management for The Home Depot, having joined the company in 1998 following a 21-year career at Bank of America. Ms. Wilson was Executive-Vice President of Bank of America and Chairman and President of Security Pacific Financial Services, a wholly owned subsidiary of BancAmerica Corporation.

Ms. Wilson began her banking career as a management trainee in the Corporate Banking Group of Security Pacific National Bank, which merged with and became Bank of America in 1992. Prior to assuming the chairmanship of Security Pacific Financial Services, she was the Executive Vice-President responsible for overseeing credit quality and policy for over 80% of Bank of America's loan portfolio.

During her Security Pacific career, Ms. Wilson spent time in London as the Managing Director of Corporate Finance for Security Pacific Hoare Govett, where she created new corporate advisory services, debt structuring products and formed a cross-border mergers and acquisitions division for European and U.S. companies. Prior to the London assignment, she was Managing Director of the Leveraged Buyout Group for the Security Pacific Merchant Bank, establishing the bank as lead in high profile transactions. Earlier, as Senior Vice-President and Regional Manager in the Corporate Banking Division with responsibility for multinational corporations, retail industry companies and California based corporations, Ms. Wilson established lead banking relationships with major players in those markets.

Ms. Wilson has served as a director on the corporate boards BioMed Realty Trust, Inc. (a real estate investment trust, until its acquisition by Blackstone Real Estate Partners VIII in 2016), Farmers Insurance Group, The Home Depot, SKM (a Russian public company), and Community National Bank. Currently she serves as Chair of the Board of non-profit San Diego Theatres Inc., is a trustee and Vice Chair of The Salk Institute, and Chair of the Audit Committee of Sharp Health Group. She remains engaged with the activities of Duke University, her alma mater.

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Ms. Wilson received master's degrees in international relations and in business administration from the University of Southern California.

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

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

Dr. Arnold has served as Sr. VP of R&D, and Chief Scientific Officer at Biocept since 2011. Dr. Arnold is a biotechnology executive, entrepreneur, and developer of innovative technologies covering therapeutics, molecular diagnostics, and genomics. Prior to joining Biocept, Dr. Arnold founded Aegea Biotechnologies to acquire, develop, and commercialize, next generation nucleic acid technologies. Dr. Arnold has served on the board of directors of numerous companies, including Asuragen and Aegea, as well as, non-profit organizations.

He has also held senior scientific and management positions at Molecular Biosystems (co-founder), Genta, Synteni, Incyte Genomics, Oasis Biosciences (co-founder), and Gen-Probe (now Hologic). In addition, Dr. Arnold was a faculty member in the UCSD School of Medicine and a member of the UCSD Cancer Center. Dr. Arnold is an inventor or co-inventor on 49 issued U.S. patents and more than 160 issued and pending patents worldwide. He is the principal inventor of the chemiluminescent Hybridization Protection Assay (HPA) and associated technologies core to Hologic assays that generate more than \$500M in product revenue annually. Dr. Arnold is also the inventor of the patented Switch-Blocker technology for detecting extremely rare genetic events that Biocept uses for interrogating ctDNA for cancer associated mutations. In addition, he has authored more than 50 scientific publications.

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

### ***Timothy C. Kennedy***

Mr. Kennedy joined us as Chief Financial Officer, Senior Vice President of Operations and Corporate Secretary in July 2016. Mr. Kennedy has over 30 years of executive, financial, and operational leadership experience, with over 25 years in the clinical diagnostics industry. Mr. Kennedy previously served as Chief Financial Officer of Millennium Health, a privately held leading urine drug testing and pharmacogenetics laboratory company, from 2013 to July 2016. Prior to joining Millennium Health, Mr. Kennedy was Chief Financial Officer and General Manager of PLUS Diagnostics, a urology, gastroenterology and oncology lab from 2008 through 2012. Prior to Plus Diagnostics, Mr. Kennedy held an ownership position in Diagnostic Imaging Management, a multi-site imaging company from 1997 to 2008, expanding from 12 to 33 free-standing centers across the United States. From 1988 to 1997, Mr. Kennedy held a number of management positions with National Health Laboratories, where he served as the Head of Finance, completing over 50 acquisitions and the merger with Roche Biomedical Labs to form LabCorp in 1995. Mr. Kennedy serves on the Board of Directors of MyCircle Health, a data services company that helps patients with chronic health conditions measure, evaluate, control and communicate daily test results to their healthcare providers and physicians. Mr. Kennedy holds a bachelor's degree in Business - Accounting/Information Technology from Keane University.

### ***Veena Singh, M.D.***

Dr. Singh joined us as Senior Vice President and Senior Medical Director in 2014. Prior to joining Biocept, she was the Medical Director at bioTheranostics, Inc. since July 2009. Dr. Singh brings experience in oncology molecular diagnostics, assay development and validation with expertise in CLIA regulations and is board certified in Anatomic and Clinical Pathology with sub-specialty board certification in Molecular Genetic Pathology. Dr. Singh was an expert panel member of the CAP/ASCO/ASCP colorectal cancer testing guideline committee. Dr. Singh completed her Anatomic and Clinical pathology residency at the University of California, San Diego and her Molecular Genetic Pathology fellowship at Cedars-Sinai Medical Center in Los Angeles. Dr. Singh obtained her medical degree from the University of Transkei, South Africa.

### ***Michael Terry***

Mr. Terry joined us as Senior Vice President, Commercial Operations in February 2017. A seasoned veteran in the molecular diagnostics and liquid biopsy industries, Mr. Terry has previously served as Executive Vice President, Commercial Operations and Corporate Development of Trovagene, Inc. from 2012 to 2014, as well as Executive Vice President of Sequenom, Inc., where he managed global commercial operations from 2003 to 2005. Mr. Terry's career also includes 4 years at GE Healthcare's Marquette Medical division, where he held key executive positions in sales management, commercial operations and eBusiness from 1997 to

2001. At GE Healthcare, he earned a certification in Six Sigma. Mr. Terry has also served as the Executive Vice President of European Operations for Lumenis Ltd., Vice President of Global Sales for Aspect Medical Systems Inc., and Chief Executive Officer of Ligand Diagnostics. Mr. Terry earned a BS in Economics and Business from the University of Wisconsin – Madison.

## **Director Independence**

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

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

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

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



## EXECUTIVE COMPENSATION

### Summary Compensation Table

The following table shows the compensation awarded to or earned in our last two fiscal years by our principal executive officer and our two most highly compensated executive officers other than our principal executive officer who were serving as executive officers as of December 31, 2017. The persons listed in the following table are referred to herein as the “named executive officers.”

Name and Principal Position	Year	Salary \$(1)	Stock Awards \$(2)	Option Awards \$(2)	Non-equity Incentive Plan Compensation \$(3)	Other Compensation \$(4)	Total (\$)
Michael W. Nall	2017	394,631(5)	112,500	509,476	— (6)	35,667(7)	1,052,274
<i>President and Chief Executive Officer</i>	2016	376,367(5)	46,500	145,636	107,250(6)	42,628(7)	718,381
Timothy C. Kennedy	2017	329,569(8)	75,000	150,834	— (9)	—	555,403
<i>CFO, SVP of Operations</i>	2016	138,504(8)	48,750	138,592	43,515(9)	—	369,361
Lyle J. Arnold, Ph.D.	2017	282,416(10)	75,000	152,086	— (11)	—	509,502
<i>SVP R&amp;D, Chief Scientific Officer</i>	2016	282,752(10)	31,000	24,919	57,573(11)	—	396,244

- (1) The “Salary (\$)” column includes salary earned for each named executive officer and the net increase/(decrease) in each named executive officer’s accrued vacation balance, or accrued vacation, in each year ended December 31.
- (2) The amounts in the “Option Awards (\$)” and “Stock Awards (\$)” columns reflect the grant date fair values of stock option and RSU awards, respectively, granted during the year. These amounts are determined in accordance with the provisions of FASB ASC Topic 718, rather than an amount paid to or realized by the executive officer. For a description of these stock option and RSU awards, see “Narrative Disclosure to Summary Compensation Table” within this “Executive Compensation” section.
- (3) The “Non-equity Incentive Compensation Plan Compensation (\$)” column includes discretionary amounts earned by each named executive officer pursuant to an employment agreement or our approved Annual Incentive Plan.
- (4) The “Other Compensation (\$)” column includes amounts earned by each named executive officer but not otherwise included in amounts within the “Salary (\$),” “Stock Awards (\$),” “Option Awards (\$),” or “Non-equity Incentive Plan Compensation (\$)” columns.
- (5) 2017 salary amount includes accrued vacation of \$18,857. 2016 salary amount includes accrued vacation of \$17,482.
- (6) 2017 non-equity incentive plan compensation amount excludes a bonus of up to \$187,887, or 50% of Mr. Nall’s annual base salary, related to the achievement of corporate performance goals during 2017 for which the amount to be awarded is expected to be determined by March 31, 2018. 2016 non-equity incentive plan compensation amount includes a bonus of \$107,250 related to the achievement of corporate performance goals during 2016.
- (7) 2017 other compensation amount includes \$20,000 commuting expenses reimbursement benefit we provided to Mr. Nall plus \$15,667 of income taxes we paid for Mr. Nall in respect of such benefit. 2016 other compensation amount includes \$24,000 commuting expenses reimbursement benefit we provided to Mr. Nall plus \$18,628 of income taxes we paid for Mr. Nall in respect of such benefit.
- (8) Mr. Kennedy commenced employment on July 25, 2016. 2017 salary amount includes accrued vacation of \$17,069. 2016 salary amount includes accrued vacation of \$3,600.
- (9) 2017 non-equity incentive plan compensation amount excludes a bonus of up to \$125,000, or 40% of Mr. Kennedy’s annual base salary, related to the achievement of both corporate and individual performance goals during 2017 for which the amount to be awarded is expected to be determined by March 31, 2018. 2016 non-equity incentive plan compensation amount includes a bonus of \$43,515 related to the achievement of both corporate and individual performance goals from Mr. Kennedy’s employment commencement date of July 25, 2016 through December 31, 2016.
- (10) 2017 salary amount includes accrued vacation of \$(7,397). 2016 salary amount includes accrued vacation of \$475.
- (11) 2017 non-equity incentive plan compensation amount excludes a bonus of up to \$101,434, or 35% of Dr. Arnold’s annual base salary, related to the achievement of corporate performance goals during 2017 for which the amount to be awarded is expected to be determined by March 31, 2018. 2016 non-equity incentive plan compensation amount includes a bonus of \$57,573 related to the achievement of both corporate and individual performance goals during 2016.

## Narrative Disclosure to Summary Compensation Table

### *Michael W. Nall*

We entered into an employment agreement effective as of August 26, 2013, as amended on November 6, 2015, with Michael W. Nall, or collectively, the CEO Employment Agreement, in connection with his appointment as our Chief Executive Officer and President. The CEO Employment Agreement provided Mr. Nall the following: (i) a base salary of \$350,000 per year; (ii) a housing allowance of \$2,000 per month; and (iii) stock options under our Amended and Restated 2013 Equity Incentive Plan, as amended, or the Amended

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2013 Plan, to purchase a number of shares of common stock equal to at least 4% of our fully diluted stock outstanding as of August 26, 2013, vesting in equal monthly installments over four years beginning August 15, 2013 with a term of 10 years. During the years ended December 31, 2016 and 2017, Mr. Nall was eligible to participate in our annual incentive plan with a target bonus amount equal to 50% of Mr. Nall's annual base salary, of which 100% was dependent on the achievement of corporate performance goals. Effective as of April 4, 2016 and April 1, 2017, Mr. Nall's base salary was increased to \$360,000 and \$372,000 per year, respectively, as approved by the compensation committee of our board of directors. Effective as of November 1, 2017, the CEO Employment Agreement was amended to reflect a base salary increase to \$412,961 and the removal of the housing allowance of \$2,000 per month, as approved by the compensation committee of our board of directors.

The CEO Employment Agreement provides that in the event of termination of Mr. Nall's employment by us without cause or his resignation for good reason, the vesting of any of his outstanding unvested stock options and RSUs which would have vested over the following 12 months will accelerate (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). Also, in the event of a change of control, if the surviving or acquiring corporation (or its parent company) does not assume or continue Mr. Nall's outstanding unvested stock options or RSUs or substitute similar stock awards for such stock options or RSUs, then all of Mr. Nall's unvested stock options and RSUs will immediately vest and become exercisable, provided Mr. Nall is providing continued service to us immediately prior to the change of control. In addition, solely with respect to Mr. Nall's unvested stock options and RSUs granted prior to November 6, 2015, in the event of a change of control where Mr. Nall's unvested stock options and RSUs are not fully accelerated, the vesting of 50% of any of Mr. Nall's outstanding unvested stock options and RSUs will accelerate on the date of the change of control and the remaining unvested stock options and RSUs will vest on the earliest of (i) the date of the termination of his employment by us without cause, (ii) the date of his resignation for good reason, or (iii) the first anniversary of the change of control (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). (For example, the foregoing would not apply to the initial stock options grant, which would fully accelerate upon a change in control.) Additionally, if during the 10-day period before a change of control or during the 12-month period following a change of control, Mr. Nall's employment is terminated without cause or Mr. Nall resigns for good reason, then the vesting of each of Mr. Nall's outstanding unvested stock options and RSUs will accelerate immediately. The CEO Employment Agreement provides that if Mr. Nall has a separation from service as a result of his discharge by us without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months' salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage).

On February 29, 2016, an option award exercisable into 16,666 shares of common stock with an estimated grant date fair value of \$49,837 was issued to Mr. Nall under the Amended 2013 Plan. The exercise price of these options of \$4.02 per share is equal to the closing price of our common stock on the date of grant. The share amount for the option award was determined by dividing the award value by \$2.99, which is the fair value per share of the option exercisable into our common stock on the date of grant, estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model include a volatility rate of 90.0%, a risk-free interest rate of 1.39%, a dividend yield of 0.00%, and an expected term of 6.08 years. The option award vests over a four-year period with 25% of all shares vesting on the one-year anniversary of the grant and the remainder vesting in equal monthly installments over the following three years beginning February 28, 2017, with a term of 10 years.

On August 31, 2015, our board of directors approved the issuance of 33,333 performance stock options with an estimated grant date fair value of \$146,529 to Mr. Nall pursuant to the Amended 2013 Plan. The exercise price of these options of \$6.03 per share is equal to the closing price of our common stock on the date of grant. The share amount for the option award was determined by dividing the award value by \$4.40, which is the fair value per share of the option exercisable into our common stock on the date of grant, estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model include a volatility rate of 90.0%, a risk-free interest rate of 1.64%, a dividend yield of 0.00%, and an expected term of 5.67 years. On February 29, 2016, our board of directors approved the issuance of 33,333 performance stock options with an estimated grant date fair value of \$95,799 to Mr. Nall pursuant to the Amended 2013 Plan. The exercise price of these options of \$4.02 per share is equal to the closing price of our common stock on the date of grant. The share amount for the option award was determined by dividing the award value by \$0.96, which is the fair value per share of the option exercisable into our common stock on the date of grant, estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model include a volatility rate of 90.0%, a risk-free interest rate of 1.24%, a dividend yield of 0.00%, and an expected term of 5.42 years. Vesting of these stock options was based on our achievement of specified objectives by December 31, 2016 as determined by our board of directors or compensation committee. Subsequent to the year ended December 31, 2016, 6,333 of the performance stock options granted on August 31, 2015 and 10,000 of the performance stock options granted on February 29, 2016 were declared vested by our board of directors in satisfaction of these awards, and the remaining 50,333 shares underlying these awards were forfeited.

On July 6, 2016, the compensation committee of our board of directors approved retention RSUs for 25,000 shares of common stock to be granted to Mr. Nall pursuant to the Amended 2013 Plan. This retention RSU award had a grant date fair value of \$1.86 per share for a total grant date fair value of \$46,500, vested fully on the one-year anniversary of the date of grant, and was subject to continuing service.

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On May 2, 2017, our board of directors approved the issuance of 300,000 time-based stock options, 200,000 performance-based stock options, 50,000 time-based RSUs, and 25,000 performance RSUs to Mr. Nall under the Amended 2013 Plan, which were granted on May 31, 2017 with per share estimated grant date fair values of \$1.04, \$0.99, \$1.50 and \$1.50, respectively. The exercise price of the time-based and performance stock options of \$1.50 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair values of the time-based and performance stock options were estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for the time-based stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.89%, a dividend yield of 0.00%, and an expected term of 6.04 years. The assumptions used in the Black-Scholes valuation model for the performance stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.79%, a dividend yield of 0.00%, and an expected term of 5.29 years. Each time-based stock option award vests over a four-year period with 25% of all shares vesting on the one-year anniversary of the vesting commencement date, or May 2, 2018, with the remainder vesting in 36 equal monthly installments over the following three years from April 2, 2018 through May 2, 2021. Vesting of the time-based stock options and RSUs granted on May 31, 2017 are subject to continuing service and occurs on the one-year anniversary of the vesting commencement date, or May 2, 2018. The performance stock options and performance RSUs granted on May 31, 2017 are subject to continuous service and vesting is as determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved, as follows:

	Percentage of Overall Performance Award Grant Subject to Vesting
<b>Target</b>	
Minimum revenue	20%
Cost of revenue reductions and improvements	15%
Increase cash generated from operations	15%
Minimum cash on-hand at December 31, 2017	15%
Minimum customer agreements, product licensing and product launch	20%
Implementation of new products and utility trials	15%
Total	100%

### ***Timothy C. Kennedy***

We entered into an employment agreement effective July 25, 2016 with Timothy Kennedy, or the CFO Employment Agreement, in connection with his appointment as our Chief Financial Officer and Senior Vice President of Operations and Corporate Secretary. The CFO Employment Agreement provides Mr. Kennedy the following: (i) a base salary of \$305,000 per year; (ii) a target annual bonus of 40% of base salary, pro-rated from employment commencement date for 2016, of which 50% shall be guaranteed only for 2016; (iii) time-based inducement stock options under our 2013 Plan to purchase 66,666 shares of common stock at its fair market value on the date of grant, with 25% of all shares vesting on the one-year anniversary of the grant and the remainder vesting in equal monthly installments over the following three years; (iv) performance inducement stock options under our 2013 Plan to purchase 33,333 shares of common stock at its fair market value on the date of grant, with vesting as determined by our board of directors or its compensation committee based on the achievement of specified goals for 2016; and (v) inducement RSUs under our 2013 Plan for 25,000 shares of common stock, with vesting occurring on the one-year anniversary of the commencement of Mr. Kennedy's employment. During 2016 and 2017, Mr. Kennedy was eligible to participate in our annual incentive plan with 80% of the annual target bonus dependent on the achievement of corporate performance goals and 20% of the annual target bonus dependent on the achievement of individual performance goals. Effective as of April 1, 2017, Mr. Kennedy's base salary was increased to \$315,000 per year as approved by the compensation committee of our board of directors.

The CFO Employment Agreement provides that if Mr. Kennedy's continuous service is terminated without cause or he resigns with good reason (at any time other than during the three months before change in control or during the 12 months following a change in control), then, provided that he gives us an effective waiver and release of claims, he will be entitled to nine months' salary paid as a lump sum on the 10th day following his separation from service, plus up to nine months of COBRA premiums, and notwithstanding any contrary terms of any stock option grant, option agreement or other equity award agreement, he shall receive accelerated vesting for all stock options and other equity awards outstanding as of the date of termination that are subject to time-based vesting requirements and that would have otherwise vested during the 12 month period following the date of his termination without a separation from service. However, if he is terminated without cause or he resigns with good reason within three months before or 12 months after a change in control, then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months' salary paid as a lump sum on the 10th day following his separation from service, plus up to 12 months of COBRA premiums, and all of his then-outstanding time-based stock options and other equity awards covering our common stock will fully vest.

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On July 29, 2016, 66,666 time-based inducement stock options and 33,333 performance inducement stock options were granted to Mr. Kennedy with per share estimated grant date fair values of \$1.45 and \$1.26, respectively. The exercise price of the time-based and performance stock options of \$1.95 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair values of the time-based and performance stock options were estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for the time-based stock options include a volatility rate of 90.0%, a risk-free interest rate of 1.17%, a dividend yield of 0.00%, and an expected term of 6.07 years. The assumptions used in the Black-Scholes valuation model for the performance stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.01%, a dividend yield of 0.00%, and an expected term of 5.21 years. The inducement RSU award granted to Mr. Kennedy on July 29, 2016 for 25,000 shares of common stock had a grant date fair value of \$1.95 per share for a total grant date fair value of \$48,750, vested fully on July 25, 2017, and was subject to continuing service. Subsequent to the year ended December 31, 2016, 16,383 of the performance stock options granted on July 29, 2016 were declared vested by our board of directors in satisfaction of the award, and the remaining 16,950 shares underlying these awards were forfeited.

On May 2, 2017, our board of directors approved the issuance of 50,000 time-based stock options, 100,000 performance-based stock options, 25,000 time-based RSUs, and 25,000 performance RSUs to Mr. Kennedy under the Amended 2013 Plan, which were granted on May 31, 2017 with per share estimated grant date fair values of \$1.04, \$0.99, \$1.50 and \$1.50, respectively. The exercise price of the time-based and performance stock options of \$1.50 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair values of the time-based and performance stock options were estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for the time-based stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.89%, a dividend yield of 0.00%, and an expected term of 6.04 years. The assumptions used in the Black-Scholes valuation model for the performance stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.79%, a dividend yield of 0.00%, and an expected term of 5.29 years. Each time-based stock option award vests over a four-year period with 25% of all shares vesting on the one-year anniversary of the vesting commencement date, or May 2, 2018, with the remainder vesting in 36 equal monthly installments over the following three years from April 2, 2018 through May 2, 2021. Vesting of the time-based stock options and RSUs granted on May 31, 2017 are subject to continuing service and occurs on the one-year anniversary of the vesting commencement date, or May 2, 2018. The performance stock options and performance RSUs granted on May 31, 2017 are subject to continuous service and vesting is as determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved, as follows:

	Percentage of Overall Performance Award Grant Subject to Vesting
<b>Target</b>	
Minimum revenue	20%
Cost of revenue reductions and improvements	15%
Increase cash generated from operations	15%
Minimum cash on-hand at December 31, 2017	15%
Minimum customer agreements, product licensing and product launch	20%
Implementation of new products and utility trials	15%
Total	100%

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

We entered into an employment agreement, or the CSO Employment Agreement, as of April 30, 2011 with Lyle J. Arnold in connection with his appointment as our Senior Vice-President of Research and Development and Chief Scientific Officer. The CSO Employment Agreement provided Dr. Arnold a base salary of \$250,000 per year. During the years ended December 31, 2016 and 2017, Dr. Arnold was eligible to participate in our annual incentive plan with a target bonus amount equal to 35% of Dr. Arnold's annual base salary, of which 80% was dependent on the achievement of corporate performance goals and 20% was dependent on the achievement of individual performance goals. Effective as of April 4, 2016 and April 1, 2017, Dr. Arnold's base salary was increased to \$283,250 and \$292,000 per year, respectively, as approved by the compensation committee of our board of directors.

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On February 29, 2016, an option award exercisable into 8,333 shares of common stock with an estimated grant date fair value of \$24,919 was issued to Dr. Arnold under the Amended 2013 Plan. The exercise price of these options of \$4.02 per share is equal to the closing price of our common stock on the date of grant. The share amount for the option award was determined by dividing the award value by \$2.99, which is the fair value per share of the option exercisable into our common stock on the date of grant, estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model include a volatility rate of 90.0%, a risk-free interest rate of 1.39%, a dividend yield of 0.00%, and an expected term of 6.08 years. The option award vests over a four-year period with 25% of all shares vesting on the one-year anniversary of the grant and the remainder vesting in equal monthly installments over the following three years beginning February 28, 2017, with a term of 10 years.

On July 6, 2016, the compensation committee of our board of directors approved retention RSUs for 16,666 shares of common stock to be granted to Dr. Arnold pursuant to the Amended 2013 Plan. This retention RSU award had a grant date fair value of \$1.86 per share for a total grant date fair value of \$31,000, vested fully on the one-year anniversary of the date of grant, and was subject to continuing service.

On May 2, 2017, our board of directors approved the issuance of 75,000 time-based stock options, 75,000 performance-based stock options, 25,000 time-based RSUs, and 25,000 performance RSUs to Dr. Arnold under the Amended 2013 Plan, which were granted on May 31, 2017 with per share estimated grant date fair values of \$1.04, \$0.99, \$1.50 and \$1.50, respectively. The exercise price of the time-based and performance stock options of \$1.50 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair values of the time-based and performance stock options were estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for the time-based stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.89%, a dividend yield of 0.00%, and an expected term of 6.04 years. The assumptions used in the Black-Scholes valuation model for the performance stock options include a volatility rate of 80.0%, a risk-free interest rate of 1.79%, a dividend yield of 0.00%, and an expected term of 5.29 years. Each time-based stock option award vests over a four-year period with 25% of all shares vesting on the one-year anniversary of the vesting commencement date, or May 2, 2018, with the remainder vesting in 36 equal monthly installments over the following three years from April 2, 2018 through May 2, 2021. Vesting of the time-based stock options and RSUs granted on May 31, 2017 are subject to continuing service and occurs on the one-year anniversary of the vesting commencement date, or May 2, 2018. The performance stock options and performance RSUs granted on May 31, 2017 are subject to continuous service and vesting is as determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved, as follows:

	Percentage of Overall Performance Award Grant Subject to Vesting
<b>Target</b>	
Minimum revenue	20%
Cost of revenue reductions and improvements	15%
Increase cash generated from operations	15%
Minimum cash on-hand at December 31, 2017	15%
Minimum customer agreements, product licensing and product launch	20%
Implementation of new products and utility trials	15%
Total	100%

### **Annual Incentive Plan**

On May 19, 2014, the compensation committee of our board of directors approved an annual incentive plan, or the Annual Incentive Plan, to provide our employees, including our executive officers, with an incentive for such employees to perform to the best of their abilities, to further our growth, development and financial success, and to enable us to attract and retain highly qualified employees. Each executive officer is eligible for an award based upon the achievement of certain corporate performance goals and objectives approved by the compensation committee and, with respect to our executive officers other than our chief executive officer, individual performance. In 2017, total compensation of \$405,543 was paid to employees, including our executive officers, pursuant to the Annual Incentive Plan related to the achievement of both corporate and individual performance goals earned in 2016. In 2018, total estimated compensation of approximately \$577,000 is expected to be paid to employees, including our executive officers, pursuant to the Annual Incentive Plan related to the achievement of both corporate and individual performance goals earned in 2017.

## OUTSTANDING EQUITY AWARDS

The following table sets forth certain information, on an award-by-award basis, concerning unexercised options to purchase common stock and common stock that has not yet vested for each named executive officer and outstanding as of December 31, 2017. On September 29, 2016, we effected a one-for-three reverse stock split of all common shares outstanding as approved by our stockholders and board of directors on September 27, 2016. All per share amounts and share numbers have been adjusted for this reverse stock split as if it had occurred on January 1, 2011.

Name	Grant Date	Option Awards				Restricted Stock Units	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable(1)	Option Exercise Price (\$)	Option Expiration Date	Number of Unvested Securities Underlying (#)(2)	Market Value of Units that are Unvested (\$)(3)
Michael W. Nall	7/31/2013	6,435	—	15.54	7/30/2023	—	—
	7/31/2013	26,898	—	15.54	7/30/2023	—	—
	6/12/2014	21,815	3,125	16.05	6/11/2024	—	—
	6/12/2014	60	—	16.05	6/11/2024	—	—
	8/31/2015	—	16,599	6.03	8/30/2025	—	—
	8/31/2015	29,166	4,235	6.03	8/30/2025	—	—
	8/31/2015	6,333	—	6.03	8/30/2025	—	—
	2/29/2016	—	4,861	4.02	2/28/2026	—	—
	2/29/2016	7,639	4,166	4.02	2/28/2026	—	—
	2/29/2016	10,000	—	4.02	2/28/2026	—	—
	5/31/2017	—	118,053	1.50	5/30/2027	—	—
	5/31/2017	—	181,947	1.50	5/30/2027	—	—
	5/31/2017	—	200,000	1.50	5/30/2027	—	—
	5/31/2017	—	—	—	—	50,000	34,695
	5/31/2017	—	—	—	—	25,000	17,348
Timothy C. Kennedy	7/29/2016	23,611	43,055	1.95	7/28/2026	—	—
	7/29/2016	16,383	—	1.95	7/28/2026	—	—
	5/31/2017	—	50,000	1.50	5/30/2027	—	—
	5/31/2017	—	100,000	1.50	5/30/2027	—	—
	5/31/2017	—	—	—	—	25,000	17,348
Lyle J. Arnold, Ph. D.	5/31/2017	—	—	—	—	25,000	17,348
	3/25/2011	1,984	—	13.86	3/24/2021	—	—
	7/31/2013	7,501	—	15.54	7/30/2023	—	—
	5/16/2014	10,451	1,215	13.14	5/15/2024	—	—
	8/31/2015	20,368	23,640	6.03	8/30/2025	—	—
	8/31/2015	13,659	666	6.03	8/30/2025	—	—
	2/29/2016	—	2,430	4.02	2/28/2026	—	—
	2/29/2016	3,819	2,084	4.02	2/28/2026	—	—
	5/31/2017	—	75,000	1.50	5/30/2027	—	—
	5/31/2017	—	75,000	1.50	5/30/2027	—	—
	5/31/2017	—	—	—	—	25,000	17,348
	5/31/2017	—	—	—	—	25,000	17,348

(1) The scheduled vesting dates, after December 31, 2017, of these options were as follows:

Mr. Nall: For the option awards granted on July 31, 2013 in the table above, all options awarded are vested and exercisable. For the first option award granted on June 12, 2014 in the table above, 520 of the unvested option awards granted will vest in January 2018 and then 521 will vest from February 2018, subject to continuing service. For the second option award granted on



June 12, 2014 in the table above, all options awarded are vested and exercisable. For the first option award granted on August 31, 2015 in the table above, either 1,041 or 1,042 of the unvested option awards will vest in each month of January through July of 2018 and January through August of 2019, and 974 will vest August of 2018, subject to continuing service. For the second option award granted on August 31, 2015 in the table above, 68 of the unvested option awards granted will vest in August 2018, 1,041 will vest in October 2018, and 1,042 will vest in each of September, November and December 2018, subject to continuing service. For the third option award granted on August 31, 2015 in the table above, all options outstanding are vested and exercisable. For the first option award granted on February 29, 2016 in the table above, 347 of the unvested option awards will vest monthly from January 2019 through January 2020, except in May and September 2019 when 348 will vest in each month, and 348 will vest in February 2020, subject to continuing service. For the second option award granted on February 29, 2016 in the table above, 347 of the unvested option awards will vest monthly in 2018, except in May and September 2018 when 348 will vest in each month, subject to continuing service. For the third option award granted on February 29, 2016 in the table above, all options outstanding are vested and exercisable. For the first option award granted on May 31, 2017 in the table above, 6,250 of the unvested option awards will vest monthly in each of January, February, and March 2019, from January through October 2020, and then from January through May 2021, with 3,249 vesting in April 2019 and 2,304 vesting in November 2020, subject to continuing service. For the second option award granted on May 31, 2017 in the table above, 75,000 of the unvested option awards granted will vest in May 2018, 6,250 will vest monthly from June 2018 through December 2018 and then from May 2019 through December 2019, and 6,250 vesting in December 2020, with 3,001 vesting in April 2019 and 3,946 vesting in November 2020, subject to continuing service. For the third option award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

Mr. Kennedy: For the first option award granted on July 29, 2016 in the table above, either 1,388 or 1,389 of the unvested option awards granted will vest from January 2018, subject to continuing service. For the second option award granted on July 29, 2016 in the table above, all options outstanding are vested and exercisable. For the first option award granted on May 31, 2017 in the table above, 12,500 of the unvested option awards granted will vest in May 2018, and either 1,041 or 1,042 will vest monthly from June 2018, subject to continuing service. For the second option award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

Dr. Arnold: For the option awards granted on March 25, 2011 and July 31, 2013 in the table above, all options awarded are vested and exercisable. For the option award granted on May 16, 2014 in the table above, 243 of the unvested option awards will vest in each month in 2018, subject to continuing service. For the first option award granted on August 31, 2015 in the table above, either 1,215 or 1,216 of the unvested option awards will vest each month, except when 548 will vest in December 2018, subject to continuing service. For the second option award granted on August 31, 2015 in the table above, 666 of the unvested option awards will vest in December 2018, subject to continuing service. For the first option award granted on February 29, 2016 in the table above, either 173 or 174 of the unvested option awards will vest in each month from January 2019, subject to continuing service. For the second option award granted on February 29, 2016 in the table above, either 173 or 174 of the unvested option awards will vest in each month during 2018, subject to continuing service. For the first option award granted on May 31, 2017 in the table above, 18,750 of the unvested option awards granted will vest in May 2018, and either 1,562 or 1,563 will vest monthly from June 2018, subject to continuing service. For the second option award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

- (2) The scheduled vesting dates, after December 31, 2017, of these RSUs were as follows:

Mr. Nall: For the first RSU award granted on May 31, 2017 in the table above, all RSUs will vest on the one-year anniversary of the vesting commencement date, or May 2, 2018, subject to continuing service. For the second RSU award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

Mr. Kennedy: For the first RSU award granted on May 31, 2017 in the table above, all RSUs will vest on the one-year anniversary of the vesting commencement date, or May 2, 2018, subject to continuing service. For the second RSU award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

Dr. Arnold: For the first RSU award granted on May 31, 2017 in the table above, all RSUs will vest on the one-year anniversary of the vesting commencement date, or May 2, 2018, subject to continuing service. For the second RSU award granted on May 31, 2017 in the table above, vesting is subject to continuous service and is to be determined by our board of directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of our corporate goals for 2017 are achieved.

- (3) The market value is equal to the product of \$0.6939, which is the closing price of our common stock on December 31, 2017, and the number of unvested RSUs.

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

Our employment agreement with Mr. Nall provides that in the event of termination of his employment by us without cause or his resignation for good reason, the vesting of any of his outstanding unvested stock options and RSUs which would have vested over the following 12 months will accelerate (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). Also, in the event of a change of control, if the surviving or acquiring corporation (or its parent company) does not assume or continue Mr. Nall's outstanding unvested stock options or RSUs or substitute similar stock awards for such stock options or RSUs, then all of Mr. Nall's unvested stock options and RSUs will immediately vest and become exercisable, provided Mr. Nall is providing continued service to us immediately prior to the change of control. In addition, solely with respect to Mr. Nall's unvested stock options and RSUs granted prior to November 6, 2015, in the event of a change of control where Mr. Nall's unvested stock options and RSUs are not fully accelerated, the vesting of 50% of any of Mr. Nall's outstanding unvested stock options and RSUs will accelerate on the date of the change of control and the remaining unvested stock options and RSUs will vest on the earliest of (i) the date of the termination of his employment by us without cause, (ii) the date of his resignation for good reason, or (iii) the first anniversary of the change of control (unless the applicable stock option or RSU agreement provides for more favorable acceleration terms). (For example, the foregoing would not apply to the initial stock options grant, which would fully accelerate upon a change in control.) Additionally, if during the 10-day period before a change of control or during the 12-month period following a change of control, Mr. Nall's employment is terminated without cause or Mr. Nall resigns for good reason, then the vesting of each of Mr. Nall's outstanding unvested stock options and RSUs will accelerate immediately. Our employment agreement with Mr. Nall further provides that if he has a separation from service as a result of his discharge by us without cause or his resignation with good reason then, provided that he gives us an effective waiver and release of claims, he will be entitled to 12 months' salary and up to 12 months of COBRA premiums (or substantially equivalent health insurance coverage).

The vesting of all stock options and RSUs awarded under the Amended 2013 Plan will accelerate fully in the event that the optionee's continuous service is terminated without cause, or the optionee resigns for good reason, within 10 days before or 12 months after a change in control. In addition, we only have the discretion to accelerate the vesting of awards under the Amended 2013 Plan in connection with a change of control if an outstanding award is not assumed, continued or substituted for by the surviving or acquiring corporation (or its parent company).

## DIRECTOR COMPENSATION

On August 10, 2015, our board of directors approved the following cash and equity compensation policies for non-employee members of our board of directors, as recommended by the compensation committee of our board of directors:

- Annual Retainer. For service as a director: an annual cash retainer of \$25,000 (in addition to any annual cash retainers otherwise paid).
- Board Chair. For service as Board Chair: an annual cash retainer of \$75,000 (in addition to any annual cash retainers otherwise paid).
- Lead Independent Director. For service as Lead Independent Director: an annual cash retainer of \$5,000 (in addition to any annual cash retainers otherwise paid).
- Audit Committee.  
For service as Chair of the audit committee: an annual cash retainer of \$15,000 (in addition to any annual cash retainers otherwise paid).  
For service as member of the audit committee other than as its Chair: an annual cash retainer of \$6,250 (in addition to any annual cash retainers otherwise paid).
- Compensation Committee.  
For service as Chair of the compensation committee: an annual cash retainer of \$10,000 (in addition to any annual cash retainers otherwise paid).  
For service as member of the compensation committee other than as its Chair: an annual cash retainer of \$5,000 (in addition to any annual cash retainers otherwise paid).
- Nominating and Corporate Governance Committee.  
For service as Chair of the nominating and corporate governance committee: an annual cash retainer of \$7,500 (in addition to any annual cash retainers otherwise paid).  
For service as member of the nominating and corporate governance committee other than as its Chair: an annual cash retainer of \$3,750 (in addition to any annual cash retainers otherwise paid).
- Initial Awards. For each non-employee director who is initially elected or appointed to the board: an option to purchase 8,333 shares of common stock. On March 27, 2017, our board of directors approved an increase in the Initial Award option amount to 30,000 shares.
- Annual Awards.  
For each non-employee director who (i) has been serving on the board for at least 6 months as of the date of any annual meeting of our stockholders and (ii) will continue to serve as a non-employee director immediately following such meeting: an option to purchase 4,166 shares of common stock. On March 27, 2017, our board of directors approved an increase in the annual award option amount to 15,000 shares.

On March 27, 2017, our board of directors approved the following cash compensation for non-employee members of our Science, Technology and Clinical Affairs Committee and equity compensation policies for non-employee members of our board of directors, as recommended by the compensation committee of our board of directors:

- Science, Technology and Clinical Affairs Committee.  
For service as Chair of the science, technology and clinical affairs committee: an annual cash retainer of \$10,000 retroactive to March 21, 2017 (in addition to any annual cash retainers otherwise paid).  
For service as member of the science, technology and clinical affairs committee other than as its Chair: an annual cash retainer of \$5,000 retroactive to March 21, 2017 (in addition to any annual cash retainers otherwise paid).
- Initial Awards. For each non-employee director who is initially elected or appointed to the board: an option to purchase 30,000 shares of common stock.
- Annual Awards.  
For each non-employee director who (i) has been serving on the board for at least 6 months as of the date of any annual meeting of our stockholders and (ii) will continue to serve as a non-employee director immediately following such meeting: an option to purchase 15,000 shares of common stock.

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

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

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

On March 31, 2017, option awards exercisable into an aggregate 24,996 shares of common stock with a vesting commencement date of June 28, 2016 were granted under the Amended 2013 Plan to the six non-employee members of our board of directors related to the grant of annual awards for the June 2016 annual meeting of our shareholders, in accordance with the annual awards amounts noted above in this "Director Compensation" section. The exercise price of these awards of \$2.13 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair value of these awards of \$1.39 per share was estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for these awards include a volatility rate of 80.0%, a risk-free interest rate of 1.95%, a dividend yield of 0.00%, and an expected term of 5.12 years.

On May 31, 2017, option awards exercisable into an aggregate 90,000 shares of common stock with a vesting commencement date of May 2, 2017 were granted under the Amended 2013 Plan to the six non-employee members of our board of directors related to the grant of annual awards for the May 2017 annual meeting of our shareholders, in accordance with the annual awards amounts noted above in this "Director Compensation" section. The exercise price of these awards of \$1.50 per share is equal to the closing price of our common stock on the date of grant, with a term of 10 years from the date of grant. The grant date fair value of these awards of \$1.00 per share was estimated using a Black-Scholes valuation model. The assumptions used in the Black-Scholes valuation model for these awards include a volatility rate of 80.0%, a risk-free interest rate of 1.81%, a dividend yield of 0.00%, and an expected term of 5.46 years.

The following table reflects all compensation awarded to, earned by or paid to the non-employee directors during 2017:

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$(1)	Restricted Stock Awards \$(1)	Total (\$)
Marsha A. Chandler	36,401	26,642	—	63,043
Bruce E. Gerhardt	35,151	26,642	—	61,793
David F. Hale	100,000	26,642	—	126,642
Bruce A. Huebner	39,845	26,642	—	66,487
Ivor Royston, M.D.	38,750	26,642	—	65,392
M. Faye Wilson	53,750	26,642	—	80,392

- (1) The amounts in the "Option Awards (\$)" and "Restricted Stock Awards (\$)" columns reflect the grant date fair values of stock option and restricted stock awards, or RSUs, respectively, granted during the year. These amounts are determined in accordance with the provisions of FASB ASC Topic 718, rather than an amount paid to or realized by the director.

## **Equity Compensation Plan Information**

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

### **2007 Equity Incentive Plan**

The following is a summary of the material terms of our 2007 Plan, as amended to date. This description is not complete. For more information, we refer you to the full text of the 2007 Plan.

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

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

We have authorized a total of 20,225 shares of common stock for issuance pursuant to all awards granted under the 2007 Plan. The number of shares issued or reserved pursuant to the 2007 Plan (or pursuant to outstanding awards) is subject to adjustment as a result of mergers, consolidations, reorganizations, stock splits, reverse stock splits, stock dividends and other changes in our common stock. Shares subject to awards that have been terminated, expired unexercised, forfeited, settled in cash or cancelled in accordance with the cancellation and regrant procedures under the 2007 Plan will again become available for issuance under the Amended 2013 Plan and shall no longer be available for issuance under the 2007 Plan. Shares of common stock used to pay the exercise price of awards will also again become available for issuance under the Amended 2013 Plan and shall no longer be available for issuance under the 2007 Plan.

However, shares in the following categories may not again be made available for issuance as awards under the Amended 2013 Plan or the 2007 Plan: (i) shares of common stock not issued or delivered as a result of the net settlement of outstanding awards, (ii) shares of common stock used to pay the exercise price of NSOs or ISOs, and (iii) shares of common stock used to pay withholding taxes related to awards.

As of December 31, 2017, 3,413 shares underlying awards issued pursuant to the 2007 Plan had been settled in shares of common stock and no longer underlie outstanding awards, 16,812 shares underlie outstanding awards, and no other shares remained available to be subjected to further awards.

*Administration.* Our board of directors administers the 2007 Plan, subject to the board's authority to delegate some or all of such administration to the compensation committee.

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

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

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

*Effectiveness of the 2007 Plan; Amendment and Termination.* The 2007 Plan became effective on March 6, 2007. The terms of the Amended 2013 Plan require that any shares available for issuance under the 2007 Plan at the time of the adoption of the Amended 2013 Plan shall become available for issuance under the Amended 2013 Plan and shall no longer be available for issuance under the 2007 Plan. The board may amend, alter or discontinue the 2007 Plan in any respect at any time, subject to certain exceptions, but no amendment may adversely affect the rights of a participant under any awards previously granted, without his or her consent, except that stockholder approval will be needed if required by applicable law.

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

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### *U.S. Federal Income Tax Consequences Associated with the 2007 Plan*

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

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

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

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

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

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

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

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



### ***Amended and Restated 2013 Equity Incentive Plan, as Amended***

The following is a summary of the material terms of our Amended 2013 Plan, as amended to date. This description is not complete. For more information, we refer you to the full text of the Amended 2013 Plan.

#### *Purpose*

The purposes of the Amended 2013 Plan are: (i) to enable us to attract and retain the types of qualified employees, officers, directors, consultants and other service providers who will contribute to our long range success; (ii) to align the interests of employees, officers, directors, consultants and other service providers with those of the stockholders; (iii) to promote the success of our business; and (iv) with respect to inducement awards, provide an inducement material for certain individuals to enter into employment with us within the meaning of NASDAQ Listing Rule 5635(c)(4).

#### *Types of Awards*

The Amended 2013 Plan authorizes the grant of the following types of awards: stock options, SARs, restricted stock, restricted stock unit awards (“RSUs”), and performance compensation awards. Awards may be granted to employees, officers, non-employee board members, consultants and other service providers of us and our affiliates. However, incentive stock options (“ISOs”) may be granted only to employees, including officers.

Inducement awards that may be granted under the Amended 2013 Plan may include: (i) non-qualified stock options (“NSOs”), (ii) SARs, and (iii) Restricted Awards. Inducement awards may only be granted to individuals who satisfy the standards for inducement grants under NASDAQ Listing Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1.

#### *Shares Available for Awards*

We have authorized a total of 3,502,730 shares of common stock for the issuance of non-inducement awards and 333,333 shares of common stock for the issuance of inducement awards under the Amended 2013 Plan. As of December 31, 2017, 168,898 shares underlying non-inducement awards issued pursuant to the Amended 2013 Plan had been settled in shares of common stock and no longer underlie outstanding awards, 2,669,071 shares underlie outstanding non-inducement awards, and 664,761 shares were available for issuance as non-inducement awards. As of December 31, 2017, 25,000 shares underlying inducement awards issued pursuant to the Amended 2013 Plan had been settled in shares of common stock and no longer underlie outstanding awards, 133,049 shares underlie outstanding inducement awards, and 175,284 shares were available for issuance as inducement awards. The number of shares of our common stock issued or reserved pursuant to the Amended 2013 Plan, or pursuant to outstanding awards, is subject to adjustment as a result of mergers, consolidations, reorganizations, stock splits, reverse stock splits, stock dividends and other changes in our common stock.

Shares subject to awards that have been cancelled, expired unexercised, or are forfeited do not count as shares issued and therefore will again to that extent become available for issuance under the Amended 2013 Plan. However, shares in the following categories may not again be made available for issuance under the Amended 2013 Plan: (i) shares of common stock used to pay the exercise or purchase price of an award, including as a result of the net exercise of outstanding stock options, (ii) shares of common stock used to pay withholding taxes related to awards, (c) shares of common stock covered by a stock-settled SAR that were not issued upon settlement of the SAR or (iv) shares of common stock repurchased by us on the open market with the proceeds of the exercise or purchase price of an award.

#### *Eligibility*

All of our 95 employees, six non-employee directors and 10 consultants as of December 31, 2017 are eligible to participate in the Amended 2013 Plan and may receive all types of awards other than ISOs. ISOs may be granted under the Amended 2013 Plan only to our employees (including officers) and employees of our affiliates.

The only persons eligible to receive grants of inducement awards under the Amended 2013 Plan are individuals who satisfy the standards for inducement grants under NASDAQ Listing Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1. A person who previously served as an employee or director will not be eligible to receive inducement awards under the Amended 2013 Plan, other than following a bona fide period of non-employment.

We refer to eligible individuals who receive awards under the Amended 2013 Plan as “participants.”

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### *Administration*

The Amended 2013 Plan will be administered by our compensation committee. The compensation committee has the discretion to determine the individuals to whom awards may be granted under the Amended 2013 Plan, the number of shares of our common stock subject to each award, the type of award, the manner in which such awards will vest and the other conditions applicable to awards. The compensation committee is authorized to interpret the Amended 2013 Plan, to establish, amend and rescind any rules and regulations relating to the Amended 2013 Plan and to make any other determinations that it deems necessary or desirable for the administration of the Amended 2013 Plan. All decisions, determinations and interpretations by the compensation committee, and any rules and regulations under the Amended 2013 Plan and the terms and conditions of or operation of any award, are final and binding on all participants.

Notwithstanding the foregoing, the board of directors also has authority to take action expressly or implicitly in the capacity of the administrator of the Amended 2013 Plan, and the board of directors also may delegate, to the extent allowed under Delaware law and subject to NASDAQ Listing Rule 5635(c)(4) and the related guidance under NASDAQ IM 5635-1 with regard to inducement awards, its authority to one or more members of the board of directors with respect to awards that do not involve covered employees within the meaning of Section 162(m) of the Code or “insiders” within the meaning of Section 16 of the Exchange Act.

The compensation committee, the board of directors and any authorized member of the board of directors authorized to administer the Amended 2013 Plan is considered to be the “Plan Administrator.”

### *Section 162(m) Limits*

The Amended 2013 Plan provides that no participant may be granted in any one calendar year (i) stock options or SARs pursuant to which, in the case of stock options, the aggregate number of shares of common stock that may be acquired thereunder, or, in the case of SARs, the aggregate number of shares of common stock covered thereby, exceeds 2,000,000 shares, or (ii) any other types of awards covering in the aggregate over 2,000,000 shares of common stock. Also, the maximum number of shares of common stock subject to performance compensation awards, other than stock options and SARs, payable to any one participant under the Amended 2013 Plan in any one performance period is 2,000,000 shares of common stock or, in the event such performance compensation award is paid in cash, the equivalent cash value thereof on the first or last day of the performance period to which such award relates, as determined by the compensation committee (or other authorized committee). The maximum amount that can be paid in any calendar year to any participant pursuant to a performance compensation award designated in cash under the Amended 2013 Plan is \$2,000,000. These limits were designed to allow us to grant awards intended to be exempt from the \$1 million limitation on the income tax deductibility of compensation paid per covered employee imposed by Section 162(m) of the Code. The exemption from Section 162(m)’s deduction limit for performance-based compensation has been repealed, effective for taxable years beginning after December 31, 2017, such that compensation paid to our covered employees in excess of \$1 million will not be deductible unless it qualifies for transition relief applicable to certain arrangements in place as of November 2, 2017.

Despite the compensation committee’s efforts to structure compensation in a manner intended to be exempt from Section 162(m) and therefore not subject to its deduction limits, because of ambiguities and uncertainties as to the application and interpretation of Section 162(m) and the regulations issued thereunder, no assurance can be given that compensation provided under the Amended 2013 Plan that was intended to satisfy the requirements for exemption from Section 162(m) in fact will. Additionally, the compensation committee reserves the right to modify compensation that was initially intended to be exempt from Section 162(m) if it determines that such modifications are consistent with our business needs.

### *Inducement Awards*

On July 25, 2016, the board of directors approved an amendment to the Amended 2013 Plan to reserve 1,000,000 pre-reverse split shares of our common stock to be used exclusively for the grant of inducement awards in compliance with NASDAQ Listing Rule 5635(c)(4). This share reserve number was automatically decreased to 333,333 upon the effectiveness of the reverse split. Under the Amended 2013 Plan, an inducement award may be granted only to an employee who has not previously been an employee or a director of us or an affiliate, or following a bona fide period of non-employment, as an inducement material to the individual’s entering into employment with us within the meaning of NASDAQ Listing Rule 5635(c)(4). In addition, all such inducement awards must be granted by a committee consisting of the majority of our independent directors or our independent compensation committee, in either case in accordance with NASDAQ Listing Rule 5635(c)(4).

### *Repricing; Cancellation and Re-Grant of Stock Awards*

Under the Amended 2013 Plan, the Plan Administrator does not have the authority to reprice any outstanding stock option or SAR by reducing the exercise or strike price of the stock option or SAR or to cancel any outstanding stock option or SAR that has an exercise or strike price greater than the then-current fair market value of our common stock in exchange for cash or other stock awards without obtaining the approval of the stockholders. Such approval must be obtained within 12 months prior to such repricing or cancellation and re-grant event.

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### *Minimum Vesting Requirements*

Under the Amended 2013 Plan, except with respect to inducement awards and subject to the provisions of the Amended 2013 Plan relating to treatment of stock awards in connection with a change in control, no stock option or SAR (including a stock option or SAR that is a performance compensation award or otherwise vests based on performance goals) will vest (or, if applicable, be exercisable) until at least 12 months following the date of grant of the award; provided, however, that up to 5% of the Share Reserve (excluding inducement shares) may be subject to stock options or SARs which do not meet such vesting (and, if applicable, exercisability) requirements.

### *Stock Options*

Stock options may be granted under the Amended 2013 Plan pursuant to stock option award agreements. The Amended 2013 Plan permits the grant of stock options that are intended to qualify as ISOs and NSOs.

The exercise price of a stock option granted under the Amended 2013 Plan may generally not be less than 100% of the fair market value of our common stock subject to the stock option on the date of grant and, in some cases (see “Limitations on Incentive Stock Options” below), may not be less than 110% of such fair market value.

The term of stock options granted under the Amended 2013 Plan may not exceed ten years and, in some cases (see “Limitations on Incentive Stock Options” below), may not exceed five years. Except as otherwise provided in a participant’s stock option award agreement or in an employment agreement with us or one of our affiliates, if a participant’s service relationship with us or any of our affiliates (referred to as “continuous service”) terminates (other than for cause and other than upon the participant’s death or disability), the participant may exercise any vested stock options for up to three months following the participant’s termination of continuous service. Except as otherwise provided in a participant’s stock option award agreement or employment agreement with us or one of our affiliates, if a participant’s continuous service terminates due to the participant’s disability or death, the participant, or his or her beneficiary, as applicable, may exercise any vested stock options for up to 12 months following the participant’s termination. Except as explicitly provided otherwise in a participant’s stock option award agreement or employment agreement with us or one of our affiliates, if a participant’s continuous service is terminated for cause (as defined in the Amended 2013 Plan), all stock options held by the participant will terminate upon the participant’s termination of continuous service and the participant will be prohibited from exercising any stock option from and after such termination date. A participant’s stock option award agreement may provide that the term of a stock option shall be extended if the exercise of the stock option following the participant’s termination of continuous service for any reason would violate the registration requirements under the Securities Act or any other state or federal securities law or rules of any securities exchange or interdealer quotation system. In no event, however, may a stock option be exercised after its original expiration date.

A participant may exercise a stock option by written notice and payment of the exercise price in cash or by check, or in the discretion of the Plan Administrator, in the form of an irrevocable commitment by a broker to pay over the net proceeds from a sale of the shares issuable under an option, the delivery of previously owned shares and/or withholding of shares deliverable upon exercise, net-exercise, or any combination of these methods, or in any other form of legal consideration that may be acceptable to the Plan Administrator.

Subject to certain minimum vesting requirements (see “Minimum Vesting Requirements” above), stock options granted under the Amended 2013 Plan may become exercisable in cumulative increments, or “vest,” as determined by the Plan Administrator at the rate specified in the stock option agreement. Shares covered by different stock options granted under the Amended 2013 Plan may be subject to different vesting schedules as the Plan Administrator may determine.

The Plan Administrator may impose limitations on the transferability of stock options granted under the Amended 2013 Plan in its discretion. Generally, a participant may not transfer a stock option granted under the Amended 2013 Plan other than by will or the laws of descent and distribution. However, ISOs can be transferred pursuant to a qualified domestic relations order and, subject to approval by the Plan Administrator, NSOs can be transferred without consideration to certain family members and other permitted transferees not prohibited by applicable tax and securities laws.

### *Limitations on Incentive Stock Options*

The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to ISOs that are exercisable for the first time by a participant during any calendar year under all of our stock plans may not exceed \$100,000. The stock options or portions of stock options that exceed this limit or otherwise fail to qualify as ISOs are treated as NSOs. No ISO may be granted to any person who, at the time of grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any affiliate unless the following conditions are satisfied:

- the exercise price of the ISO must be at least 110% of the fair market value of the common stock subject to the ISO on the date of grant; and

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- the term of the ISO must not exceed five years from the date of grant.

Subject to adjustment for certain changes in our capitalization, the aggregate maximum number of shares of our common stock that may be issued pursuant to the exercise of ISOs under the Amended 2013 Plan is 3,522,955 shares, including any shares authorized under the 2007 Plan that become subsequently available for issuance under the Amended 2013 Plan. The aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of ISOs granted under the Amended 2013 Plan is the number of shares subject to the Amended 2013 Plan's Share Reserve not including the inducement grant pool.

### *Stock Appreciation Rights*

SARs may be granted under the Amended 2013 Plan pursuant to SAR award agreements. Each SAR is denominated in common stock share equivalents. The strike price of each SAR will be determined by the Plan Administrator but will generally not be less than 100% of the fair market value of the common stock subject to the SAR on the date of grant. Subject to certain minimum vesting requirements (see "Minimum Vesting Requirements" above), the Plan Administrator may also impose restrictions or conditions upon the vesting of SARs that it deems appropriate. The appreciation distribution payable upon exercise of a SAR may be paid in shares of our common stock, in cash, in a combination of cash and stock, or in any other form of consideration determined by the Plan Administrator. Generally, the treatment of a SAR upon termination of a participant's continuous service and restrictions on transfer of a SAR will be determined by the Plan Administrator and set forth in the SAR award agreement.

### *Restricted Stock Awards*

Restricted stock awards may be granted under the Amended 2013 Plan pursuant to restricted stock award agreements. A restricted stock award may be granted in consideration for cash, the participant's past services performed for us or any of our affiliates, or future services to be performed for us or any of our affiliates, subject to applicable law and if permitted by the Plan Administrator. Shares of our common stock acquired under a restricted stock award may be subject to forfeiture to or repurchase by us in accordance with a vesting schedule to be determined by the Plan Administrator, which may include performance-based conditions. Rights to acquire shares of our common stock under a restricted stock award may be transferred only upon such terms and conditions as are set forth in the restricted stock award agreement. Subject to the terms of the restricted stock award agreement, dividends paid on restricted stock generally will be subject to the same vesting conditions as apply to the shares subject to the restricted stock award. Generally, the treatment of a restricted stock award upon termination of a participant's continuous service will be determined by the Plan Administrator and set forth in the restricted stock award agreement.

### *Restricted Stock Unit Awards*

RSU awards may be granted under the Amended 2013 Plan pursuant to RSU award agreements. A RSU may be settled by the delivery of shares of our common stock, in cash, in a combination of cash and stock, or in any other form of consideration determined by the Plan Administrator and set forth in the RSU award agreement. RSUs may be subject to vesting in accordance with a vesting schedule to be determined by the Plan Administrator, which may include performance-based conditions. Subject to the terms of the RSU award agreement, dividend equivalents generally may be credited in respect of shares of our common stock covered by a RSU, provided that any additional shares credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying RSU. The treatment of a RSU upon termination of a participant's continuous service will be determined by the Plan Administrator and set forth in the RSU award agreement.

### *Performance Compensation Awards*

The Amended 2013 Plan allows us to grant performance compensation awards, which are awards denominated in shares of our common stock, cash or a combination thereof, which are earned during a specified performance period subject to the attainment of performance criteria. Performance compensation awards may have been structured to qualify as performance-based compensation that is not subject to the \$1 million limitation on the income tax deductibility of compensation paid per covered employee imposed by Section 162(m) of the Code. The Amended 2013 Plan provides for maximum amounts that may be granted to any participant in a calendar year attributable to performance compensation awards (see "Section 162(m) Limitations" above). However, as described above, the exemption from Section 162(m)'s deduction limit for performance-based compensation has been repealed, effective for taxable years beginning after December 31, 2017, such that compensation paid to our covered employees in excess of \$1 million will not be deductible unless it qualifies for transition relief applicable to certain arrangements in place as of November 2, 2017.

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Vesting of performance compensation awards may be subject to a requirement of continuous service and/or the satisfaction of one or more performance goals. The performance goals may vary from participant to participant, group to group, and period to period. Performance goals may be weighted for different factors and measures. The length of any performance period, the performance goals to be achieved during the performance period, and the measure of whether and to what degree such performance goals have been attained will be determined by the Plan Administrator, except that to the extent the performance compensation award is intended to be “performance-based compensation” under Section 162(m) of the Code, the Plan Administrator shall be our compensation committee or another committee that consists solely of two or more non-employee directors who are “outside directors” under the requirements of Section 162(m) of the Code.

In granting a performance stock or cash award that was intended to qualify as “performance-based compensation” under Section 162(m) of the Code, our compensation committee (or other qualified committee) set a period of time, or a performance period, over which the attainment of one or more goals, or performance goals, will be measured. Within the time period prescribed by Section 162(m) of the Code (no later than the earlier of the 90th day of a performance period and the date on which 25% of the performance period has elapsed, and in any event at a time when the achievement of the performance goals remains substantially uncertain), our compensation committee (or other qualified committee) will establish the performance goals, based upon one or more criteria, or performance criteria, enumerated in the Amended 2013 Plan and described below. As soon as administratively practicable following the end of the performance period, our compensation committee (or other qualified committee) will certify in writing whether the performance goals have been satisfied.

Performance goals under the Amended 2013 Plan will be based on any one or more of the following performance criteria: (a) net earnings or net income (before or after taxes); (b) basic or diluted earnings per share (before or after taxes); (c) net revenue or net revenue growth; (d) gross revenue; (e) gross profit or gross profit growth; (f) net operating profit (before or after taxes); (g) return on assets, capital, invested capital, equity, or sales; (h) cash flow (including, but not limited to, operating cash flow, free cash flow, and cash flow return on capital); (i) earnings before or after taxes, interest, depreciation and/or amortization; (j) gross or operating margins; (k) improvements in capital structure; (l) budget and expense management; (m) productivity ratios; (n) economic value added or other value added measurements; (o) share price (including, but not limited to, stock price growth measures and total stockholder return); (p) expense targets; (q) margins; (r) operating efficiency; (s) working capital targets; (t) enterprise value; (u) safety record; (v) regulatory milestones; (w) scientific milestones; (x) customer acquisition; (y) completion of partnering agreement; (z) workforce retention; (aa) completion of acquisitions or business expansion; and (bb) individual business objectives.

Performance goals may be based on a Biocept, Inc. or affiliate-wide basis, with respect to one or more business units, divisions, or our operational units or an affiliate or any combination thereof, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Our compensation committee or other authorized committee (or, to the extent that an award is not intended to qualify as “performance-based compensation” under Section 162(m) of the Code, the Plan Administrator) is authorized to make appropriate adjustments in the method of calculating the attainment of performance goals for a performance period based on the following events (provided, however, that to the extent that an award is intended to qualify as “performance-based compensation” under Section 162(m) of the Code, any such adjustment may be made only as permitted under Section 162(m) of the Code): (a) asset write-downs; (b) litigation or claim judgments or settlements; (c) the effect of changes in tax laws, accounting principles, or other laws or regulatory rules affecting reported results; (d) any reorganization and restructuring programs; (e) extraordinary nonrecurring items as described in Accounting Principles Board Opinion No. 30 (or any successor or pronouncement thereto) and/or in management’s discussion and analysis of financial condition and results of operations appearing in our annual report to stockholders for the applicable year; (f) acquisitions or divestitures; (g) any other specific unusual or nonrecurring events, or objectively determinable category thereof; (h) foreign exchange gains and losses; and (i) a change in our fiscal year.

### *Transferability*

Awards granted under the Amended 2013 Plan generally may not be transferred in any manner other than by will or by the laws of descent and distribution and awards generally may not be transferred if the participant is to receive consideration in connection with the transfer. Stock options may be transferred in the limited circumstances described above under the section entitled “Stock Options.”

### *Clawback Policy*

The Amended 2013 Plan provides that rights, payments and benefits with respect to an award granted under the Amended 2013 Plan will be subject to reduction, cancellation forfeiture or recoupment in recovery under any law, government regulation or listing requirement as well as any clawback policy that we adopt pursuant to such laws, regulations or requirements.

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### *Changes to Capital Structure*

In the event of certain capitalization adjustments, the Plan Administrator will appropriately adjust: (i) the class(es) and maximum number of securities subject to the Amended 2013 Plan; (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of ISOs; (iii) the class(es) and maximum number of securities that may be awarded to any participant as intended to qualify for exemption from the Section 162(m) deduction limitations; (iv) the class(es) and number of securities and price per share of stock subject to outstanding stock awards; and (v) the class(es) and maximum number of securities that may be issued pursuant to inducement awards.

### *Change in Control*

In the event of a change in control of us (as defined in the Amended 2013 Plan and described below) in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue outstanding awards under the Amended 2013 Plan or substitute similar stock awards for such outstanding awards, then the Plan Administrator may, in its discretion and upon at least 10 days' advance notice to the affected persons, accelerate the vesting (and exercisability, as applicable) of outstanding awards under the Amended 2013 Plan in full or in part to a date prior to the effective time of the change in control transaction and, to the extent not exercised (if applicable) at or prior to the effective time of the transaction, cancel all outstanding awards upon or immediately before the change in control and pay to the holders thereof, in cash or stock, or any combination thereof, the value of such awards (including, at the Plan Administrator's discretion, any unvested portion of the award) based upon the value per share of common stock received or to be received or deemed received by our other stockholders in the transaction. In the case of any stock option or SAR with an exercise price that equals or exceeds the price paid for a share of common stock in connection with the change in control, the Plan Administrator may cancel the option or SAR without the payment of consideration therefor.

In addition, in the event of a participant's termination of continuous service without cause or resignation for good reason during the 10 day period before a change in control or during the 12 month period following a change in control, all stock options and SARs under the Amended 2013 Plan will become immediately exercisable with respect to 100% of the shares subject to such stock options or SARs, and/or the restricted period will expire immediately with respect to 100% of the shares of restricted stock or RSUs as of the date of the participant's termination or resignation.

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

For purposes of the Amended 2013 Plan, a change in control generally will be deemed to occur in the event: (i) the direct or indirect sale, transfer, conveyance or other disposition (other than by way of a merger or consolidation) of all or substantially all of the properties or our assets and our subsidiaries, to any person or group that is not one of our subsidiaries; (ii) the "incumbent directors" (as described below) cease to constitute at least a majority of the board of directors; (iii) a person, entity or group acquires beneficial ownership of 50% or more of either our then outstanding shares of common stock or of the combined voting power of our then outstanding securities; (iv) there is a consummated reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving us that requires our stockholder approval. Certain acquisitions and other transactions are exempted from the definition of a change in control, as further described in the Amended 2013 Plan, including a transaction where (a) immediately after such transaction more than 50% of the total voting power of the resulting entity is represented by the combined voting power of our outstanding voting securities immediately before the transaction in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction, (b) no person or group or any employee benefit plan sponsored or maintained by the surviving entity is the beneficial owner of 50% or more of the total voting power of the parent company of the surviving entity in the transaction and (c) at least a majority of the members of the board of directors of the parent company of the surviving entity were members of our board of directors at the time of approval of the initial agreement providing for such transaction. "Incumbent directors" for purposes of the definition of "change in control" means the individuals who are on the board of directors as of the original effective date of the Amended 2013 Plan (July 31, 2013) or individuals whose nomination or election was approved by a vote of at least two-thirds of the incumbent directors then still on the board of directors.

### *Plan Amendments and Termination*

The Plan Administrator will have the authority to amend or terminate the Amended 2013 Plan at any time. However, except as otherwise provided in the Amended 2013 Plan or an award agreement, no amendment or termination of the Amended 2013 Plan may



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materially impair a participant's rights under his or her outstanding awards without the participant's consent. We will obtain stockholder approval of any amendment to the Amended 2013 Plan as required by applicable law and listing requirements. No ISOs may be granted under the Amended 2013 Plan after March 27, 2027.

### *U.S. Federal Income Tax Consequences Associated with the Amended 2013 Plan*

The following is a general summary of the principal United States federal income taxation consequences to participants and us under current law with respect to participation in the Amended 2013 Plan. This summary is not intended to be exhaustive and does not discuss the income tax laws of any city, state or foreign jurisdiction in which a participant may reside or the rules applicable to deferred compensation under Section 409A of the Code. Our ability to realize the benefit of any tax deductions described below depends on our generation of taxable income as well as the requirement of reasonableness, the provisions of Section 162(m) of the Code and the satisfaction of our tax reporting obligations.

*Non-Statutory Stock Options.* Generally, there is no taxation upon the grant of an NSO if the stock option is granted with an exercise price equal to the fair market value of the underlying stock on the grant date. On exercise of an NSO the participant will recognize ordinary income in an amount equal to the excess, if any, of the fair market value of the shares on the date each such stock option is exercised over the stock option exercise price. The participant's basis for the stock for purposes of determining gain or loss on subsequent disposition of such shares generally will be the fair market value of the common stock on the date the participant exercises such stock option. Any subsequent gain or loss will be generally taxable as capital gains or losses. Subject to certain restrictions and limitations, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*Incentive Stock Options.* Generally, a participant is not subject to ordinary income tax upon the grant or exercise of an ISO, although the amount by which the fair market value of a share of stock acquired on exercise of an ISO exceeds the exercise price of the ISO generally will be an adjustment included in the participant's alternative minimum taxable income for the year in which the ISO is exercised. If a participant holds a share received on exercise of an ISO for more than two years from the date the stock option was granted and more than one year from the date the stock option was exercised, which is referred to as the required holding period, the difference, if any, between the amount realized on a sale or other taxable disposition of that share and the participant's tax basis in that share will be long-term capital gain or loss.

If, however, a participant disposes of a share acquired on exercise of an ISO before the end of the required holding period, which is referred to as a disqualifying disposition, the participant generally will recognize ordinary income in the year of the disqualifying disposition equal to the excess, if any, of the fair market value of the share on the date the ISO was exercised over the exercise price. However, if the sales proceeds are less than the fair market value of the share on the date of exercise of the ISO, the amount of ordinary income recognized by the participant will not exceed the gain, if any, realized on the sale. If the amount realized on a disqualifying disposition exceeds the fair market value of the share on the date of exercise of the ISO, that excess will be short-term or long-term capital gain, depending on whether the holding period for the share exceeds one year.

Upon a disqualifying disposition of shares in the year in which the stock option is exercised, there will be no adjustment for alternative minimum tax purposes with respect to those shares. In computing alternative minimum taxable income, the tax basis of a share acquired on exercise of an ISO is increased by the amount of the adjustment taken into account with respect to that share for alternative minimum tax purposes in the year the stock option is exercised.

We are not allowed an income tax deduction with respect to the grant or exercise of an ISO or the disposition of a share acquired on an exercise of an ISO after the required holding period. If there is a disqualifying disposition of a share, however, we are allowed a deduction in an amount equal to the ordinary income includible in income by the participant, subject to Section 162(m) of the Code and provided that amount constitutes an ordinary and necessary business expense for us and is reasonable in amount, and either the participant includes that amount in income or we timely satisfy our reporting requirements with respect to that amount.

An ISO exercised more than three months after a participant terminates employment, other than by reason of death or disability, will be taxed as a NSO, and the participant will have been deemed to have received income on the exercise taxable at ordinary income rates. We will be entitled to a tax deduction equal to the participant's ordinary income, if any.

*SARs.* In general, the tax treatment of a SAR is similar to that of a NSO.

*Restricted Stock Awards.* Generally, the recipient of a restricted stock award will recognize ordinary income at the time the shares are received equal to the excess, if any, of the fair market value of the shares received over any amount paid by the recipient for the shares. If a share is not vested when it is received, the participant generally will not recognize income until the share becomes vested, at which time the participant will recognize ordinary income equal to the excess, if any, of the fair market value of the share on the



date it becomes vested over any amount paid by the participant in exchange for the share. A participant may file an election with the Internal Revenue Service, within 30 days following his or her receipt of the restricted stock award, to recognize ordinary income, as of the date the participant receives the award, equal to the excess, if any, of the fair market value of the share on the date the award is granted over any amount paid by the participant for the share. The participant's basis for the determination of gain or loss upon the subsequent disposition of shares acquired from restricted stock awards will be the amount paid for such shares plus any ordinary income recognized either when the share is received or when the share becomes vested.

Subject to the satisfaction of certain reporting requirements and other conditions as described above, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*RSU Awards.* Generally, a participant who receives a RSU structured to either comply with or be exempt from the requirements of Section 409A of the Code will recognize ordinary income at the time the shares of our common stock are delivered equal to the excess, if any, of the fair market value of the shares of our common stock received over any amount paid by the participant in exchange for the shares of our common stock. The participant's basis in the shares will be the amount paid plus any ordinary income recognized when the shares are delivered. Subject to the satisfaction of certain reporting requirements and other conditions as described above, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*Dividend Equivalents.* A participant who receives a dividend equivalent with respect to an award generally will not recognize taxable income at the time of grant, and we will not be entitled to a deduction at that time. When a dividend equivalent is paid, the participant generally will recognize ordinary income. Subject to the satisfaction of certain reporting requirements and other conditions as described above, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*Performance Compensation Awards.* A participant who has been granted a performance compensation award generally will not recognize taxable income at the time of grant, and we will not be entitled to a deduction at that time. When an award is paid, whether in cash or common stock, the participant generally will recognize ordinary income. Subject to the satisfaction of certain reporting requirements and other conditions as described above, we will generally be entitled to a tax deduction equal to the taxable ordinary income realized by the participant.

*Impact of Section 409A of the Code.* The Amended 2013 Plan provides for the grant of various types of awards which may not be exempt from Section 409A of the Code. If an award is subject to Section 409A of the Code, and if the requirements of Section 409A of the Code are not met, the taxable events as described above could apply earlier than described and also could result in the imposition of additional taxes and penalties.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Other than compensation arrangements for named executive officers and directors, we describe below each transaction and series of similar transactions, since January 1, 2015, to which we were a party or will be a party, in which the amount exceeds \$120,000 (or, if less, 1% of the average of our total assets amounts at December 31, 2016 and 2017) and in which any related person had or will have a direct or indirect material interest.

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

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

From time to time, Claire K. T. Reiss, who until the closing of our public offering on October 19, 2016 was a beneficial owner of more than 10% of our common stock and was also a director of Biocept, individually and through entities affiliated with her has loaned us operating funds through various convertible and non-convertible debt instruments. These entities consist of Reisung Enterprises, Inc., of which Mrs. Reiss is the owner and president, and family trusts of which Mrs. Reiss is the trustee. Mrs. Reiss resigned from the board of directors on August 14, 2013.

One of Mrs. Reiss’ family trusts participated in our May 2016 public offering, purchasing 204,758 shares of our common stock and warrants to purchase up to 143,330 shares of our common stock for total proceeds of \$614,273. The warrants purchased in this public offering are exercisable at a per share price of \$3.90 until May 2021.

One of Mrs. Reiss’ family trusts participated in our October 2016 public offering, purchasing 227,272 shares of our common stock and warrants to purchase up to 227,272 shares of our common stock for total proceeds of \$250,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***Edward Neff***

Edward Neff, who was a member of our board of directors until September 8, 2017, is an uncle of Mr. Nall and is the chief executive officer and owner of Systems, Machines, Automation Components Corporation (SMAC), a company which had loaned us operating funds under convertible debt arrangements and provided financing for certain fixed asset purchases prior to our initial public offering in February 2014.

Mr. Neff participated in our May 2016 public offering, purchasing 33,333 shares of our common stock and warrants to purchase up to 23,333 shares of our common stock for total proceeds of \$100,000. The warrants purchased in this public offering are exercisable at a per share price of \$3.90 until May 2021.

SMAC participated in our October 2016 public offering, purchasing 227,272 shares of our common stock and warrants to purchase up to 227,272 shares of our common stock for total proceeds of \$250,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

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

Hale BioPharma Ventures LLC participated in our February 2015 public offering, purchasing 13,333 shares of our common stock and warrants to purchase up to 13,333 shares of our common stock for total proceeds of \$50,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

Pursuant to a sublease agreement dated March 30, 2015, we subleased 9,849 square feet, plus free use of an additional area, of our San Diego facility to an entity affiliated with Mr. Hale for \$12,804 per month, with a refundable security deposit of \$12,804 received from the subtenant. The initial term of the sublease expired on July 31, 2015 and was subject to renewal on a month-to-month basis thereafter. On February 1, 2017, we received notice from the subtenant terminating the sublease effective March 31, 2017. During the three months ended September 30, 2017, the total amount of the \$12,804 security deposit previously received from the subtenant was applied against approximately \$16,000 in additional rents owed as a result of the subtenant continuing to occupy the subleased areas beyond March 31, 2017, and the balance of approximately \$3,200 due to us was waived. A total of \$102,432, \$153,648 and \$51,216 in rental income was recorded to other income/(expense) in our unaudited condensed statements of operations and comprehensive loss during the years ended December 31, 2015, 2016 and 2017, respectively.

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A retirement account of Mr. Hale participated in our May 2016 public offering, purchasing 16,667 shares of our common stock and warrants to purchase up to 11,666 shares of our common stock for total proceeds of \$50,000. The warrants purchased in this public offering are exercisable at a per share price of \$3.90 until May 2021.

Hale BioPharma Ventures LLC participated in our October 2016 public offering, purchasing 90,090 shares of our common stock and warrants to purchase up to 90,909 shares of our common stock for total proceeds of \$100,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***M. Faye Wilson***

Ms. Wilson participated in our February 2015 public offering, purchasing 1,333 shares of our common stock and warrants to purchase up to 1,333 shares of our common stock for total proceeds of \$5,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

Ms. Wilson participated in our October 2016 public offering, purchasing 13,636 shares of our common stock and warrants to purchase up to 13,636 shares of our common stock for total proceeds of \$15,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

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

Mr. Gerhardt participated in our February 2015 public offering, purchasing 6,666 shares of our common stock and warrants to purchase up to 6,666 shares of our common stock for total proceeds of \$25,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

Mr. Gerhardt participated in our May 2016 public offering, purchasing 8,333 shares of our common stock and warrants to purchase up to 5,833 shares of our common stock for total proceeds of \$25,000. The warrants purchased in this public offering are exercisable at a per share price of \$3.90 until May 2021.

Mr. Gerhardt participated in our October 2016 public offering, purchasing 50,000 shares of our common stock and warrants to purchase up to 50,000 shares of our common stock for total proceeds of \$55,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

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

A retirement account of Dr. Royston participated in our February 2015 public offering, purchasing 4,000 shares of our common stock and warrants to purchase up to 4,000 shares of our common stock for total proceeds of \$15,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

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

Mr. Huebner participated in our February 2015 public offering, purchasing 4,000 shares of our common stock and warrants to purchase up to 4,000 shares of our common stock for total proceeds of \$15,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

Mr. Huebner participated in our October 2016 public offering, purchasing 20,000 shares of our common stock and warrants to purchase up to 20,000 shares of our common stock for total proceeds of \$22,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

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

Dr. Chandler participated in our February 2015 public offering, purchasing 666 shares of our common stock and warrants to purchase up to 666 shares of our common stock for total proceeds of \$2,500. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

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Dr. Chandler participated in our October 2016 public offering, purchasing 4,545 shares of our common stock and warrants to purchase up to 4,545 shares of our common stock for total proceeds of \$5,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

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

Mr. Nall participated in our February 2015 public offering, purchasing 4,000 shares of our common stock and warrants to purchase up to 4,000 shares of our common stock for total proceeds of \$15,000. The warrants purchased in this public offering are exercisable at a per share price of \$4.68 until February 2020.

A family trust of Mr. Nall's participated in our October 2016 public offering, purchasing 36,363 shares of our common stock and warrants to purchase up to 36,363 shares of our common stock for total proceeds of \$40,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***Timothy C. Kennedy***

Mr. Kennedy participated in our October 2016 public offering, purchasing 36,363 shares of our common stock and warrants to purchase up to 36,363 shares of our common stock for total proceeds of \$40,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***Lyle J. Arnold***

Lyle J. Arnold, Ph.D., our Senior Vice-President of Research and Development and Chief Scientific Officer, is the controlling person of Aegea Biotechnologies, Inc. On June 2, 2012, we entered into an Assignment and Exclusive Cross-License Agreement, or the Cross-License Agreement, with Aegea regarding the Target-Selector technology. Under the Agreement, each party has an undivided joint ownership interest in all of the patents and other intellectual property rights for such technology. We obtained an exclusive, worldwide, royalty-free, fully-paid, irrevocable, sublicensable license for all applications in the fields of oncology clinical testing and oncology diagnostics (including both laboratory developed tests and IVD tests as applied to the oncology field) and oncology basic and clinical research that is performed internally by us, as a service offered by us, or in a bona fide collaboration between us and one or more third parties (where the sample types tested are tissue, whole blood, bone marrow, cerebrospinal fluid or derivatives of any of such sample types); provided that any such collaboration must not be solely or primarily directed to providing research reagents or research technologies to such collaborator, and must not involve the sale or resale of patented research reagents or the licensing of technologies for patented research applications by such collaborator to third parties. Under the Agreement's license, we are free of any obligation to obtain further consent from Aegea or to account to Aegea. Aegea obtained an exclusive, worldwide, royalty-free, fully-paid, irrevocable sublicensable license for all applications in all other fields, without any obligation to obtain further consent from us or to account to us. We were given responsibility for prosecuting some of the relevant patent applications, and Aegea was given responsibility for prosecuting others, but the two parties will share all patent prosecution and maintenance costs equally. We received payments totaling \$25,763, \$19,047 and \$15,325 during the years ended December 31, 2015, 2016, and 2017, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement.

Dr. Arnold participated in our October 2016 public offering, purchasing 45,000 shares of our common stock and warrants to purchase up to 45,000 shares of our common stock for total proceeds of \$49,500. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***Veena Singh, M.D.***

Dr. Singh participated in our October 2016 public offering, purchasing 10,000 shares of our common stock and warrants to purchase up to 10,000 shares of our common stock for total proceeds of \$11,000. The warrants purchased in this public offering are exercisable at a per share price of \$1.10 until October 2021.

### ***Indemnification Agreements***

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

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directors and executive officers and certain prior directors and executive officers. These agreements will require us to indemnify these individuals to the fullest extent permitted under California law against liabilities that may arise by reason of their service to us, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

**Policies and Procedures for Related Party Transactions**

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

***Equity Awards***

We have granted stock options and RSUs to our executive officers and directors. For additional information, see “Executive Compensation—Outstanding Equity Awards.”

## PRINCIPAL SHAREHOLDERS

The following table sets forth the beneficial ownership of our common stock as of January 9, 2018 by:

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

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before March 10, 2018, which is 60 days after January 9, 2018. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

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

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<b><i>5% Stockholders</i></b>		
Ally Bridge LB Healthcare Master Fund Limited(1)	4,582,306	12.5%
<b><i>Named Executive Officers and Directors:</i></b>		
David F. Hale(2)	349,552	*%
Marsha A. Chandler, Ph. D.(3)	34,899	*%
Bruce E. Gerhardt, CPA(4)	149,199	*%
Bruce A. Huebner(5)	69,617	*%
Michael W. Nall(6)	227,102	*%
Ivor Royston, M.D.(7)	39,332	*%
M. Faye Wilson, MBA(8)	64,281	*%
Timothy C. Kennedy(9)	140,498	*%
Lyle J. Arnold, Ph. D.(10)	171,284	*%
All Executive Officers and Directors as a group (11 persons)(11)	1,355,123	3.8%

\* denotes less than 1%.

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- (1) Includes 1,434,639 shares of common stock issuable upon exercise of warrants held by Ally Bridge LB Healthcare Master Fund Limited and exercisable until August 2022 at a price of \$1.50 per share, pursuant to the price set in our October 2016 public offering and according to a Schedule 13D/A filed with the SEC on August 17, 2017 by (i) Ally Bridge LB Healthcare Master Fund Limited, a limited company incorporated under the laws of the Cayman Islands, (ii) Ally Bridge LB Management Limited, a limited company incorporated under the laws of the Cayman Islands, (iii) Mr. Fan Yu, a director and executive officer of Ally Bridge LB Healthcare Master Fund Limited and Ally Bridge LB Management Limited and (iv) Mr. Bin Li, a director and executive officer of Ally Bridge LB Healthcare Master Fund Limited and Ally Bridge LB Management Limited (Ally Bridge LB Healthcare Master Fund Limited, Ally Bridge LB Management Limited, Mr. Yu and Mr. Li collectively being referred to as the “Reporting Persons”). The address of the principal business and principal office of each of the Reporting Persons is Unit 1602, 16/F, Wheelock House, 20 Pedder Street, Central, Hong Kong. Ally Bridge LB Management Limited owns the sole voting share in Ally Bridge LB Healthcare Master Fund Limited. Mr. Fan Yu and Mr. Bin Li are the shareholders and directors of Ally Bridge LB Management Limited. Ally Bridge LB Management Limited, by virtue of it being the holder of sole voting share of Ally Bridge LB Healthcare Master Fund Limited, and each of Mr. Yu and Mr. Li, by virtue of being a shareholder and director of Ally Bridge LB Management Limited, may be deemed to have voting control and investment discretion over the securities held by Ally Bridge LB Healthcare Master Fund Limited. Each of Ally Bridge LB Management Limited, Mr. Yu and Mr. Li disclaims beneficial ownership of such securities and the filed Schedule 13D shall not be deemed an admission that any of them is the beneficial owner of, or has any pecuniary interest in, such securities for any purposes. In addition, pursuant to Section 13(d)(3) of the Exchange Act, the Reporting Persons, the other sponsors and certain of their respective affiliates may, on the basis of the facts described elsewhere in the filed Schedule 13D/A, be considered to be a “group”. Ally Bridge LB Healthcare Master Fund Limited has the power to vote or direct the vote and to dispose or direct the disposition of the warrants to purchase 1,434,639 shares of common stock. Ally Bridge LB Management Limited may, by virtue of its or their ownership interest in Ally Bridge LB Healthcare Master Fund Limited, and each of Mr. Yu and Mr. Li, as a shareholder and director of Ally Bridge LB Management Limited, may be deemed to share with Ally Bridge LB Healthcare Master Fund Limited the power to vote or to direct the vote and to dispose or to direct the disposition of the warrants to purchase 1,434,639 shares of common stock. Each of Ally Bridge LB Management Limited, Mr. Yu and Mr. Li disclaims such power to vote or direct the vote or power to dispose or direct the disposition of the warrants to purchase 1,434,639 shares of common stock for all other purposes.
- (2) Includes 57,700 shares of common stock underlying stock options. Includes shares held by Mr. Hale’s individual retirement account, shares held by Hale BioPharma Ventures LLC, which is controlled by Mr. Hale, and shares held by the Hale Family Trust, which is controlled by Mr. Hale as co-trustee. The calculation of the percentage of shares beneficially owned also includes 7,391 shares, 13,333 shares, and 90,909 shares for which common stock warrants held by Hale BioPharma Ventures LLC are exercisable at per share prices of \$30.00, \$4.68, and \$1.10, respectively, according to prices set in our initial, February 2015, and October 2016 public offerings. The calculation of the percentage of shares beneficially owned also includes 11,666 shares for which common stock warrants held by Mr. Hale’s individual retirement account are exercisable at a price of \$3.90 per share, according to the price set in our May 2016 public offering.
- (3) Includes 21,950 shares of common stock underlying stock options. The number of shares beneficially owned also includes outstanding shares held by a family trust affiliated with Dr. Chandler. The calculation of the percentage of shares beneficially owned includes 833 shares, 666 shares, and 4,545 shares for which common stock warrants held by Dr. Chandler are exercisable at per share prices of \$30.00, \$4.68 and \$1.10, respectively, according to prices set in our initial, February 2015, and October 2016 public offerings.
- (4) Includes 16,871 shares of common stock underlying stock options. The calculation of the percentage of shares beneficially owned also includes 166 shares, 6,666 shares, 5,833 shares, and 50,000 shares for which common stock warrants held by Mr. Gerhardt are exercisable at per share prices of \$30.00, \$4.68, \$3.90, and \$1.10, respectively, according to prices set in our initial, February 2015, May 2016, and October 2016 public offerings.
- (5) Includes 21,617 shares of common stock underlying stock options. The calculation of the percentage of shares beneficially owned also includes 4,000 shares and 20,000 shares for which common stock warrants held by Mr. Huebner are exercisable at per share prices of \$4.68 and \$1.10, respectively, according to the prices set in our February 2015 and October 2016 public offerings.
- (6) Includes 112,164 shares of common stock underlying stock options. Includes outstanding shares held by a family trust. The calculation of the percentage of shares beneficially owned also includes 4,000 shares for which common stock warrants held by Mr. Nall are exercisable at a price of \$4.68 per share, according to the price set in our February 2015 public offering. The calculation of the percentage of shares beneficially owned also includes 36,363 shares for which common stock warrants held by a family trust are exercisable at a price of \$1.10 per share, according to the price set in our October 2016 public offering.
- (7) Includes 18,038 shares of common stock underlying stock options. Includes shares owned by Dr. Royston’s individual retirement account, a family trust and an individual trust account. The calculation of the percentage of shares beneficially owned also includes 4,000 shares for which common stock warrants held by Dr. Royston’s individual retirement account are exercisable at a price of \$4.68 per share according to the price set in our February 2015 public offering.



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- (8) Includes 26,205 shares of common stock underlying stock options. Includes shares held by Ms. Wilson's individual retirement account as well as Wilson Boyles & Co., LLC, a company controlled by Ms. Wilson. The calculation of the percentage of shares beneficially owned also includes 416 shares, 1,333 shares, and 13,636 shares for which common stock warrants held by Ms. Wilson are exercisable at per share prices of \$30.00, \$4.68, and \$1.10, respectively, according to prices set in our initial, February 2015, and October 2016 public offerings.
- (9) Includes 42,772 shares of common stock underlying stock options. The calculation of percentage of shares beneficially owned also includes warrants to purchase up to 36,363 shares of common stock exercisable at \$1.10 per share, according to the price set in our October 2016 public offering.
- (10) Includes 61,046 shares of common stock underlying stock options. The calculation of percentage of shares beneficially owned also includes warrants to purchase up to 45,000 shares of common stock exercisable at \$1.10 per share, according to the price set in our October 2016 public offering.
- (11) Includes 31,233 shares of common stock, 68,126 shares of common stock underlying stock options, and 10,000 shares of common stock underlying warrants exercisable at \$1.10 per share for executive officers not named in the table above.

## PRICE RANGE OF OUR COMMON STOCK

On January 19, 2018, the closing price for our common stock as reported on The NASDAQ Capital Market was \$0.665 per share. The following table sets forth the ranges of high and low sales prices per share of our common stock as reported on The NASDAQ Capital Market for the periods indicated. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

	<b>Common Stock</b>	
	<b>High</b>	<b>Low</b>
<b>Fiscal Year Ended December 31, 2018</b>		
First Quarter (through January 19, 2018)	\$0.82	\$0.63
<b>Fiscal Year Ended December 31, 2017</b>		
Fourth Quarter	\$1.35	\$0.60
Third quarter	\$1.64	\$1.11
Second quarter	\$2.26	\$1.24
First quarter	\$3.39	\$0.78
<b>Fiscal Year Ended December 31, 2016</b>		
Fourth quarter	\$1.60	\$0.74
Third quarter	\$2.40	\$1.42
Second quarter	\$4.29	\$1.68
First quarter	\$5.64	\$3.15

As of the date of this prospectus, our amended certificate of incorporation authorizes us to issue 150,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.0001 per share. As of January 19, 2018, there were 201 stockholders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

As of January 19, 2018, we had outstanding warrants to purchase shares of our common stock as follows:

- Warrants exercisable for 86,073 shares of our common stock at an exercise price of \$30.00 per share, issued to investors pursuant to our June 2013 note and warrant purchase agreement. These warrants are exercisable until February 2019.
- Warrant exercisable for 16,753 shares of our common stock at an exercise price of \$30.00 per share, issued to our landlord in connection with our September 2013 lease amendment which was effective as of August 1, 2013. This warrant is exercisable until February 2019.
- Warrant exercisable for 529 shares of our common stock at an exercise price of \$75.60 per share, issued to our landlord in connection with our September 2012 lease amendment. This warrant is exercisable until September 2019.
- Warrant exercisable for 31,666 shares of our common stock at an exercise price of \$37.50 per share, issued to the representative of the underwriters in connection with our initial public offering in February 2014. This warrant is exercisable until February 2019.
- Warrant exercisable for 17,655 shares of our common stock at an exercise price of \$14.16 per share, issued to Oxford Finance LLC in connection with a loan and security agreement dated April 30, 2014. This warrant is exercisable through April 2024.
- Warrants exercisable for 581,153 shares of our common stock at an exercise price of \$4.68 per share, issued to participants in our public offering in February 2015. These warrants are exercisable until February 2020.
- Warrants exercisable for 1,163,526 shares of our common stock at an exercise price of \$3.90 per share, issued to participants in our public offering in May 2016. These warrants are exercisable until May 2021.
- Warrants exercisable for 2,910,281 shares of our common stock at an exercise price of \$1.10 per share, issued to participants in our public offering in October 2016. These warrants are exercisable until October 2021.
- Warrant exercisable for 1,434,639 shares of our common stock at an exercise price of \$1.50 per share, issued to Ally Bridge LB Healthcare Master Fund Limited in a private placement transaction in August 2017. This warrant is exercisable until August 2022.
- Warrants exercisable for 2,160,000 shares of our common stock at an exercise price of \$2.50 per share, issued to participants in an offering of our common stock in March 2017. These warrants are exercisable until October 2022.
- Warrant exercisable for 246,250 shares of our common stock at an exercise price of \$0.85 per share, issued to the placement agent in connection with an offering of our common stock in December 2017. This warrant is exercisable from June 5, 2018 until December 2022.

## DILUTION

If you purchase shares of our common stock in this offering, you will experience dilution to the extent of the difference between the combined public offering price per share and related warrants in this offering and our as adjusted net tangible book value per share immediately after this offering assuming no value is attributed to the warrants, and such warrants are accounted for and classified as equity. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the number of outstanding shares of our common stock. As of September 30, 2017, our net tangible book value was approximately \$4.0 million, or approximately \$0.13 per share.

After giving effect to the assumed sale by us of 18,796,992 shares of our common stock, Series A warrants to purchase up to 14,097,744 shares of our common stock and Series B warrants to purchase up to 4,699,248 shares of our common stock in this offering at an assumed combined public offering price of \$0.665 per share and related warrants (the last reported sale price of our common stock on The NASDAQ Capital Market on January 19, 2018), after deducting the estimated placement agent fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2017 would have been approximately \$15.2 million, or approximately \$0.31 per share. This represents an immediate increase in net tangible book value of \$0.18 per share to existing stockholders and an immediate dilution of \$0.355 per share to new investors purchasing shares of our common stock and related warrants in this offering, attributing none of the assumed combined public offering price to the warrants offered hereby. The following table illustrates this per share dilution:

Assumed combined public offering price per share and related warrant	\$0.665
Net tangible book value per share as of September 30, 2017	\$0.13
Increase in net tangible book value per share after this offering	0.18
As adjusted net tangible book value per share after this offering	0.31
Dilution per share to new investors	<u>\$0.355</u>

A \$0.25 increase (decrease) in the assumed combined public offering price of \$0.665 per share and related warrant would result in an increase (decrease) in our as adjusted net tangible book value of approximately \$4.4 million or approximately \$0.09 per share, and would result in an increase (decrease) in the dilution to new investors of approximately \$0.16 per share, assuming that the number of shares of our common stock and related warrants sold by us remains the same, after deducting the estimated placement agent fees and estimated offering expenses payable by us.

We may also increase or decrease the number of shares of common stock and related warrants we are offering from the assumed number of share of common stock and related warrants set forth above. An increase of 1.0 million in the assumed number of shares of common stock and related warrants sold by us in this offering would result in an increase in our as adjusted net tangible book value of approximately \$0.6 million or approximately \$0.01 per share, and would result in a decrease in the dilution to new investors of approximately \$0.01 per share, assuming that the assumed combined public offering price remains the same, after deducting the estimated placement agent fees and estimated offering expenses payable by us. A decrease of 1.0 million in the assumed number of shares of common stock and related warrants sold by us in this offering would result in a decrease in our as adjusted net tangible book value of approximately \$0.6 million or approximately \$0.01 per share, and would result in an increase in the dilution to new investors of approximately \$0.01 per share, assuming that the assumed combined public offering price remains the same, after deducting the estimated placement agent fees and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares and related warrants sold in this offering and other terms of this offering determined at pricing.

The foregoing discussion and table do not take into account further dilution to new investors that could occur upon the exercise of outstanding options or warrants having a per share exercise price less than the per share offering price to the public in this offering. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The table and discussion above are based on 30,258,743 shares of our common stock outstanding as of September 30, 2017 and excludes as of such date:

- 2,484,286 shares of our common stock issuable upon the exercise of stock options, with a weighted-average exercise price of \$3.93 per share;
- 360,920 shares of our common stock issuable upon the settlement of outstanding restricted stock units;
- 8,402,275 shares of our common stock issuable upon the exercise of outstanding warrants, with a weighted-average exercise price of \$2.69 per share;

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- 246,250 shares of our common stock issuable upon the exercise of outstanding warrants by the placement agent of a registered direct offering of our common stock in December 2017, with an exercise price of \$0.85 per share;
- 4,925,000 shares of our common stock issued in a registered direct offering of our common stock in December 2017; and
- 813,771 other shares of our common stock reserved for future issuance under our 2013 Amended and Restated Equity Incentive Plan.

## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

We are offering 18,796,992 shares of our common stock and warrants, at an assumed combined public offering price of \$0.665 per share and related warrants (the last reported sale price of our common stock on January 19, 2018). We will offer each share of our common stock together with 0.75 of a Series A warrant to purchase one share of our common stock and 0.25 of a Series B warrant to purchase one share of our common stock. The shares of our common stock and related warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the warrants offered hereby.

The following description of our capital stock is not complete and is subject to and qualified in its entirety by our amended certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, and by the relevant provisions of the Delaware General Corporation Law.

### **Common Stock**

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

#### ***Voting Rights***

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

#### ***Dividend Rights***

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

#### ***Liquidation Rights***

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

#### ***Other Matters***

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

All of our outstanding shares of common stock are fully paid and nonassessable.

### **Registration Rights**

Under the terms of the warrants issued to certain designees of the representative of the underwriters in connection with our initial public offering, the holders have demand and piggyback registration rights. The holder(s) of at least 51% of the registrable securities, as defined in the warrants, have the right, subject to specified exceptions, to make one demand that we file a registration statement to register all or a portion of their shares. These demand registration rights expire on February 4, 2019, and a demand pursuant to such rights must be made prior to February 4, 2018.

In addition, the holder of each warrant has the right to include its shares in any registration statement we file. If we register any securities for public sale, the holder will have the right to include its shares in the registration statement, provided that the underwriters of any such underwritten offering will have the right to limit the number of shares to be included in the registration statement. These piggyback registration rights expire on February 4, 2021.

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

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

### ***Section 203 of the Delaware General Corporation Law***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years before the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

### ***Certificate of Incorporation and Bylaws***

Our certificate of incorporation and/or bylaws provide that:

- our board of directors is classified into three classes of equal (or roughly equal) size, with all directors serving for a three-year term and the directors of only one class being elected at each annual meeting of stockholders, so that the terms of the classes of directors are “staggered”;
- the authorized number of directors can be changed only by resolution of our board of directors;
- our bylaws may be amended or repealed by our board of directors or our stockholders;
- no action can be taken by stockholders except at an annual or special meeting of the stockholders called in accordance with our bylaws, and stockholders may not act by written consent, unless the stockholders amend the certificate of incorporation to provide otherwise;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board;
- our board of directors will be authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;

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- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

### **Potential Effects of Authorized but Unissued Stock**

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

### **Warrants**

The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions of the form of warrant for a complete description of the terms and conditions of the warrants.



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*Form.* The warrants will be issued in book-entry form under a warrant agent agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us, and shall initially be represented by one or more book-entry certificates deposited with DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. You should review a copy of the form of warrant, which is attached as an exhibit to the registration statement of which this prospectus forms a part, for a complete description of the terms and conditions of the warrants.

*Exercisability.* The warrants are exercisable at any time after their original issuance, expected to be \_\_\_\_\_, 2018, and at any time up to the date that is five years after their original issuance with respect to the Series A warrants and six months after their original issuance with respect to the Series B warrants. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

*Exercise Limitation.* A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

*Exercise Price.* The warrants will have an exercise price of not less than 100% of the last reported sale price of our common stock on the trading day immediately preceding the pricing of this offering. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Transferability.* Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

*Exchange Listing.* There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

*Fundamental Transactions.* If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the warrant following such fundamental transaction.

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*Rights as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

**Transfer Agent and Warrant Agent**

The transfer agent of our common stock and the warrants being offered hereby is Continental Stock Transfer & Trust Company.

## PLAN OF DISTRIBUTION

### Placement Agency Agreement

In connection with this offering, we will enter into a placement agency agreement with Dawson James Securities, Inc., pursuant to which Dawson James Securities, Inc. will agree to act as our exclusive placement agent on a best efforts basis in connection with the sale of our common stock and warrants. The placement agent will not purchase or sell any securities offered by us under this prospectus for its own account, nor will it be required to arrange the purchase or sale of any specific number or dollar amount of the securities, but the placement agent will agree to act as our agent and to use its reasonable best efforts to arrange for the sale of all of the securities in this offering. The placement agent may engage selected dealers to assist in the placement of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering.

The placement agency agreement will provide that the obligations of the placement agent are subject to certain conditions precedent, including, among other things, the absence of any material adverse change in our business and the receipt of customary legal opinions, letters and certificates. In addition, we will make certain representations and warranties in the placement agency agreement and we will agree to certain covenants in the placement agent agreement.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the Securities Act and the Exchange Act, including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities; and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Upon closing, we will deliver to each purchaser delivering funds the number of shares of common stock and warrants purchased by such purchaser in electronic format.

### Fees and Expenses

We will pay the placement agent a fee equal to 7% of the gross proceeds from the sale of the common stock and warrants in this offering. We have also agreed to reimburse the placement agent for its expenses in connection with this offering, up to \$85,000, and have agreed to reimburse the placement agent for its reasonable “blue sky” fees and expenses, of \$25,000.

We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately \$340,000. Because there is no minimum offering amount required as a condition to closing in this offering, the actual offering amount, placement agent fees and proceeds to us, if any, in this offering may be substantially less than the maximum offering amounts set forth in this prospectus.

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### **Indemnification**

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and liabilities arising from breaches of representations and warranties contained in the placement agency agreement, or to contribute to payments that the placement agent may be required to make in respect of those liabilities.

### **Lock-up Agreements**

We, our officers, directors and certain of our stockholders have agreed, subject to limited exceptions, for a period of 90 days after the date of the placement agency agreement, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the placement agency agreement or thereafter acquired without the prior written consent of the placement agent. The placement agent may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

### **Listing, Transfer Agent and Warrant Agent**

Our common stock is listed on The NASDAQ Capital Market under the symbol “BIOC.” There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited. The transfer agent of our common stock is Continental Stock Transfer & Trust Company. Continental Stock Transfer & Trust Company will act as the warrant agent for the warrants.

### **Electronic Distribution**

This prospectus in electronic format may be made available on websites or through other online services maintained by the placement agent, or by its affiliates. Other than this prospectus in electronic format, the information on the placement agent’s website and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as placement agent, and should not be relied upon by investors.

### **Other**

From time to time, the placement agent and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received and, may in the future receive, customary fees. In the course of their businesses, the placement agent and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the placement agent and their affiliates may at any time hold long or short positions in such securities or loans. Dawson James served as placement agent for a public offering we completed in December 2017, pursuant to which Dawson James received cash commissions, placement agent warrants to purchase 246,250 shares of common stock at an exercise price of \$0.85 per share, and we granted Dawson James a right of first refusal to act as managing underwriter or placement agent for any and all future equity, equity-linked or debt (excluding commercial bank debt) offerings during the six months following the consummation of the December offering. Except as set forth in the preceding sentence, the placement agent has not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus and we do not expect to retain the placement agent to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

## LEGAL MATTERS

The validity of the shares of common stock and warrants being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. The placement agent is being represented by Schiff Hardin LLP, Washington, DC.

## EXPERTS

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our balance sheets as of December 31, 2015 and 2016, and the related statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the two years in the period ended December 31, 2016, as set forth in their report, which report expresses an unqualified opinion and includes an explanatory paragraph relating to the uncertainty of our ability to continue as a going concern. We have included such financial statements in this prospectus and in this registration statement in reliance on the report of Mayer Hoffman McCann P.C. given on their authority as experts in accounting and auditing.

## MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning the pharmaceutical industry, including our market opportunity, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly-available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors."

## 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 and warrants 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 and warrants 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](http://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.

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**BIOCEPT, INC.**

**FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying balance sheets of **Biocept, Inc.** as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, shareholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of **Biocept, Inc.** as of December 31, 2016 and 2015, and the results of its operations and its cash flows the years then ended in conformity with accounting principles generally accepted in the United States of America.

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

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



**Biocept, Inc.**

**Balance Sheets**

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

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

**Biocept, Inc.**

**Statements of Operations and Comprehensive Loss**

	<b>For the year ended December 31,</b>	
	<b>2015</b>	<b>2016</b>
Revenues:	\$ 609,909	\$ 3,223,096
Costs and expenses:		
Cost of revenues	4,596,158	6,920,111
Research and development expenses	2,857,770	2,713,367
General and administrative expenses	5,686,398	6,560,425
Sales and marketing expenses	3,880,386	5,054,230
Total costs and expenses	17,020,712	21,248,133
Loss from operations	(16,410,803)	(18,025,037)
Other income/(expense):		
Interest expense, net	(639,547)	(525,880)
Other income	102,432	153,648
Total other income/(expense):	(537,115)	(372,232)
Loss before income taxes	(16,947,918)	(18,397,269)
Income tax expense	(1,608)	(2,053)
Net loss and comprehensive loss	<u><u>\$(16,949,526)</u></u>	<u><u>\$(18,399,322)</u></u>
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:		
Basic	5,512,989	9,578,285
Diluted	<u>5,512,989</u>	<u>9,578,285</u>
Net loss per common share:		
Basic	\$ (3.07)	\$ (1.92)
Diluted	<u><u>\$ (3.07)</u></u>	<u><u>\$ (1.92)</u></u>

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

**Biocept, Inc.**

**Statements of Shareholders' Equity/ (Deficit)**

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

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

**Biocept, Inc.**

**Statements of Cash Flows**

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

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

**Non-cash Investing and Financing Activities:**

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

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

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

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

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

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

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

**BIOCEPT, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. The Company and Business Activities**

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

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

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

**2. Liquidity and Going Concern Uncertainty**

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

While the Company is currently in the commercialization stage of operations, the Company has not yet achieved profitability and anticipates that it will continue to incur net losses for the foreseeable future. Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred stock, proceeds from the exercise of warrants to purchase common stock, proceeds from the issuance of debt, and revenues from laboratory services. The Company's principal uses of cash have included cash used in operations, payments relating to purchases of property and equipment and repayments of borrowings. The Company expects that the principal uses of cash in the future will be for continuing operations, hiring of sales and marketing personnel and increased sales and marketing activities, funding of research and development, capital expenditures, and general working capital requirements. The Company expects that, as revenues grow, sales and marketing and research and development expenses will continue to grow, albeit at a slower rate and, as a result, the Company will need to generate significant growth in net revenues to achieve and sustain income from operations.

Subsequent to the closing of the Company's public offering in February 2015, cash proceeds of approximately \$9.8 million have been received by the Company from the exercise of warrants sold in this offering, while approximately \$2.7 million in gross warrant proceeds remain outstanding and available to be exercised at \$4.68 per share until their expiration in February 2020. In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as the Company's public float is less than \$75 million. A public offering of the Company's common stock and warrants to purchase its common stock was effected under this shelf registration statement on April 29, 2016, the closing of which occurred on May 4, 2016, pursuant to which the Company received net cash

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proceeds of approximately \$4.3 million (see Note 4). Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately \$4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at \$3.90 per share until their expiration in May 2021. In connection with its public offering in May 2016, the Company has agreed to certain contractual terms that limit its ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. A public offering of the Company's common stock and warrants to purchase its common stock was effected under an underwriting agreement dated October 14, 2016 between the Company, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, the closing of which occurred on October 19, 2016, pursuant to which the Company received net cash proceeds of approximately \$9.0 million (see Note 4). Subsequent to December 31, 2016, cash proceeds of approximately \$5.3 million have been received by the Company from the exercise of warrants sold in this offering, while approximately \$5.4 million in gross warrant proceeds remain outstanding and available to be exercised at \$1.10 per share until their expiration in October 2021.

### **Management's Plan to Continue as a Going Concern**

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Until the Company can generate significant cash from operations, including assay revenues, management's plans to obtain such resources for the Company include proceeds from offerings of the Company's equity securities or debt, or transactions involving product development, technology licensing or collaboration. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all.

### **3. Summary of Significant Accounting Policies**

#### **Basis of Presentation**

The financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America. Certain prior period amounts have been reclassified to conform to the current period presentation.

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

#### **Use of Estimates**

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates these estimates and judgments, including those related to inventories, long-lived assets, income taxes, and stock-based compensation. The Company bases its estimates on various assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

#### **Revenue Recognition**

Four basic criteria must be met before the Company recognizes revenue: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. For contract partners, revenue is recorded based upon the contractually agreed upon fee schedule. When assessing collectability, the Company considers whether there is sufficient payment history to reliably estimate a payor's individual payment patterns. For new tests where there is limited evidence of payment history at the time the tests are completed, the Company recognizes revenue equal to the amount of cash received until such time as reimbursement experience can be established.

Approximately 11% and 7% of the Company's revenues for the years ended December 31, 2015 and 2016, respectively, resulted from agreements with contracted partners not associated with third party insurance or payor reimbursement. This revenue is derived from clinical laboratory testing performed in the Company's laboratories under agreements with such partners. As there is a contractually agreed upon price, and collectability from the partners is reasonably assured, revenues for these tests are recognized at the time the test is completed and results are delivered.



## **Cash**

The Company places its cash with reputable financial institutions that are insured by the Federal Deposit Insurance Corporation, or FDIC. At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company has not experienced any losses in its cash and believes they are not exposed to any significant credit risk.

## **Fair Value Measurement**

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

## **Concentration of Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments.

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

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

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

## **Accounts Receivable**

Accounts receivable are carried at original invoice amounts, less an estimate for doubtful receivables, based on a review of all outstanding amounts on a periodic basis. The estimate for doubtful receivables is determined from an analysis of the accounts receivable on a quarterly basis, and is recorded as bad debt expense. As the Company only recognizes revenue to the extent collection is expected and reasonably assured, bad debt expense related to receivables from patient service revenue is recorded in general and administrative expense in the statement of operations and comprehensive loss. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received. As of December 31, 2015 and 2016, management determined that all of the amounts recorded as accounts receivable were collectible, and no allowance for doubtful accounts was needed.

## **Inventories**

Inventories are valued at the lower of cost or market value. Cost is determined by the average cost method. The Company records adjustments to its inventory for estimated obsolescence or diminution in market value equal to the difference between the cost of the inventory and the estimated market value. At the point of loss recognition, a new cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. In addition, the Company records a liability for firm, noncancelable, and unconditional purchase commitments with contract manufacturers and suppliers for quantities in excess of the Company's future demand forecasts consistent with its valuation of excess and obsolete inventory.

## **Fixed Assets**

Fixed assets consist of machinery and equipment, furniture and fixtures, computer equipment and software, leasehold improvements, financed equipment and construction in process. Fixed assets are stated at cost less accumulated depreciation and amortization. Additions, improvements, and major renewals are capitalized. Maintenance, repairs, and minor renewals are expensed as incurred. Depreciation is determined using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leasehold improvements are amortized over the life of the lease or the asset, whichever is shorter. Depreciation expense for the years ended December 31, 2015 and 2016 was approximately \$261,000 and \$322,000, respectively.

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

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

## **Stock-based Compensation**

The Company measures and recognizes compensation expense for all stock-based awards made to employees and directors based on their grant date fair values. The Company estimates the fair value of stock option awards on the date of grant using the Black-Scholes option pricing model, while the fair value of restricted stock unit awards, or RSUs, is determined by the Company's stock price on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straight-line method. The Company estimates forfeitures at the time of grant and revises these estimates in subsequent periods if actual forfeitures differ from those estimates (see Note 10).

The Company determines the fair value of the stock-based compensation awards granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable. All issuances of equity instruments issued to non-employees as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. These awards are recorded in expense and additional paid-in capital in shareholders' equity over the applicable service periods based on the fair value of the options at the end of each period.

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

## **Research and Development**

Research and development costs are expensed as incurred. The amounts expensed in the years ended December 31, 2015 and 2016 were approximately \$2,858,000 and \$2,713,000, respectively, which includes salaries of research and development personnel.

## **Income Taxes**

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

Deferred tax assets are reduced by a valuation allowance when, in management's opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. The Company's valuation allowance is based on available evidence, including its current year operating loss, evaluation of positive and negative evidence with respect to certain specific deferred tax assets including evaluation sources of future taxable income to support the realization of the deferred tax assets. The Company has established a full valuation allowance on the deferred tax assets as of December 31, 2015 and 2016, and therefore has not recognized any income tax benefit or expense in the periods presented.

A tax benefit from uncertain tax positions may be recognized by the Company when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

The Company recognizes interest and/or penalties related to income tax matters in income tax expense. There is no accrual for interest or penalties for income taxes on the balance sheets at December 31, 2015 and 2016, and the Company has not recognized interest and/or penalties in the statements of operations and comprehensive loss for the years ended December 31, 2015 and 2016.

### **Recent Accounting Pronouncements**

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

In June 2014, the FASB issued authoritative guidance requiring share-based payments with a performance target which affects vesting and that could be achieved after the requisite service period be treated as a performance condition. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company adopted this guidance for the reporting period beginning on January 1, 2016. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

In August 2014, the FASB issued authoritative guidance requiring management to evaluate whether there are conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. This guidance is effective for the annual reporting period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company adopted this guidance during the year ended December 31, 2016. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

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

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

In February 2016, the FASB issued authoritative guidance requiring, among other things, that entities recognize the assets and liabilities arising from leases on the balance sheet under revised criteria, while the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria in the previous leases guidance. In transition,

lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company anticipates that the adoption of this guidance will materially affect its statement of financial position and will require changes to its processes. The Company has not yet made any decision on the timing of adoption or method of adoption with respect to the optional practical expedients, but expects to during 2018.

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

In March 2016, the FASB issued authoritative guidance requiring entities to assess whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts, and clarifies what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts. This guidance is effective on a modified retrospective basis for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

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

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

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

#### **4. Sales of Equity Securities**

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

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In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as the Company's public float is less than \$75 million. Pursuant to an exclusive placement agent agreement dated April 25, 2016 between the Company and H.C. Wainwright & Co., LLC, or Wainwright, and a securities purchase agreement dated April 29, 2016 between the Company and the purchasers signatory thereto, a public offering of 1,662,191 shares of the Company's common stock and warrants to purchase up to an aggregate of 1,163,526 shares of common stock was effected under this registration statement at a combined offering price of \$3.00. All warrants sold in this offering have a per share exercise price of \$3.90, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the purchasers occurred on May 4, 2016, pursuant to which the Company received, after deducting \$0.7 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, approximately \$4.3 million of net cash proceeds. Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately \$4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at \$3.90 per share until their expiration in May 2021. In connection with its public offering in May 2016, the Company has agreed to certain contractual terms that limit its ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

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

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

## **5. Fair Value Measurement**

The estimated fair value of the April 2014 Credit Facility at December 31, 2016 approximated carrying value, which was determined using a discounted cash flow analysis. The analysis considered interest rates of instruments with similar maturity dates, which involved the use of significant unobservable Level 3 inputs.

In connection with the closing of the Company's February 2015 public offering, warrants were issued to buy (in the aggregate) up to 2,666,666 shares of common stock with an estimated grant date fair value of approximately \$7.7 million, which was recorded as an offset to additional paid-in capital within common stock issuance costs. Also in connection with the closing of the Company's follow-on public offering on February 13, 2015, the underwriters were granted a 45 day option from the closing date of the offering to

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purchase up to 400,000 additional shares of common stock at a price of \$3.75 per share and/or additional warrants to purchase up to 400,000 shares of common stock at a price of \$0.0003 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any. The estimated aggregate grant date fair value of these over-allotment options and warrants of approximately \$1.6 million was also recorded to common stock issuance costs as a component of additional paid-in capital. The fair values of these over-allotment options and all common stock warrants issued in this offering were estimated using Black-Scholes valuation models with the following assumptions:

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

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

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

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

	<b>Over-allotment Options</b>	<b>Warrants</b>
Stock price	\$ 0.93	\$ 0.93
Exercise price	\$ 1.0331	\$ 1.10
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.25%	1.24%
Expected life (in years)	0.08	5.00
Expected volatility	12.9%	80.0%



## 6. Balance Sheet Details

The following provides certain balance sheet details:

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

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

## 7. April 2014 Credit Facility

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

On June 30, 2016, the Company entered into an amendment of the April 2014 Credit Facility. This amendment required the Company to make interest-only payments on the term loan from July 1, 2016 through September 30, 2016, and also requires an additional final payment of \$50,000 to the lender. The terms of the amendment require the amortization of the outstanding amount due under the term loan to commence at the end of the applicable interest-only period, with monthly payments of principal and interest, in arrears, being made by the Company to the lender in consecutive monthly installments following such interest-only period. Additionally, pursuant to the amendment the aggregate outstanding principal amount of the Company's permitted indebtedness, consisting of capitalized lease obligations and purchase money indebtedness outstanding at any time, was increased to \$1.2 million. The June 30, 2016 amendment of the April 2014 Credit Facility was accounted for as a modification of debt under applicable accounting guidance. On March 27, 2017, the Company received a waiver from the lender regarding exceeding the permitted indebtedness limit during the month ended January 31, 2017.



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

A warrant to purchase up to 17,655 shares of the Company's common stock at an exercise price of \$14.16 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014. Issuance costs of \$102,498 associated with the term loan under the April 2014 Credit Facility were recorded as a discount to outstanding debt as of the closing date, resulting in net proceeds of \$4,897,502. The estimated fair value of the warrant issued of \$233,107 was also recorded as a discount to outstanding debt as of the closing date. The discounts and other issuance costs are amortized to interest expense utilizing the effective interest method over the underlying term of the loan, with a total unamortized discount of \$78,408 remaining at December 31, 2016. The effective annual interest rate associated with the April 2014 Credit Facility was 11.50% and 13.87% at December 31, 2015 and 2016, respectively. As of December 31, 2016, total principal payments of \$1,934,665 and \$1,201,409 were due under the April 2014 Credit Facility during the years ending December 31, 2017 and 2018, respectively.

## 8. Equipment Financings

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

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

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

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

## 9. Supplier Financings

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

## 10. Stock-Based Compensation

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

### Equity Incentive Plans

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

### Stock Options

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

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

The assumptions used in the Black-Scholes pricing model for options granted during the years ended December 31, 2015 and 2016 are as follows:

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

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

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

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

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

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

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

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

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

On July 25, 2016, the Company entered into an employment agreement with its new Chief Financial Officer, Senior Vice President of Operations and Secretary, or CFO. Pursuant to the terms of this employment agreement, on July 29, 2016 the CFO was granted inducement stock option awards with an exercise price of \$1.95 per share to purchase up to (i) 66,666 shares of the Company's common stock with an estimated grant date fair value of \$1.45 per share, 25% of which will vest on the one-year anniversary of the commencement of the CFO's employment with the Company, and remainder of which will vest in equal monthly installments over the

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following three years, and (ii) 33,333 shares of the Company's common stock with an estimated grant date fair value of \$1.26 per share, which vest upon the Company's achievement of specified corporate goals for 2016 and the consummation of a specified financing transaction. Subsequent to the year ended December 31, 2016, 16,383 stock options were declared vested by our Board of Directors in satisfaction of the 33,333 performance option award granted on July 29, 2016, and the remaining 16,950 shares underlying this award was forfeited.

### Restricted Stock

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

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

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

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

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

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

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

## Stock-based Compensation Expense

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

	Years Ended December 31,	
	2015	2016
<b>Stock Options</b>		
Cost of revenues	\$ 68,660	\$ 115,266
Research and development expenses	103,138	123,330
General and administrative expenses	933,018	1,071,490
Sales and marketing expenses	149,917	142,741
Total expenses related to stock options	1,254,733	1,452,827
<b>RSUs</b>		
Cost of revenues	—	32,338
Research and development expenses	10,724	30,261
General and administrative expenses	112,367	38,274
Sales and marketing expenses	—	40,247
Total stock-based compensation	<u>\$1,377,824</u>	<u>\$1,593,947</u>

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

## 11. Common Stock Warrants Outstanding

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

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

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

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

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

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

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

## 12. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the years ended December 31, 2015 and 2016, the outstanding RSUs, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

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

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

	<u>For the year ended December 31,</u>	
	<u>2015</u>	<u>2016</u>
Preferred warrants outstanding (number of common stock equivalents)	529	529
Common warrants outstanding	784,230	11,623,987
RSUs outstanding	25,752	174,249
Common options outstanding	713,659	896,662
<u>Total anti-dilutive common share equivalents</u>	<u>1,524,170</u>	<u>12,695,427</u>

## 13. 401(k) Plan

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

## 14. Income Taxes

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

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

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

	For the year ended December 31,	
	2015	2016
Income tax at statutory rate	\$ (5,762,293)	\$ (6,255,072)
State liability	(334,494)	(260,835)
Permanent items	34,852	67,151
Stock compensation	334,609	157,250
Nondeductible interest	(316)	21,548
Expiration of net operating losses	796,699	—
Research and development credit	(164,967)	(170,950)
State rate change	746,238	44,421
Estimated section 382 limitation	48,484,354	9,256,295
Other	(1,041)	96,406
Valuation allowance	(44,132,033)	(2,954,161)
Provision for income tax	<u>\$ 1,608</u>	<u>\$ 2,053</u>

Deferred income taxes are provided for temporary differences in recognizing certain income and expense items for financial and tax reporting purposes. The deferred tax assets consisted primarily of the income tax benefits from estimated net operating loss carryforwards, deferred rent, and estimated research and development credits. Valuation allowances have been recorded to fully offset deferred tax assets at December 31, 2015 and 2016, as it is more likely than not that the assets will not be utilized.

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

For the years ended December 31, 2015 and 2016, the Company has evaluated the various tax positions reflected in its income tax returns for both federal and state jurisdictions, to determine if the Company has any uncertain tax positions on the historical tax returns. The Company recognizes the impact of an uncertain tax position on an income tax return at the largest amount that the relevant taxing authority is more-likely-than not to sustain upon audit. The Company does not recognize uncertain income tax positions if they have less than 50 percent likelihood of being sustained. Based on this assessment, the Company believes there are no tax positions for which a liability for unrecognized tax benefits should be recorded as of December 31, 2015 or 2016. The Company is subject to taxation in the United States, California and other states. The Company may earn taxable income in some states in future periods for which there are no net operating loss carryforward credits to offset the resulting taxes owed to these states. The Company's federal filings prior to 2012 and the Company's state filings prior to 2011 are no longer subject to examination. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. Due to the existence of the valuation allowance, future changes in unrecognized tax benefits will not impact the Company's effective tax rate. The Company is currently not under examination by any taxing authorities and does not believe its unrecognized tax benefits will significantly change in the next twelve months.



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The tax effects of carryforwards and other temporary differences that give rise to deferred tax assets consist of the following:

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

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

Upon the occurrence of an ownership change under Section 382 of the Code as outlined above, utilization of the estimated net operating loss and research and development credit carryforwards are subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company’s stock at the time of the ownership change by the applicable long-term, tax-exempt rate, which could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the estimated net operating loss or research and development credit carryforwards before utilization. The Company has not yet completed an analysis to determine whether an ownership change has occurred, however, the Company believes ownership changes likely occurred during both 2015 and 2016. As a result, the Company has estimated that the use of its net operating loss is limited and has disclosed in the table above only the amounts it estimates could be used in the future, which remain fully offset by a valuation allowance to reduce the net asset to zero.

### 15. Related Party Transactions

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

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

Seven members of the Company’s Board of Directors, including its Chief Executive Officer, and all three of the Company’s other executive officers participated in the Company’s public offering in October 2016, purchasing an aggregate of 534,088 shares of common stock and warrants to purchase up to an aggregate of 534,088 shares of common stock for total gross proceeds to the Company of \$587,497. Additionally, a trust affiliated with a beneficial owner of more than 10% of the Company’s outstanding common stock prior to the Company’s public offering in October 2016, Claire K.T. Reiss, participated in the Company’s public offering in October 2016, purchasing 227,272 shares of its common stock and warrants to purchase up to 227,272 shares of its common stock for total gross proceeds to the Company of \$249,999. Further, several of the Company’s employees and one of its consultants participated in the Company’s public offering in October 2016, purchasing an aggregate of 79,090 shares of its common stock and warrants to purchase up to an aggregate of 79,090 shares of its common stock for total aggregate gross proceeds to the Company of \$86,999.

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

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

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

## **16. Commitments and Contingencies**

### **Operating Leases**

The Company leases office, laboratory, and warehouse space at its San Diego, California facility under a non-cancelable operating lease. The initial lease was for an eight-year term expiring in 2012. In November 2011, the Company extended the lease term through October 31, 2018 and expanded the original premises by 9,849 square feet. Under the amended lease, the landlord delivered the expanded premises in May 2013. In September 2013, the Company extended the lease term through July 31, 2020. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent. During each of the years ended December 31, 2015 and 2016, total rent expense recorded in the Company's statements of operations and comprehensive loss was approximately \$1,272,000.

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

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

### **Purchase Commitment**

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

### **Legal Proceedings**

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

## 17. Selected Quarterly Financial Data (Unaudited)

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

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<b>December 31, 2015</b>				
Balance sheet data:				
Cash	\$19,294,706	\$ 16,523,975	\$12,541,919	\$ 8,821,329
Total assets	20,899,513	18,317,659	14,196,386	10,586,918
Total non-current liabilities	5,083,216	4,234,552	3,877,362	3,553,395
Total shareholders' equity	13,582,795	11,049,961	6,928,277	3,692,735
Statement of operations and comprehensive loss data:				
Revenues	\$ 150,002	\$ 76,768	\$ 164,856	\$ 218,283
Cost of revenues <sup>1</sup>	1,147,682	1,013,075	1,159,710	1,275,691
Research and development expenses <sup>1</sup>	651,420	744,242	677,729	784,379
General and administrative expenses	1,292,049	1,359,226	1,630,608	1,404,515
Sales and marketing expenses	709,456	851,109	1,055,653	1,264,168
Loss from operations	(3,650,605)	(3,890,884)	(4,358,844)	(4,510,470)
Net loss	\$ (3,800,728)	\$ (4,035,105)	\$ (4,496,193)	\$ (4,617,500)
Net loss per common share: <sup>2</sup>				
Basic	\$ (1.10)	\$ (0.67)	\$ (0.72)	\$ (0.73)
Diluted	\$ (1.10)	\$ (0.67)	\$ (0.72)	\$ (0.73)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	3,457,556	6,005,145	6,242,604	6,307,316
Diluted	3,457,556	6,005,145	6,242,604	6,307,316

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

<sup>2</sup> Basic and diluted net loss per common share are computed independently for each of the components and quarters presented. Therefore, the sum of quarterly basic and diluted per share information may not equal annual basic and diluted net loss per common share.

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	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<b>December 31, 2016</b>				
Balance sheet data:				
Cash	\$ 4,572,750	\$ 3,751,570	\$ 678,855	\$ 4,609,332
Total assets	6,780,830	6,303,153	3,282,549	7,578,326
Total non-current liabilities	3,132,372	3,134,593	2,793,258	2,526,113
Total shareholders' equity/(deficit)	(489,231)	(419,402)	(4,556,158)	658,661
Statement of operations and comprehensive loss data:				
Revenues	\$ 221,369	\$ 662,860	\$ 1,047,280	\$ 1,291,587
Cost of revenues	1,474,790	1,669,571	1,876,288	1,899,462
Research and development expenses	728,076	716,279	600,613	668,399
General and administrative expenses	1,487,224	1,517,664	1,918,543	1,636,994
Sales and marketing expenses	1,304,899	1,291,709	1,278,455	1,179,167
Loss from operations	(4,773,620)	(4,532,363)	(4,626,619)	(4,092,435)
Net loss	\$(4,875,198)	\$ (4,594,174)	\$ (4,743,076)	\$ (4,186,874)
Net loss per common share: <sup>1</sup>				
Basic	\$ (0.74)	\$ (0.60)	\$ (0.57)	\$ (0.27)
Diluted	\$ (0.74)	\$ (0.60)	\$ (0.57)	\$ (0.27)
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	6,566,992	7,702,286	8,370,691	15,620,049
Diluted	6,566,992	7,702,286	8,370,691	15,620,049

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

## 18. Subsequent Events

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

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

**Biocept, Inc.**

**Condensed Balance Sheets**

	<u>December 31,</u> <u>2016</u>	<u>September 30,</u> <u>2017</u> (unaudited)
Current assets:		
Cash	\$ 4,609,332	\$ 5,879,025
Accounts receivable, net	128,969	1,133,372
Inventories, net	549,045	775,106
Prepaid expenses and other current assets	484,649	412,916
Total current assets	5,771,995	8,200,419
Fixed assets, net	1,806,331	2,919,796
Total assets	<u>\$ 7,578,326</u>	<u>\$ 11,120,215</u>
Current liabilities:		
Accounts payable	\$ 960,486	\$ 1,593,048
Accrued liabilities	1,160,036	2,174,385
Supplier financings	75,691	121,043
Current portion of equipment financings	262,674	304,585
Current portion of credit facility, net	1,934,665	1,645,136
Total current liabilities	4,393,552	5,838,197
Non-current portion of equipment financings	778,643	950,123
Non-current portion of credit facility, net	1,123,001	—
Non-current portion of interest payable	227,177	—
Non-current portion of deferred rent	397,292	305,816
Total liabilities	6,919,665	7,094,136
Commitments and contingencies (see Note 11)		
Shareholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 authorized; no shares issued and outstanding at December 31, 2016 and September 30, 2017.	—	—
Common stock, \$0.0001 par value, 150,000,000 authorized; 17,499,397 issued and outstanding at December 31, 2016; 30,258,743 issued and outstanding at September 30, 2017.	1,750	3,026
Additional paid-in capital	174,292,781	193,606,087
Accumulated deficit	(173,635,870)	(189,583,034)
Total shareholders' equity	658,661	4,026,079
Total liabilities and shareholders' equity	<u>\$ 7,578,326</u>	<u>\$ 11,120,215</u>

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

**Biocept, Inc.**

**Condensed Statements of Operations and Comprehensive Loss**

**(Unaudited)**

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2017	2016	2017
Net revenues	\$ 1,047,280	\$ 1,111,411	\$ 1,931,509	\$ 4,073,437
Costs and expenses:				
Cost of revenues	1,876,288	2,487,054	5,020,649	6,985,213
Research and development expenses	600,613	856,698	2,044,968	2,455,947
General and administrative expenses	1,918,543	1,834,771	4,923,431	5,539,432
Sales and marketing expenses	1,278,455	1,675,852	3,875,063	4,701,030
Total costs and expenses	5,673,899	6,854,375	15,864,111	19,681,622
Loss from operations	(4,626,619)	(5,742,964)	(13,932,602)	(15,608,185)
Other income/ (expense):				
Interest expense	(154,869)	(88,269)	(393,029)	(385,172)
Other income	38,412	12,804	115,236	51,216
Total other income/ (expense):	(116,457)	(75,465)	(277,793)	(333,956)
Loss before income taxes	(4,743,076)	(5,818,429)	(14,210,395)	(15,942,141)
Income tax expense	—	(2,877)	(2,053)	(5,023)
Net loss and comprehensive loss	<u><u>\$ (4,743,076)</u></u>	<u><u>\$ (5,821,306)</u></u>	<u><u>\$ (14,212,448)</u></u>	<u><u>\$ (15,947,164)</u></u>
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	<u>8,370,691</u>	<u>29,605,953</u>	<u>7,549,663</u>	<u>25,816,181</u>
Diluted	<u>8,370,691</u>	<u>29,605,953</u>	<u>7,549,663</u>	<u>25,816,181</u>
Net loss per common share:				
Basic	<u>\$ (0.57)</u>	<u>\$ (0.20)</u>	<u>\$ (1.88)</u>	<u>\$ (0.62)</u>
Diluted	<u>\$ (0.57)</u>	<u>\$ (0.20)</u>	<u>\$ (1.88)</u>	<u>\$ (0.62)</u>

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

**Biocept, Inc.**

**Condensed Statements of Cash Flows**

**(Unaudited)**

	<b>For the nine months ended September 30,</b>	
	<b>2016</b>	<b>2017</b>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$(14,212,448)	\$(15,947,164)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	246,864	394,708
Inventory reserve	(40,708)	(22,431)
Stock-based compensation	1,164,979	1,232,149
Non-cash interest expense related to credit facility and other financing activities	60,951	23,983
Increase/ (decrease) in cash resulting from changes in:		
Accounts receivable, net	(51,464)	(1,004,403)
Inventory	(107,538)	(203,630)
Prepaid expenses and other current assets	501,532	431,355
Accounts payable	991,846	508,176
Accrued liabilities	152,860	671,407
Accrued interest	58,684	71,417
Deferred rent	(22,839)	(52,143)
Net cash used in operating activities	(11,257,281)	(13,896,576)
<b>Cash Flows from Investing Activities:</b>		
Purchases of fixed assets	(391,196)	(1,055,549)
Net cash used in investing activities	(391,196)	(1,055,549)
<b>Cash Flows from Financing Activities:</b>		
Net proceeds from issuance of common stock and warrants	4,798,576	10,583,898
Proceeds from exercise of common stock warrants	—	7,498,535
Payments on equipment financings	(86,336)	(109,811)
Payments on supplier and other third-party financings	(427,934)	(314,270)
Payments on credit facility	(778,303)	(1,436,534)
Net cash provided by financing activities	3,506,003	16,221,818
Net increase/ (decrease) in Cash	(8,142,474)	1,269,693
Cash at Beginning of Period	8,821,329	4,609,332
Cash at End of Period	<u>\$ 678,855</u>	<u>\$ 5,879,025</u>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid during the period for:		
Interest	<u>\$ 282,142</u>	<u>\$ 285,260</u>
Income taxes	<u>\$ 2,053</u>	<u>\$ 5,023</u>

**Non-cash Investing and Financing Activities:**

During the nine months ended September 30, 2016 and 2017, Biocept, Inc., or the Company, financed insurance premiums of \$434,475 and \$359,622, respectively, through third-party financings.

Fixed assets purchased totaling \$755,458 and \$362,729 during the nine months ended September 30, 2016 and 2017, respectively, were recorded as equipment financing obligations and were excluded from cash purchases in the Company's unaudited condensed statements of cash flows. During the nine months ended September 30, 2016, fixed assets with an aggregate net book value of \$270,377, which had previously been recorded as equipment financings with remaining outstanding balances owed totaling \$239,994, were effectively disposed of and replaced with upgraded equipment recorded as equipment financings. During the nine months ended September 30, 2017, fixed assets with an aggregate net book value of \$34,491 were exchanged with a lender as partial payment on an outstanding equipment financing obligation balance.



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The amount of unpaid fixed asset purchases excluded from cash purchases in the Company's unaudited condensed statements of cash flows decreased from \$64,300 at December 31, 2015 to \$8,637 at September 30, 2016, and increased from \$58,066 at December 31, 2016 to \$204,501 at September 30, 2017.

An offering of the Company's common stock and warrants to purchase its common stock closed on May 4, 2016 (see Note 3). In connection with the closing of this offering, warrants were issued to purchase up to an aggregate of 1,163,526 shares of common stock at an exercise price of \$3.90 per share with a term of five years and an estimated grant date fair value of approximately \$2.0 million, which was recorded as an offset to additional paid-in capital.

An offering of the Company's common stock and warrants to purchase its common stock occurred on March 31, 2017 (see Note 3). In the offering, warrants were issued to purchase up to an aggregate of 2,160,000 shares of common stock at an exercise price of \$2.50 per share with a term of five years and an estimated grant date fair value of approximately \$2.8 million, which was recorded as an offset to additional paid-in capital (see Note 4). Additionally, approximately \$728,000 of fees and costs directly associated with the offering were recorded as an offset to additional paid-in capital within common stock issuance costs in accordance with applicable accounting guidance.

An offering of the Company's common stock and warrants to purchase its common stock occurred on August 9, 2017 (see Note 3). In the offering, warrants were issued to purchase up to an aggregate of 1,434,639 shares of common stock at an exercise price of \$1.50 per share with a term of five years and an estimated grant date fair value of approximately \$1.5 million, which was recorded as an offset to additional paid-in capital (see Note 4). Additionally, approximately \$176,000 of fees and costs directly associated with the offering were recorded as an offset to additional paid-in capital within common stock issuance costs in accordance with applicable accounting guidance.

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

**BIOCEPT, INC.**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(Unaudited)**

**1. The Company, Business Activities and Basis of Presentation**

**The Company and Business Activities**

The Company was founded in California in May 1997 and is an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or liquid biopsy. The Company's current and planned assays are intended to provide information to aid healthcare providers to identify specific oncogenic alterations that may qualify a subset of cancer patients for targeted therapy at diagnosis, progression or for monitoring in order to identify specific resistance mechanisms. Often, traditional methodologies such as tissue biopsies are insufficient or unavailable to provide the molecular subtype information necessary for clinical decisions. The Company's assays have the potential to provide more contemporaneous information on the characteristics of a patient's disease compared with traditional methodologies such as tissue biopsy and radiographic imaging. Additionally, commencing in October 2017, the Company's pathology program initiative provides the unique ability for pathologists to participate in the interpretation of liquid biopsy results, and is available to pathology practices and hospital systems throughout the United States. Further, the Company's proprietary blood collection tubes, which allow for the intact transport of research use only liquid biopsy samples from regions around the world, are anticipated to be sold to laboratory supply distributor(s) commencing in 2018.

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

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

**Basis of Presentation**

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

The unaudited condensed financial statements included in this Form 10-Q have been prepared in accordance with the U.S. Securities and Exchange Commission, or SEC, instructions for Quarterly Reports on Form 10-Q. Accordingly, the condensed financial statements are unaudited and do not contain all the information required by U.S. Generally Accepted Accounting Principles, or GAAP, to be included in a full set of financial statements. The balance sheet at December 31, 2016 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by GAAP for a complete set of financial statements. The audited financial statements for the year ended December 31, 2016, filed with the U.S. Securities and Exchange Commission, or SEC, with our Annual Report on Form 10-K on March 28, 2017 include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

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

*Reverse Stock Split*

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

### *Revenue Recognition and Related Reserves*

The Company's commercial revenues are generated from diagnostic services provided to physicians and billed to third-party insurance payers such as managed care organizations, Medicare and Medicaid and patients for any deductibles, coinsurance or copayments that may be due. The Company recognizes revenue in accordance with the provision of ASC 954-605, Health Care Entities—Revenue Recognition, which requires that four basic criteria must be met prior to recognition of revenue: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. Commencing on March 31, 2017, the Company recognizes commercial revenue related to billings for assays delivered and billed to Medicare and other third-party payers on an accrual basis when amounts that will ultimately be realized can be estimated upon delivery, whereby prior to March 31, 2017, the Company recognized revenues for its commercial diagnostic services on a cash basis as collected because the amounts ultimately expected to be received could not be estimated upon delivery due to insufficient collection history experience.

The Company bills third-party payers on a fee-for-service basis at the Company's list price and third-party commercial revenue is recorded net of contractual discounts, payer-specific allowances and other reserves. The Company's development services revenues are supported by contractual agreements and generated from assay development services provided to entities, as well as certain other diagnostic services provided to physicians. Diagnostic services are completed upon the delivery of assay results to the prescribing physician, at which time the Company bills for the service.

The Company's gross commercial revenues billed are subject to estimated deductions for such contractual discounts, payer-specific allowances and other reserves to arrive at reported net revenues, which relate to differences between amounts billed and corresponding amounts estimated to be subsequently collected. These third-party payer discounts and sales allowances are estimated based on a number of assumptions and factors, including historical payment trends, seasonality associated with the annual reset of patient deductible limits on January 1 of each year, and current and estimated future payments. Specifically, the Company maintains four such reserves: the reserve for contractual discounts, the reserve for aged non-patient receivables, the reserve for estimated patient receivables, and the reserve for other payer-specific sales allowances. The reserve for contractual discounts relates to discounts to gross amounts billed to Medicare and contracted third-party payers to arrive at the deemed "allowed expense" amount covered by that payer. The Company's contracted third-party commercial sales are recorded using an actual or contracted fee schedule at the time of sale, while estimated fee schedules are maintained for each non-contracted payer separately as part of other payer-specific sales allowances. Contractual discounts are recorded at the transaction level at the time of sale based on a fee schedule that is maintained for each contracted third-party payer. The Company periodically adjusts fee schedules for both contracted and non-contracted third-party payers based upon historical payment trends. The reserve for aged non-patient receivables reduces gross amounts billed to non-contracted third-party payers for amounts estimated to be collected according to the age of the outstanding balance. The reserve for estimated patient receivables reduces gross amounts billed to third-party payers for amounts estimated to be collected directly from individual patients, such as copayments, deductibles, or amounts otherwise designated as patient responsibility. The reserve for other payer-specific sales allowances relates to the amounts billed to non-contracted third-party payers that are estimated to not be covered by that specific payer's coverage policies, as well as estimated necessary adjustments to gross amounts billed based on historical collection experience for a particular third-party payer unrelated to the age of outstanding balances.

The estimates of amounts that will ultimately be realized from commercial diagnostic services require significant judgment by management. Patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that they have not met their annual deductible limit under their insurance policy, if any, or if their insurance otherwise declines to reimburse the Company. Adjustments to the estimated payment amounts are recorded at the time of final collection and settlement of each transaction as an adjustment to commercial revenue. The estimation process used to determine third-party payer discounts and sales allowance has been applied on a consistent basis since March 31, 2017, and no significant subsequent adjustments have been necessary to increase or decrease these discounts and allowances as a result of changes in underlying estimates.

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The composition of the Company's gross and net revenues recognized during the three and nine-months ended September 30, 2016 and 2017 is as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2017	2016	2017
Commercial revenues recognized upon delivery	\$ —	\$ 3,602,194	\$ —	\$ 12,298,790
Development services revenues recognized upon delivery	71,723	67,394	170,052	211,736
Commercial revenues recognized upon cash collection	975,557	102,234	1,761,457	1,158,277
Total gross revenues	1,047,280	3,771,822	1,931,509	13,668,803
Provisions for contractual discounts	—	(1,729,805)	—	(4,545,128)
Provisions for aged non-patient receivables	—	(152,889)	—	(598,532)
Provisions for estimated patient receivables	—	27,909	—	(90,931)
Provisions for other payer-specific sales allowances	—	(805,626)	—	(4,360,775)
Net revenues	<u>\$ 1,047,280</u>	<u>\$ 1,111,411</u>	<u>\$ 1,931,509</u>	<u>\$ 4,073,437</u>

During the nine months ended September 30, 2017, the Company recorded \$839,431 in nonrecurring net revenue as a result of recognizing revenue on an accrual basis commencing on March 31, 2017 associated with cases delivered on or prior to December 31, 2016, representing a corresponding decrease in net loss per common share of \$0.03. The incremental net revenue as a result of recognizing revenue on an accrual basis commencing on March 31, 2017, or the total amount of net revenue recorded in excess of the amount of commercial cash collections, was \$125,007 and \$1,041,890 during the three and nine-months ended September 30, 2017, respectively, representing corresponding decreases in net loss per common share of zero and \$0.04, respectively.

A summary of activity in the Company's gross and net accounts receivable balances, as well as corresponding reserves, during the nine months ended September 30, 2017 is as follows:

	Balance at December 31, 2016	Amounts Recognized Upon Delivery	Settlements Upon Adjudication	Balance at September 30, 2017
Accounts receivable, gross	\$ 128,969	\$ 12,510,526	\$ (5,649,054)	\$ 6,990,441
Reserve for contractual discounts	—	(4,545,128)	2,399,458	(2,145,670)
Reserve for aged non-patient receivables	—	(598,532)	70,950	(527,582)
Reserve for estimated patient receivables	—	(90,931)	1,072	(89,859)
Reserve for other payer-specific sales allowances	—	(4,360,775)	1,266,817	(3,093,958)
Accounts receivable, net	<u>\$ 128,969</u>	<u>\$ 2,915,160</u>	<u>\$ (1,910,757)</u>	<u>\$ 1,133,372</u>

### *Concentration of Risk*

Concentrations of credit risk with respect to revenues are primarily limited to geographies to which the Company provides a significant volume of its services, and to specific third-party payers of the Company's services such as Medicare, insurance companies, and other third-party payers. The Company's client base consists of a large number of geographically dispersed clients diversified across various customer types.

The Company's third-party payers that represent more than 10% of total net revenues in any period presented, and their related net revenue amount as a percentage of total net revenues, during the three and nine-months ended September 30, 2016 and 2017 were as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2017	2016	2017
Medicare and Medicare Advantage	63%	45%	54%	41%
Blue Cross Blue Shield	15%	16%	12%	17%
United Healthcare	19%	14%	19%	12%

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The Company's third-party payers that represent more than 10% of total net accounts receivable, and their related net accounts receivable balance as a percentage of total net accounts receivable, at September 30, 2017 were as follows:

Blue Cross Blue Shield	27%
Medicare and Medicare Advantage	20%
United Healthcare	14%

### *Recent Accounting Pronouncements*

In May 2014, and as subsequently updated and amended from time to time, the Financial Accounting Standards Board, or the FASB, issued authoritative guidance that requires entities to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This proposed guidance has been deferred and would be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. As the Company has not yet completed its final review of the impact of the new guidance but expects to during 2017, the Company has not determined whether the adoption of this guidance will have a material impact on its financial statements or disclosures. The Company is still evaluating disclosure requirements under the new guidance, and will continue to evaluate additional changes, modifications or interpretations to the guidance which may impact the current conclusions. The Company expects to adopt the new standard for the fiscal year beginning January 1, 2018 and anticipates that the modified retrospective application method will be applied.

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

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

In February 2016, the FASB issued authoritative guidance requiring, among other things, that entities recognize the assets and liabilities arising from leases on the balance sheet under revised criteria, while the classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria in the previous leases guidance. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company anticipates that the adoption of this guidance will materially affect its statement of financial position and will require changes to its processes. The Company expects to adopt this guidance for the reporting period beginning on January 1, 2019, and has not yet made any decision on the method of adoption with respect to the optional practical expedients, but expects to during 2018.

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

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In March 2016, the FASB issued authoritative guidance requiring entities to assess whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts, and clarifies what steps are required when assessing whether the economic characteristics and risks of call (put) options are clearly and closely related to the economic characteristics and risks of their debt hosts. This guidance is effective on a modified retrospective basis for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this guidance for the reporting period beginning January 1, 2017. The adoption of this guidance did not have a material impact on the Company's financial statements or disclosures.

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

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

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

In January 2017, the FASB issued authoritative guidance eliminating the "Step 2" requirement for an entity to determine the fair value of its assets and liabilities for goodwill impairment testing in the same manner that would be required for those assumed in a business combination. Instead, the amended guidance allows an entity to perform goodwill impairment testing by comparing the fair value of a reporting unit with its carrying amount. This guidance is effective for any goodwill impairment tests in fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning January 1, 2020, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently have any recorded goodwill.

In February 2017, the FASB issued authoritative guidance clarifying the definition of the term "in substance nonfinancial asset" when accounting for transfers of financial and nonfinancial assets, and other matters concerning the transfer, sale and partial sale of nonfinancial assets to both consolidated entities and non-consolidated counterparties. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2018, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company has not historically engaged in transfers, sales or partial sales of nonfinancial assets.

In March 2017, the FASB issued authoritative guidance shortening the amortization period to the earliest call date for certain purchased callable debt securities held at a premium. This guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2019, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently hold any callable debt securities.

In May 2017, the FASB issued authoritative guidance clarifying what modifications to a share-based payment award may be considered substantive, and therefore requiring the application of modification accounting. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2018, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently expect any significant modifications to outstanding share-based payment awards.

In July 2017, the FASB issued authoritative guidance changing the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features, whereby a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock, and also clarifying existing disclosure requirements for equity-classified instruments. This guidance is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2020, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently hold any significant financial instruments with down round features.

In August 2017, the FASB issued authoritative guidance that expands and refines hedge accounting for both nonfinancial and financial risk components and align the recognition and presentation of the effects of the hedging instrument and the hedged item in the financial statements. This guidance is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early application is permitted. The Company currently intends to adopt this guidance for the fiscal year beginning on January 1, 2019, and does not anticipate that the adoption of this guidance will have a material impact on its financial statements or disclosures because the Company does not currently hold any financial instruments accounted for as a hedging activity.

## **2. Liquidity and Going Concern Uncertainty**

As of September 30, 2017, cash totaled \$5.9 million and the Company had an accumulated deficit of \$189.6 million. For the year ended December 31, 2016 and the nine month period ended September 30, 2017, the Company incurred net losses of \$18.4 million and \$15.9 million, respectively. At September 30, 2017, the Company had aggregate net interest-bearing indebtedness of \$3.3 million, of which \$2.4 million was due within one year, in addition to \$3.4 million of other non-interest bearing current liabilities. In February 2016, the Company signed a firm, non-cancelable, and unconditional commitment in an aggregate amount of \$1,062,500 with a vendor to purchase certain inventory items, payable in minimum quarterly amounts of \$62,500 through May 2020, under which \$625,000 remained outstanding at September 30, 2017 (see Note 11). These factors raise substantial doubt about the Company's ability to continue as a going concern for the one-year period following the date that these unaudited condensed financial statements were issued. The accompanying unaudited condensed financial statements have been prepared assuming that the Company will continue as a going concern. The unaudited condensed financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

While the Company is currently in the commercialization stage of operations, the Company has not yet achieved profitability and anticipates that it will continue to incur net losses for the foreseeable future. Historically, the Company's principal sources of cash have included proceeds from the issuance of common and preferred stock, proceeds from the exercise of warrants to purchase common stock, proceeds from the issuance of debt, and revenues from laboratory services. The Company's principal uses of cash have included cash used in operations, payments relating to purchases of property and equipment and repayments of borrowings. The Company expects that the principal uses of cash in the future will be for continuing operations, hiring of sales and marketing personnel and increased sales and marketing activities, funding of research and development, capital expenditures, and general working capital requirements. The Company expects that, as revenues grow, sales and marketing and research and development expenses will continue to grow, albeit at a slower rate and, as a result, the Company will need to generate significant growth in net revenues to achieve and sustain income from operations.

In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as the Company's public float is less than \$75 million. A public offering of the Company's common stock and warrants to purchase its common stock closed on May 4, 2016, pursuant to which the Company received net cash proceeds of approximately \$4.3 million (see Note 3). Subsequent to the closing of this offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately \$4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at \$3.90 per share until their expiration in May 2021. A second offering of the Company's common stock was effected under this shelf registration statement on March 28, 2017, the closing of which occurred on March 31, 2017, pursuant to which the Company received net cash proceeds of approximately \$8.6 million (see Note 3). In a concurrent private placement, the Company sold unregistered warrants to purchase up to 2,160,000 shares of the Company's common stock that closed concurrently with the March 31, 2017 offering of common stock sold pursuant to this shelf registration statement. Subsequent to the closing of the sales of these unregistered warrants, no warrants sold have been exercised, with \$5.4 million in gross warrant proceeds remaining outstanding and available to be exercised at \$2.50 per share until their expiration in October 2022. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings. A public offering of the Company's common stock and warrants to purchase its common stock was effected under an underwriting agreement dated October 14, 2016 between the Company, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, the closing of which occurred on October 19, 2016, pursuant to which the Company received net cash proceeds of approximately \$9.0 million (see Note 3). Subsequent to the closing of this offering, cash proceeds of approximately \$7.5 million have been received from the exercise of warrants sold in this offering, while approximately \$3.2 million in gross warrant proceeds remain outstanding and available to be exercised at \$1.10 per share until their expiration in October 2021.



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Pursuant to a common stock and warrant purchase agreement dated August 9, 2017 between the Company and Ally Bridge LB Healthcare Master Fund Limited, or Ally Bridge, the Company received net cash proceeds of approximately \$2.0 million as a result of the sale of its common stock and warrants. Subsequent to August 9, 2017, no additional cash proceeds had been received from the exercise of warrants sold in this offering, with approximately \$2.2 million in gross warrant proceeds remaining outstanding and available to be exercised at \$1.50 per share until their expiration in August 2022.

### **Management's Plan to Continue as a Going Concern**

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Until the Company can generate significant cash from operations, including assay revenues, management's plans to obtain such resources for the Company include proceeds from offerings of the Company's equity securities or debt, or transactions involving product development, technology licensing or collaboration. Management can provide no assurances that any sources of a sufficient amount of financing will be available to the Company on favorable terms, if at all.

### **3. Sales of Equity Securities**

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

In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as the Company's public float is less than \$75 million. Pursuant to an exclusive placement agent agreement dated April 25, 2016 between the Company and H.C. Wainwright & Co., LLC, and a securities purchase agreement dated April 29, 2016 between the Company and the purchasers signatory thereto, a public offering of 1,662,191 shares of the Company's common stock and warrants to purchase up to an aggregate of 1,163,526 shares of common stock was effected under this registration statement at a combined offering price of \$3.00. All warrants sold in this offering have a per share exercise price of \$3.90, are exercisable immediately and expire five years from the date of issuance. The estimated grant date fair value of these warrants of approximately \$2.0 million was recorded as an offset to additional paid-in capital upon the closing of this offering. The closing of the sale of these securities to the purchasers occurred on May 4, 2016, pursuant to which the Company received, after deducting \$0.7 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, approximately \$4.3 million of net cash proceeds. Subsequent to the closing of this offering on May 4, 2016, no warrants sold in this offering have been exercised, with approximately \$4.5 million in gross warrant proceeds remaining outstanding and available to be exercised at \$3.90 per share until their expiration in May 2021. Pursuant to an exclusive placement agent agreement dated March 28, 2017 between the Company and Roth Capital Partners, LLC as lead placement agent, and WestPark Capital and Chardan Capital as co-placement agents, a securities purchase agreement for a second offering of 4,320,000 shares of the Company's common stock was effected under this registration statement at per share price of \$2.15, which closed on March 31, 2017. In a concurrent private placement, the Company sold unregistered warrants to purchase up to an aggregate of 2,160,000 shares of the Company's common stock that closed concurrently with the March 2017 offering of common stock sold pursuant the shelf registration statement, of which none have been subsequently exercised. All warrants sold in this offering have a per share exercise price of \$2.50 and expire on October 1, 2022. The estimated grant date fair value of these warrants of approximately \$2.8 million was recorded as an offset to additional paid-in capital upon the closing of this offering (see Note 4). At the closing of these sales on March 31, 2017, the Company received, after deducting \$0.7 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, approximately \$8.6 million of net cash proceeds. In connection with the closing of the offering, the Company has agreed to certain contractual terms that limit its ability to issue variable rate securities for a period of one year following the closing of the offering, with certain exceptions. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

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Pursuant to an underwriting agreement dated October 14, 2016 between the Company, Roth Capital Partners, LLC and Feltl and Company, Inc., as underwriters named therein, a public offering of 9,100,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 9,100,000 shares of common stock was effected at a combined offering price of \$1.10. The estimated grant date fair value of these warrants of approximately \$5.2 million was recorded as an offset to additional paid-in capital upon the closing of this offering. Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of \$1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of \$0.0009 per warrant to cover overallocments, if any, of which the underwriters exercised their overallocment option to purchase 627,131 option warrants for total proceeds to the Company of \$564. The estimated aggregate grant date fair value of the overallocment options and warrants of approximately \$0.8 million was recorded as an offset to additional paid-in capital upon the closing of this offering. All warrants sold in this offering have a per share exercise price of \$1.10, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the underwriters occurred on October 19, 2016, when the Company received, after deducting \$1.0 million of costs directly associated with the offering that were recorded as an offset to additional paid-in capital under applicable accounting guidance, \$9.0 million of net cash proceeds. Subsequent to the closing of this offering, approximately \$7.5 million of additional cash proceeds had been received from the exercise of warrants sold in this offering. As such, the total net increase in capital as a result of the sale of these shares and warrants has been \$16.5 million.

Pursuant to a common stock and warrant purchase agreement dated August 9, 2017 between the Company and Ally Bridge, an offering of 1,466,667 shares of the Company's common stock and warrants to purchase up to an aggregate of 1,434,639 shares of common stock was effected at a combined offering price of \$1.50 per unit for total gross proceeds to the Company of \$2.2 million. Subsequent to the closing of this offering, no additional cash proceeds had been received from the exercise of warrants sold in this offering. As such, the total increase in capital as a result of the sale of the common stock and warrants has been approximately \$2.0 million after deducting \$0.2 million of associated costs incurred, which were offset against these proceeds under applicable accounting guidance.

#### 4. Fair Value Measurement

The estimated fair value of the credit facility entered into with Oxford Finance LLC in April 2014, or the April 2014 Credit Facility, at September 30, 2017 approximated its carrying value, which was determined using a discounted cash flow analysis. The analysis considered interest rates of instruments with similar maturity dates, which involved the use of significant unobservable Level 3 inputs.

#### Other Fair Value Measurements

As of the closing of the Company's March 31, 2017 offering, the estimated grant date fair value of \$1.31 per share associated with the warrants to purchase up to 2,160,000 shares of common stock issued in this offering, or a total of approximately \$2.8 million, was recorded as an offset to additional paid-in capital, and was estimated using a Black-Scholes valuation model with the following assumptions:

Stock price	\$2.13
Exercise price	\$2.50
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	1.93%
Expected life (in years)	5.00
Expected volatility	80.0%

As of the closing of the Company's August 9, 2017 offering, the estimated grant date fair value of \$1.03 per share associated with the warrant to purchase up to 1,434,639 shares of common stock issued in this offering, or a total of approximately \$1.5 million, was recorded as an offset to additional paid-in capital, and was estimated using a Black-Scholes valuation model with the following assumptions:

Stock price	\$ 1.39
Exercise price	\$ 1.50
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	1.81%
Expected life (in years)	5.00
Expected volatility	100.0%

## 5. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2016	September 30, 2017
<b>Fixed Assets</b>		
Machinery and equipment	\$ 2,728,468	\$ 2,938,281
Furniture and office equipment	143,726	147,976
Computer equipment and software	620,582	1,526,482
Leasehold improvements	517,968	550,246
Financed equipment	1,559,690	1,922,418
Construction in process	169,896	7,481
Total fixed assets, gross	5,740,330	7,092,884
Less accumulated depreciation and amortization	(3,933,999)	(4,173,088)
Total fixed assets, net	<u>\$ 1,806,331</u>	<u>\$ 2,919,796</u>
<b>Accrued Liabilities</b>		
Accrued interest	\$ 20,776	\$ 324,406
Accrued payroll	168,727	477,889
Accrued vacation	364,953	503,380
Accrued bonuses	422,868	625,682
Accrued sales commissions	77,844	48,390
Current portion of deferred rent	67,085	106,418
Accrued other	37,783	88,220
Total accrued liabilities	<u>\$ 1,160,036</u>	<u>\$ 2,174,385</u>

## 6. April 2014 Credit Facility

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

On June 30, 2016, the Company entered into an amendment of the April 2014 Credit Facility. This amendment required the Company to make interest-only payments on the term loan from July 1, 2016 through September 30, 2016, and also requires an additional final payment of \$50,000 to the lender. The terms of the amendment require the amortization of the outstanding amount due under the term loan to commence at the end of the applicable interest-only period, with monthly payments of principal and interest, in arrears, being made by the Company to the lender in consecutive monthly installments following such interest-only period. Additionally, pursuant to the amendment the aggregate outstanding principal amount of the Company's permitted indebtedness, consisting of capitalized lease obligations and purchase money indebtedness outstanding at any time, was increased to \$1.2 million. The June 30, 2016 amendment of the April 2014 Credit Facility was accounted for as a modification of debt under applicable accounting guidance. On June 28, 2017, the Company entered into an amendment of the April 2014 Credit Facility whereby the aggregate outstanding principal amount of the Company's permitted indebtedness was increased to \$3.0 million.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to the Company and any subsidiaries created in the future. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, selling assets, and suffering a change in control, in each case subject

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to certain exceptions. The April 2014 Credit Facility also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the term loan under the April 2014 Credit Facility, including foreclosure against the Company's properties securing the April 2014 Credit Facility, including its cash. These events of default include, among other things, the Company's failure to pay any amounts due under the April 2014 Credit Facility, a breach of covenants under the April 2014 Credit Facility, insolvency, a material adverse change, the occurrence of any default under certain other indebtedness in an amount greater than \$250,000, and a final judgment against the Company in an amount greater than \$250,000.

A warrant to purchase up to 17,655 shares of the Company's common stock at an exercise price of \$14.16 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014. Issuance costs of \$102,498 associated with the term loan under the April 2014 Credit Facility were recorded as a discount to outstanding debt as of the closing date, resulting in net proceeds of \$4,897,502. The estimated fair value of the warrant issued of \$233,107 was also recorded as a discount to outstanding debt as of the closing date. The discounts and other issuance costs are amortized to interest expense utilizing the effective interest method over the underlying term of the loan, with total unamortized discounts of \$78,408 and \$54,405 remaining at December 31, 2016 and September 30, 2017, respectively. The effective annual interest rate associated with the April 2014 Credit Facility was 13.87% at both December 31, 2016 and September 30, 2017. As of September 30, 2017, total remaining principal payments of \$498,132 and \$1,201,409 were due under the April 2014 Credit Facility during the fiscal years ending December 31, 2017 and 2018, respectively.

## 7. Equipment Financings

The Company leases certain laboratory equipment under arrangements accounted for as capital leases and classified as equipment financings. The financed equipment is depreciated on a straight-line basis over periods ranging from 5 to 7 years. The total gross value of fixed assets capitalized under such financing arrangements was \$1,559,690 and \$1,922,418 at December 31, 2016 and September 30, 2017, respectively. Total accumulated depreciation related to financed equipment was approximately \$525,000 and \$681,000 at December 31, 2016 and September 30, 2017, respectively. Total depreciation expense related to financed equipment was approximately \$40,000 and \$52,000 for the three months ended September 30, 2016 and 2017, respectively. Total depreciation expense related to financed equipment was approximately \$93,000 and \$160,000 for the nine months ended September 30, 2016 and 2017, respectively. Fixed assets purchased totaling \$362,729 during the nine months ended September 30, 2017 were recorded as equipment financings. The aggregate weighted average effective annual interest rate related to the equipment financings was 13.18% and 13.79% at December 31, 2016 and September 30, 2017, respectively, and the maturity dates on such outstanding arrangements range from June 2018 to September 2024.

The following schedule sets forth the remaining future minimum lease payments outstanding under financed equipment arrangements, as well as corresponding remaining sales tax and maintenance obligation payments that are expensed as incurred, due within each respective fiscal year ending December 31, as well as the present value of the total amount of remaining minimum lease payments, as of September 30, 2017:

	Minimum Lease Payments	Maintenance and Sales Tax Obligation Payments
2017	\$ 79,763	\$ 8,954
2018	338,273	58,355
2019	313,529	68,925
2020	277,291	54,768
2021	267,665	48,802
Thereafter	522,397	88,313
Total payments	1,798,918	328,117
Less amount representing interest	(544,210)	—
Present value of payments	<u>\$1,254,708</u>	<u>\$ 328,117</u>

At September 30, 2017, the present value of minimum lease payments due within one year was \$304,585.

On September 15, 2017, and as amended on October 17, 2017, the Company executed an equipment financing commitment with a third-party lender for total proceeds to the Company of \$150,848, which was funded by the lender on November 2, 2017. Under the terms of the amended equipment financing agreement, which was accounted for as a sale-leaseback transaction, fixed assets previously purchased by the Company with aggregate gross and net book values of approximately \$167,000 and \$156,000, respectively, were granted as a security interest to the third-party lender, with the principal balance plus annual interest of 10.24% to be repaid in 36 equal monthly installments through November 2020 for a total of \$175,814.

## 8. Stock-Based Compensation

### Equity Incentive Plans

The Company maintains two equity incentive plans: the Amended and Restated 2013 Equity Incentive Plan, or the 2013 Plan, and the 2007 Equity Incentive Plan, or the 2007 Plan. The 2013 Plan includes a provision that shares available for grant under the Company's 2007 Plan become available for issuance under the 2013 Plan and are no longer available for issuance under the 2007 Plan. On July 25, 2016, the Company's Board of Directors approved an amendment to the 2013 Plan to reserve 333,333 shares of the Company's common stock exclusively for the grant of stock awards to employees who have not previously been an employee or director of the Company, except following a bona fide period of non-employment, as an inducement material to the individual's entering into employment with the Company, as defined under applicable Nasdaq Listing Rules. At the Company's annual meeting of stockholders held on May 2, 2017, the Company's stockholders approved amendments to the 2013 Plan, which included an increase in the number of non-inducement shares of common stock authorized for issuance under the 2013 Plan by 2,500,000. As of September 30, 2017, under all plans, a total of 3,522,955 non-inducement shares were authorized for issuance, 2,712,157 non-inducement stock options and restricted stock units, or RSUs, were issued and outstanding, and 638,487 non-inducement shares were available for grant. As of September 30, 2017, a total of 333,333 inducement shares were authorized for issuance, 133,049 inducement stock options and RSUs were issued and outstanding, and 175,284 inducement shares were available for grant under the 2013 Plan.

### Stock Options

A summary of stock option activity for the nine months ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term in Years
Outstanding at December 31, 2016	896,662	\$ 8.80	8.5
Granted	1,711,196	\$ 1.49	
Exercised	—		
Cancelled/forfeited/expired	(123,572)	\$ 5.13	8.7
Outstanding at September 30, 2017	2,484,286	\$ 3.93	8.9
Vested and unvested expected to vest at September 30, 2017	2,267,826	\$ 4.16	8.8

The intrinsic values of options outstanding at December 31, 2016 and September 30, 2017 were zero and \$5,507, respectively, and the intrinsic value of options vested and unvested expected to vest at September 30, 2017 was \$4,951. The total weighted-average grant date fair value of the 229,501 stock options that vested during the nine months ended September 30, 2017 was \$5.40.

The assumptions used in the Black-Scholes pricing model for stock options granted during the nine months ended September 30, 2017 were as follows:

Stock and exercise prices	\$1.22 – \$2.13
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	1.79% – 2.08%
Expected life (in years)	5.12 – 6.09
Expected volatility	70.0% – 90.0%

Using the assumptions described above, with stock and exercise prices being equal on date of grant, the weighted-average estimated fair value of options granted in the nine months ended September 30, 2017 was \$1.03 per share.

On August 31, 2015, the Company's Board of Directors approved the issuance of 33,333 performance stock options with an estimated grant date fair value of \$4.40 per share and an exercise price of \$6.03 per share to its Chief Executive Officer, or CEO, pursuant to the 2013 Plan. On February 29, 2016, the Company's Board of Directors approved the issuance of 33,333 performance stock options with an estimated grant date fair value of \$2.87 per share and an exercise price of \$4.02 per share to its CEO pursuant to the 2013 Plan. Vesting of these stock options was based on the Company's achievement of specified objectives by December 31, 2016 as determined

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by the Company's Board of Directors or the Compensation Committee of the Board of Directors. During the nine months ended September 30, 2017, 6,333 of the performance stock options granted on August 31, 2015 and 10,000 of the performance stock options granted on February 29, 2016 were declared vested by the Company's Board of Directors, and the remaining 50,333 shares underlying these awards were forfeited.

On July 25, 2016, the Company entered into an employment agreement with its new Chief Financial Officer, Senior Vice President of Operations and Secretary, or CFO. Pursuant to the terms of this employment agreement, on July 29, 2016 the CFO was granted inducement stock option awards with an exercise price of \$1.95 per share to purchase up to (i) 66,666 shares of the Company's common stock with an estimated grant date fair value of \$1.45 per share, 25% of which vested on the one-year anniversary of the commencement of the CFO's employment with the Company, and remainder of which vest in equal monthly amounts over the following three years, and (ii) 33,333 shares of the Company's common stock with an estimated grant date fair value of \$1.26 per share, which vested upon the Company's achievement of specified corporate goals for 2016 and the consummation of a specified financing transaction. During the nine months ended September 30, 2017, 16,383 shares of the performance option award granted on July 29, 2016 were declared vested by the Company's Board of Directors, and the remaining 16,950 shares underlying this award were forfeited.

On May 2, 2017, the Company's Board of Directors approved the issuance of an aggregate of 550,000 performance stock options to be granted on May 31, 2017 to certain of the Company's employees and all of its executive officers pursuant to the 2013 Plan, of which 200,000 performance stock options were granted to the Company's CEO, 100,000 performance stock options were granted to its CFO, and 75,000 performance stock options were granted to each of its Chief Scientific Officer, Senior Vice President and Senior Medical Director, Senior Vice President. Each performance stock option granted on May 31, 2017 has an exercise price of \$1.50 per share, an estimated grant date fair value of \$0.99 per share, and is subject to vesting as determined by the Company's Board of Directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of the Company's corporate goals for 2017 are achieved, as follows:

	Percentage of Overall Performance Stock Option Grant Subject to Vesting
<b>Target</b>	
Minimum revenue	20%
Cost of revenue reductions and improvements	15%
Increase cash generated from operations	15%
Minimum cash on-hand at December 31, 2017	15%
Minimum customer agreements, product licensing and product launch	20%
Implementation of new products and utility trials	15%
Total	100%

## **Restricted Stock**

A summary of RSU activity for the nine months ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2016	174,249	\$ 2.68
Granted	350,000	\$ 1.50
Vested and issued	(155,829)	\$ 1.96
Forfeited	(7,500)	\$ 2.12
Outstanding at September 30, 2017	360,920	\$ 1.87
Vested and unvested expected to vest at September 30, 2017	301,420	\$ 1.95

At September 30, 2017, the intrinsic values of RSUs outstanding and RSUs unvested and expected to vest were \$443,932 and \$370,747, respectively. Of the 360,920 RSUs outstanding at September 30, 2017, 10,920 are fully vested. On July 6, 2016, the Compensation Committee of the Company's Board of Directors approved retention RSUs for an aggregate of 58,332 shares of



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common stock to three of the Company's executive officers pursuant to the 2013 Plan, including retention RSUs for 25,000 shares of common stock to its CEO. Each of these retention RSUs has a grant date fair value of \$1.86 per share for a grant date fair value of \$108,498 to all three officers, in aggregate. These retention RSUs vested fully on the one-year anniversary of the date of grant, and were subject to continuing service by the holders of such RSUs. Pursuant to the terms of the Company's employment agreement with its CFO dated July 25, 2016, the CFO was granted an inducement RSU award on July 29, 2016 covering 25,000 shares of the Company's common stock with a grant date fair value of \$1.95 per share, 100% of which vested on the one-year anniversary of the commencement of the CFO's employment with the Company.

On May 2, 2017, the Company's Board of Directors approved the issuance of an aggregate of 175,000 time-based RSUs and 175,000 performance RSUs to be granted on May 31, 2017 to certain of the Company's employees and all of its executive officers pursuant to the 2013 Plan, of which 50,000 time-based RSUs and 25,000 performance RSUs were granted to its CEO, and 25,000 time-based RSUs and 25,000 performance RSUs were granted to each other executive officer. Each RSU granted on May 31, 2017 has a grant date fair value of \$1.50 per share. Vesting of the time-based RSUs granted on May 31, 2017 is subject to continuing service and occurs on the one year anniversary of the vesting commencement date, or May 2, 2018, while the performance RSUs are subject to continuous service and vesting is as determined by the Company's Board of Directors based on the achievement of specified corporate goals for 2017, provided that none shall vest unless a minimum level of 70% of the Company's corporate goals for 2017 are achieved, as follows:

	Percentage of Overall Performance RSU Grant Subject to Vesting
<b>Target</b>	
Minimum revenue	20%
Cost of revenue reductions and improvements	15%
Increase cash generated from operations	15%
Minimum cash on-hand at December 31, 2017	15%
Minimum customer agreements, product licensing and product launch	20%
Implementation of new products and utility trials	15%
Total	100%

## Stock-based Compensation Expense

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2017	2016	2017
<b>Stock Options</b>				
Cost of revenues	\$ 34,119	\$ 59,720	\$ 89,606	\$ 133,105
Research and development expenses	28,189	53,405	87,153	121,834
General and administrative expenses	292,381	178,671	829,516	528,406
Sales and marketing expenses	51,924	40,181	91,164	100,327
Total expenses related to stock options	406,613	331,977	1,097,439	883,672
<b>RSUs</b>				
Cost of revenues	14,918	20,417	16,834	58,717
Research and development expenses	14,131	20,418	15,583	57,490
General and administrative expenses	6,668	74,521	7,676	160,927
Sales and marketing expenses	22,939	28,355	27,447	71,343
Total stock-based compensation	\$ 465,269	\$ 475,688	\$ 1,164,979	\$ 1,232,149

Stock-based compensation expense was recorded net of estimated forfeitures of 0% - 8% per annum during the nine months ended September 30, 2016 and 2017. As of September 30, 2017, total unrecognized stock-based compensation expense related to unvested stock options and RSUs, adjusted for estimated forfeitures, was approximately \$2,128,000 and is expected to be recognized over a weighted-average period of approximately 2.3 years.



## 9. Common Stock Warrants Outstanding

A summary of equity-classified common stock warrant activity for the nine months ended September 30, 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2016	11,623,957	\$ 1.93	4.6
Issued	3,594,639	\$ 2.10	
Exercised	(6,816,850)	\$ 1.10	
Expired	—	—	
Outstanding at September 30, 2017	8,401,746	\$ 2.68	4.2

All warrants outstanding at September 30, 2017 are exercisable, except for the 2,160,000 warrants issued on March 31, 2017, which first became exercisable for a five-year period commencing on October 1, 2017. The intrinsic value of equity-classified common stock warrants outstanding at September 30, 2017 was \$378,337.

## 10. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the three and nine months ended September 30, 2016 and 2017, the outstanding RSUs, warrants, and common stock options have been excluded from the calculation of diluted loss per common share because their effect would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

On September 29, 2016, the Company effected a one-for-three reverse stock split of all common shares outstanding. The calculation of weighted-average shares outstanding has been adjusted for this reverse stock split as if it had occurred on December 31, 2015.

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

	For the three and nine-months ended September 30,	
	2016	2017
Preferred warrants outstanding (number of common stock equivalents)	529	529
Common warrants outstanding	1,896,826	8,401,746
RSUs outstanding	176,749	360,920
Common options outstanding	926,608	2,484,286
Total anti-dilutive common share equivalents	3,000,712	11,247,481

## 11. Commitments and Contingencies

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

In February 2016, the Company signed a firm, non-cancelable, and unconditional commitment in an aggregate amount of \$1,062,500 with a vendor to purchase certain inventory items, payable in minimum quarterly amounts of \$62,500 through May 2020. At September 30, 2017, a balance of \$625,000 remained outstanding under this purchase commitment.

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Payments totaling \$328,117 for future sales tax and maintenance obligations associated with financed equipment were outstanding at September 30, 2017, which are expensed as incurred (see Note 7).

On September 15, 2017, and as amended on October 17, 2017, the Company executed an equipment financing commitment with a third-party lender for total proceeds to the Company of \$150,848, under which the financing commitment was funded by the lender on November 2, 2017 (see Note 7).

### **12. Related Party Transactions**

A member of the Company's management is the controlling person of Aegea Biotechnologies, Inc., or Aegea. On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement, or the Cross-License Agreement, with Aegea. The Company received payments totaling \$19,047 and \$15,325 during the year ended December 31, 2016 and the nine months ended September 30, 2017, respectively, from Aegea as reimbursements for shared patent costs under the Cross-License Agreement.

Pursuant to a sublease agreement dated March 30, 2015, the Company subleased 9,849 square feet, plus free use of an additional area, of its San Diego facility to an entity affiliated with the Company's non-executive Chairman for \$12,804 per month, with a refundable security deposit of \$12,804 received from the subtenant. The initial term of the sublease expired on July 31, 2015, and was subject to renewal on a month-to-month basis thereafter. On February 1, 2017, the Company received notice from the subtenant terminating the sublease effective March 31, 2017. During the three months ended September 30, 2017, the total amount of the \$12,804 security deposit previously received from the subtenant was applied against approximately \$16,000 in additional rents owed as a result of the subtenant continuing to occupy the subleased areas beyond March 31, 2017, and the balance of approximately \$3,200 due to the Company was waived. A total of \$115,236 and \$51,216 in rental income was recorded to other income/(expense) in the Company's unaudited condensed statements of operations and comprehensive loss during the nine months ended September 30, 2016 and 2017, respectively.

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

Seven members of the Company's Board of Directors, including its CEO, and all three of the Company's other executive officers participated in the Company's public offering in October 2016, purchasing an aggregate of 534,088 shares of common stock and warrants to purchase up to an aggregate of 534,088 shares of common stock for total gross proceeds to the Company of \$587,497. Additionally, a trust affiliated with Claire K.T. Reiss, who at the time was the beneficial owner of more than 10% of the Company's outstanding common stock, participated in the Company's public offering in October 2016, purchasing 227,272 shares of its common stock and warrants to purchase up to 227,272 shares of its common stock for total gross proceeds to the Company of \$249,999. Further, several of the Company's employees and one of its consultants participated in the Company's public offering in October 2016, purchasing an aggregate of 79,090 shares of its common stock and warrants to purchase up to an aggregate of 79,090 shares of its common stock for total aggregate gross proceeds to the Company of \$86,999.

### **13. Subsequent Events**

On September 15, 2017, and as amended on October 17, 2017, the Company executed an equipment financing commitment with a third-party lender for total proceeds to the Company of \$150,848, which was funded by the lender on November 2, 2017 (see Note 7).

**18,796,992 Shares of Common Stock**  
**Series A Warrants to Purchase Up to 14,097,744 Shares of Common Stock**  
**Series B Warrants to Purchase Up to 4,699,248 Shares of Common Stock**



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**PROSPECTUS**

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**Dawson James Securities, Inc.**

**WestPark Capital, Inc.**

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than placement agent fees, paid or 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.

<b>Item</b>	<b>Amount</b>
SEC registration fee	\$ 3,113
Legal fees and expenses	225,000
Accounting fees and expenses	50,000
Printing and engraving expenses	25,000
Transfer agent and registrar fees and expenses	2,000
Miscellaneous fees and expenses	144,887
<b>Total</b>	<b>\$450,000</b>

**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, 2015, 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.

***Ally Bridge Private Placement***

On August 9, 2017, the Registrant entered into a common stock and warrant purchase agreement with Ally Bridge LB Healthcare Master Fund Limited pursuant to which the Registrant issued and sold in a private placement an aggregate of 1,466,667 shares of common stock, together with a warrant to purchase an additional 1,434,639 shares of common stock, for an aggregate purchase price of approximately \$2.2 million. The warrant has an exercise price per share equal to \$1.50, is immediately exercisable and will expire on the fifth anniversary of the original issuance date.

Pursuant to the common stock and warrant purchase agreement, the Registrant agreed to file a registration statement to cover the resale of the shares of common stock issued to Ally Bridge LB Healthcare Master Fund Limited, as well as the shares of common stock issuable upon exercise of the warrant issued to Ally Bridge LB Healthcare Master Fund Limited, and to keep such registration statement effective until the date on which all of the 2,901,306 shares registered for resale under the registration statement have been sold or can be sold publicly without condition or restriction under Rule 144 under the Securities Act.

***Registered Direct and Private Warrant Issuance***

On March 28, 2017, the Registrant entered into a Securities Purchase Agreement with certain purchasers identified on the signature pages thereto, pursuant to which the Registrant sold, in a registered direct offering, an aggregate of 4,320,000 shares of common stock at a negotiated purchase price of \$2.15 per share, pursuant to an effective shelf registration statement on Form S-3. The Registrant received aggregate gross proceeds of approximately \$9.3 million, before deducting fees to the placement agent and other offering expenses payable by the Registrant.

In a concurrent private placement, the Registrant also sold to the purchasers a warrant to purchase one half of a share of common stock for each share purchased for cash in the offering. The warrants sold in the offering are exercisable beginning on the six-month anniversary of the date of issuance at an exercise price of \$2.50 per share and will expire five years following the date they become exercisable. The warrants are exercisable on a “cashless” basis in certain circumstances.

Roth Capital Partners, LLC acted as the lead placement agent for the offering, and WestPark Capital and Chardan Capital acted as co-placement agents and were entitled to a cash fee of 6.0% of the gross proceeds paid to the Registrant in the offering and reimbursement of certain out-of-pocket expenses.

***Aspire Capital, LLC Transaction***

On December 21, 2015, the Registrant issued to Aspire Capital, LLC 55,000 shares of common stock as a commitment fee and sold to Aspire Capital, LLC 208,334 shares of common stock at \$4.80 per share for gross proceeds of \$1,000,000. Subsequently, the Registrant sold to Aspire Capital, LLC an aggregate of 173,145 shares of common stock for total proceeds of \$544,051.

***Compensatory Issuances***

In 2015, the Registrant granted 441,288 common stock options (at a \$6.01 weighted-average exercise price per share).

In 2016, the Registrant granted 290,399 common stock options (at a \$2.51 weighted-average exercise price per share) and 165,829 common stock restricted stock units to service providers.

In the nine months ended September 30, 2017, the Registrant granted 1,711,196 common stock options (at a \$1.49 weighted average exercise price per share) and 350,000 common stock restricted stock units to service providers.

***Conversions and Exercises***

In February 2015:

- Warrants for an aggregate 2,666,666 shares of the Registrant’s common stock were issued to participants, including several insiders, of the Registrant’s February 2015 public offering and are exercisable at a price of \$4.68 per share, with total proceeds of \$9,760,060 received from the exercises of such warrants subsequent to February 13, 2015. Each of the members of the Registrant’s Board of Directors participated in the Registrant’s February 2015 public offering, purchasing an aggregate 47,331 shares of the Registrant’s common stock and warrants to purchase up to an aggregate of 47,331 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:
  - Affiliate of David F. Hale, Chairman—13,333
  - Affiliate of Edward Neff, Director —13,333
  - Bruce A. Huebner, Director—4,000
  - Bruce E. Gerhardt, Director—6,666
  - Marsha A. Chandler, Director—666
  - Michael W. Nall, President and CEO, Director—4,000
  - M. Faye Wilson, Director—1,333
  - Retirement account of Ivor Royston, M.D., Director—4,000

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### **Item 16. Exhibits and Financial Statement Schedules.**

#### *(a) Exhibits*

The following exhibits are being filed with this Registration Statement:

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
1.1†	Form of Placement Agency Agreement.
3.1	<a href="#">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).</a>
3.2	<a href="#">Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).</a>
3.3	<a href="#">Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).</a>
3.4	<a href="#">Amendment to Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2017).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> and <a href="#">3.4</a> .
4.2	<a href="#">Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 28, 2017).</a>
4.3	<a href="#">Form of Representative's Warrant, dated February 10, 2014 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 20, 2013).</a>
4.4	<a href="#">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).</a>
4.5	<a href="#">Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on February 6, 2015).</a>
4.6	<a href="#">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).</a>
4.7	<a href="#">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).</a>
4.8	<a href="#">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).</a>
4.9	<a href="#">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).</a>
4.10	<a href="#">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).</a>
4.11	<a href="#">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).</a>



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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
4.12	<a href="#"><u>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).</u></a>
4.13	<a href="#"><u>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).</u></a>
4.14	<a href="#"><u>Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated April 29, 2016, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).</u></a>
4.15	<a href="#"><u>Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.16 of the Registrant's Post-Effective Amendment to Registration Statement on Form S-1 (File No. 333-213111), filed with the SEC on October 14, 2016).</u></a>
4.16	<a href="#"><u>Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated March 28, 2017, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2017).</u></a>
4.17	<a href="#"><u>Common Stock Purchase Warrant issued by the Registrant in favor of Ally Bridge LB Healthcare Master Fund Limited under the Common Stock and Warrant Purchase Agreement dated August 9, 2017 (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on August 10, 2017).</u></a>
4.18	<a href="#"><u>Common Stock Purchase Warrant issued by the Registrant in favor of Dawson James Securities, Inc. under the Securities Purchase Agreement dated December 5, 2017.</u></a>
4.19†	Form of Warrant to Purchase Common Stock.
5.1†	Opinion of Cooley LLP.
10.1+	<a href="#"><u>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).</u></a>
10.2+	<a href="#"><u>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).</u></a>
10.3+	<a href="#"><u>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).</u></a>
10.4+	<a href="#"><u>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).</u></a>
10.5+	<a href="#"><u>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).</u></a>
10.6+	<a href="#"><u>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).</u></a>
10.7	<a href="#"><u>Lease, between the Registrant and Nexus Equity VIII LLC, dated March 31, 2004 (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).</u></a>

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.8	<a href="#"><u>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).</u></a>
10.9	<a href="#"><u>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).</u></a>
10.10	<a href="#"><u>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).</u></a>
10.11	<a href="#"><u>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).</u></a>
10.12	<a href="#"><u>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).</u></a>
10.13	<a href="#"><u>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).</u></a>
10.14+	<a href="#"><u>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).</u></a>
10.15+	<a href="#"><u>Employment Agreement, between the Registrant and Veena Singh, dated December 1, 2014 (incorporated by reference to Exhibit 10.41 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on January 21, 2015).</u></a>
10.16+	<a href="#"><u>Employment Agreement Amendment between the Registrant and Michael W. Nall, dated November 6, 2015 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 9, 2015).</u></a>
10.17	<a href="#"><u>Letter Agreement, dated April 25, 2016, by and between Biocept, Inc. and H.C. Wainwright &amp; Co., LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).</u></a>
10.18+	<a href="#"><u>Employment Agreement between the Registrant and Timothy Kennedy, dated July 25, 2016 (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 27, 2016).</u></a>
10.19	<a href="#"><u>Second Amendment to Loan and Security Agreement by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC, dated as of June 30, 2016 (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 5, 2016).</u></a>
10.20+	<a href="#"><u>Biocept, Inc. Amended and Restated 2013 Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit agreement for use thereunder (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 5, 2017).</u></a>
10.21	<a href="#"><u>Third Amendment to Loan and Security Agreement by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC, dated as of June 28, 2017 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2017).</u></a>
10.22+	<a href="#"><u>Second Amendment to Employment Agreement by and between the Registrant and Michael W. Nall dated November 1, 2017.</u></a>

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
21.1	<a href="#"><u>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).</u></a>
23.1	<a href="#"><u>Consent of Mayer Hoffman McCann P.C.</u></a>
24.1	<a href="#"><u>Power of Attorney (previously filed).</u></a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

† To be filed by amendment.

+ Indicates management contract or compensatory plan.

### *(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.

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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 of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Diego, State of California, on the 22<sup>nd</sup> day of January 2018.

BIOCEPT, INC.

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

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael W. Nall</u> Michael W. Nall	Chief Executive Officer, President and Director (Principal Executive Officer)	January 22, 2018
<u>/s/ Timothy C. Kennedy</u> Timothy C. Kennedy	Chief Financial Officer, Senior VP of Operations and Secretary (Principal Financial Officer and Principal Accounting Officer)	January 22, 2018
<u>/s/ Marsha A. Chandler*</u> Marsha A. Chandler	Director	January 22, 2018
<u>/s/ Bruce E. Gerhardt*</u> Bruce E. Gerhardt	Director	January 22, 2018
<u>/s/ Bruce A. Huebner*</u> Bruce A. Huebner	Director	January 22, 2018
<u>/s/ M. Faye Wilson*</u> M. Faye Wilson	Director	January 22, 2018

\*By: /s/ Timothy C. Kennedy  
Timothy C. Kennedy  
Attorney-in-fact

THE REGISTERED HOLDER OF THIS PURCHASE WARRANT BY ITS ACCEPTANCE HEREOF, AGREES THAT IT WILL NOT SELL, TRANSFER OR ASSIGN THIS PURCHASE WARRANT EXCEPT AS HEREIN PROVIDED AND THE REGISTERED HOLDER OF THIS PURCHASE WARRANT AGREES THAT IT WILL NOT SELL, TRANSFER, ASSIGN, PLEDGE OR HYPOTHECATE THIS PURCHASE WARRANT FOR A PERIOD OF ONE HUNDRED EIGHTY DAYS FOLLOWING DECEMBER 5, 2017 (THE "EFFECTIVE DATE") TO ANYONE OTHER THAN (I) DAWSON JAMES SECURITIES, INC. OR A PLACEMENT AGENT OR A SELECTED DEALER IN CONNECTION WITH THE OFFERING FOR WHICH THIS WARRANT WAS ISSUED TO THE PLACEMENT AGENT AS CONSIDERATION (THE "OFFERING"), OR (II) A BONA FIDE OFFICER OR PARTNER OF DAWSON JAMES SECURITIES, INC. OR OF ANY SUCH PLACEMENT AGENT OR SELECTED DEALER.

THIS PURCHASE WARRANT IS NOT EXERCISABLE PRIOR TO JUNE 5, 2018. VOID AFTER 5:00 P.M., EASTERN TIME, DECEMBER 5, 2022.

### COMMON STOCK PURCHASE WARRANT

For the Purchase of 246,250 Shares of Common Stock  
of  
BIOCEPT INC.

1. Purchase Warrant. THIS CERTIFIES THAT, in consideration of funds duly paid by or on behalf of DAWSON JAMES SECURITIES, INC. ("**Holder**"), as registered owner of this Purchase Warrant, to Biocept Inc., a Delaware corporation (the "**Company**"), Holder is entitled, at any time or from time to time beginning June 5, 2018 (the "**Commencement Date**"), and at or before 5:00 p.m., Eastern time, December 5, 2022 (the "**Expiration Date**"), but not thereafter, to subscribe for, purchase and receive, in whole or in part, up to **246,250** shares of common stock of the Company, par value \$0.0001 per share (the "**Shares**"), subject to adjustment as provided in Section 6 hereof. If the Expiration Date is a day on which banking institutions are authorized by law to close, then this Purchase Warrant may be exercised on the next succeeding day which is not such a day in accordance with the terms herein. During the period ending on the Expiration Date, the Company agrees not to take any action that would terminate this Purchase Warrant. This Purchase Warrant is initially exercisable at **\$0.85** per Share; provided, however, that upon the occurrence of any of the events specified in Section 6 hereof, the rights granted by this Purchase Warrant, including the exercise price per Share and the number of Shares to be received upon such exercise, shall be adjusted as therein specified. The term "**Exercise Price**" shall mean the initial exercise price or the adjusted exercise price, depending on the context.

#### 2. Exercise.

2.1 Exercise Form. In order to exercise this Purchase Warrant, the exercise form attached hereto must be duly executed and completed and delivered to the Company, together with this Purchase Warrant and payment of the Exercise Price for the Shares being purchased payable in cash by wire transfer of immediately available funds to an account designated by the Company or by certified check or official bank check. If the subscription rights represented hereby shall not be exercised at or before 5:00 p.m., Eastern time, on the Expiration Date, this Purchase Warrant shall become and be void without further force or effect, and all rights represented hereby shall cease and expire.

2.2 Cashless Exercise. In lieu of exercising this Purchase Warrant by payment of cash or check payable to the order of the Company pursuant to Section 2.1 above, Holder may elect to receive the number of Shares equal to the value of this Purchase Warrant (or the portion thereof being exercised), by surrender of this Purchase Warrant to the Company, together with the exercise form attached hereto, in which event the Company will issue to Holder Shares in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

- X = The number of Shares to be issued to Holder;
- Y = The number of Shares for which the Purchase Warrant is being exercised;
- A = The fair market value of one Share; and
- B = The Exercise Price.

For purposes of this Section 2.2, the fair market value of a Share is defined as follows:

- (i) if the Company's common stock is traded on a national securities exchange, the OTCQB or OTCQX, the value shall be deemed to be the closing price on such exchange, the OTCQB or OTCQX, as the case may be, prior to the exercise form being submitted in connection with the exercise of the Purchase Warrant; or
- (ii) if the Company's common stock is not then traded on a securities exchange, the OTCQB or OTCQX and if prices for the Company's common stock are then reported on the "Pink Sheets" published by OTC Markets Group, Inc., the value shall be deemed to be the closing bid prior to the exercise form being submitted in connection with the exercise of the Purchase Warrant so reported; provided, however, if there is no active public market, the value shall be the fair market value thereof, as determined in good faith by the Company's Board of Directors.

2.3 Legend. Each certificate for the securities purchased under this Purchase Warrant shall bear a legend as follows unless such securities have been registered under the Securities Act of 1933, as amended (the "**Act**"):

"The securities represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "**Act**"), or applicable state law. Neither the securities nor any interest therein may be offered for sale, sold or otherwise transferred except pursuant to an effective registration statement under the Act, or pursuant to an exemption from registration under the Act and applicable state law which, in the opinion of counsel to the Company, is available."

2.4 Resale of Shares. Holder and the Company acknowledge that as of the date hereof the Staff of the Division of Corporation Finance of the SEC has published Compliance & Disclosure Interpretation 528.04 in the Securities Act Rules section thereof, stating that the holder of securities issued in connection with a public offering may not rely upon Rule 144 promulgated under the Act to establish an exemption from registration requirements under Section 4(a)(1) under the Act, but may nonetheless apply Rule 144 constructively for the resale of such shares in the following manner: (a) provided that six months has elapsed since the last sale under the registration statement, an underwriter or finder may resell the securities in accordance with the provisions of Rule 144(c), (e), and (f), except for the notice requirement; (b) a purchaser of the shares from an underwriter receives restricted securities unless the sale is made with an appropriate, current prospectus, or unless the sale is made pursuant to the conditions contained in (a) above; (c) a purchaser of the shares from an underwriter who receives restricted securities may include the underwriter's holding period, provided that the underwriter or finder is not an affiliate of the issuer; and (d) if an underwriter transfers the shares to its employees, the employees may tack the firm's holding period for purposes of Rule 144(d), but they must aggregate sales of the distributed shares with those of other employees, as well as those of the underwriter or finder, for a six-month period from the date of the transfer to the employees. Holder and the Company also acknowledge that the Staff of the Division of Corporation Finance of the SEC has



advised in various no-action letters that the holding period associated with securities issued without registration to a service provider commences upon the completion of the services, which the Company agrees and acknowledges shall be the closing of the Offering, and that Rule 144(d)(3)(ii) provides that securities acquired from the issuer solely in exchange for other securities of the same issuer shall be deemed to have been acquired at the same time as the securities surrendered for conversion (which the Company agrees is the date of the initial issuance of this Purchase Warrant). In the event that following a request by Holder to transfer the Shares in accordance with Compliance & Disclosure Interpretation 528.04 counsel for the Company reasonably concludes that Compliance & Disclosure Interpretation 528.04 no longer may be relied upon as a result of changes in applicable laws, regulations, or interpretations of the SEC Division of Corporation Finance, or as a result of judicial interpretations not known by the Company or its counsel on the date hereof (either, a “Registration Trigger Event”), then the Company shall promptly, and in any event within five (5) business days following the request, provide written notice to Holder of such determination. As a condition to giving such notice, the Company shall offer Holder a single demand registration right pursuant to an agreement in form acceptable to the Holder; provided that notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 2 shall terminate on the fifth anniversary of the Effective Date. In the absence of such conclusion by counsel for the Company, the Company shall, upon request of Holder given no earlier than six months after the final closing of the Offering, instruct its transfer agent to permit the transfer of such shares in accordance with Compliance & Disclosure Interpretation 528.04, provided that Holder has provided such documentation as shall be reasonably be requested by the Company to establish compliance with the conditions of Compliance & Disclosure Interpretation 528.04.

### 3. Transfer.

3.1 General Restrictions. The registered Holder of this Purchase Warrant agrees by his, her or its acceptance hereof, that such Holder will not: (a) sell, transfer, assign, pledge or hypothecate this Purchase Warrant for a period of one hundred eighty (180) days following the Effective Date to anyone other than: (i) Dawson James Securities, Inc. (“**Dawson**”) or a placement agent underwriter or a selected dealer participating in the Offering, or (ii) a bona fide officer or partner of Dawson or of any such placement agent or selected dealer, in each case in accordance with FINRA Conduct Rule 5110(g)(1), or (b) cause this Purchase Warrant or the securities issuable hereunder to be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of this Purchase Warrant or the securities hereunder, except as provided for in FINRA Rule 5110(g)(2). After 180 days after the Effective Date, transfers to others may be made subject to compliance with or exemptions from applicable securities laws. In order to make any permitted assignment, the Holder must deliver to the Company the assignment form attached hereto duly executed and completed, together with the Purchase Warrant and payment of all transfer taxes, if any, payable in connection therewith. The Company shall within five (5) Business Days transfer this Purchase Warrant on the books of the Company and shall execute and deliver a new Purchase Warrant or Purchase Warrants of like tenor to the appropriate assignee(s) expressly evidencing the right to purchase the aggregate number of Shares purchasable hereunder or such portion of such number as shall be contemplated by any such assignment.

3.2 Restrictions Imposed by the Act. The securities evidenced by this Purchase Warrant shall not be transferred unless and until: (i) if required by applicable law, the Company has received the opinion of counsel for the Company that the securities may be transferred pursuant to an exemption from registration under the Act and applicable state securities laws (the Company hereby agrees that the opinion of Schiff Hardin LLP shall also be accepted in lieu of an opinion from Company counsel), or (ii) a registration statement or a post-effective amendment to the Registration Statement relating to the offer and sale of such securities has been filed by the Company and declared effective by the U.S. Securities and Exchange Commission (the “**Commission**”) and compliance with applicable state securities law has been established.

### 4. Piggyback Registration Rights.

4.1 Grant of Right. Whenever the Company proposes to register any shares of its common stock under the Act (other than (i) a registration effected solely to implement an employee benefit plan or a transaction to which Rule 145 of the Act is applicable, (ii) a registration statement on Form S-4, S-8 or any successor form thereto or another form not available for registering the Shares issuable upon exercise of this Warrant for sale to the public, or (iii) the Company’s Registration Statement on Form S-1 (File No. 333-221648) first filed with the Commission

on November 17, 2017), whether for its own account or for the account of one or more stockholders of the Company (a “Piggyback Registration”), the Company shall give prompt written notice (in any event no later than ten (10) Business Days prior to the filing of such registration statement) to the Holder of the Company’s intention to effect such a registration and, subject to the remaining provisions of this Section 4.1, shall include in such registration the Shares underlying this Warrant (the “**Registrable Securities**”) that the Holders have requested to be included within such registration. If a Piggyback Registration is an underwritten offering and the managing underwriter advises the Company in writing that in its opinion the number of shares of common stock proposed to be included in such registration, including all Shares issuable upon exercise of this Warrant (if the Holder has elected to include such shares in such Piggyback Registration) and all other shares of common stock proposed to be included in such underwritten offering, exceeds the number of shares of common stock which can be sold in such offering and/or that the number of shares of common stock proposed to be included in any such registration would adversely affect the price per share of the common stock to be sold in such offering, the Company shall include in such registration (i) first, the number of shares of common stock that the Company proposes to sell and (ii) second, the number of shares of common stock, if any, requested to be included therein by selling stockholders (including the Holder) allocated pro rata among all such persons on the basis of the number of shares of common stock request to be included in such Piggyback Registration owned by each such person or in such other manner as they may otherwise agree. If any Piggyback Registration is initiated as a primary underwritten offering on behalf of the Company, the Company shall select the investment banking firm or firms to act as the managing underwriter or underwriters in connection with such offering. Notwithstanding anything to the contrary, the obligations of the Company pursuant to this Section 4.1 shall terminate on the earlier of (i) the fifth anniversary of the effective date of the Registration Statement pursuant to which the Offering is being made and (ii) the date that the Holder can sell its Registrable Securities pursuant to Rule 144 during any ninety (90) day period.

4.2 Indemnification. The Company shall indemnify the Holder(s) of the Registrable Securities to be sold pursuant to any registration statement hereunder and each person, if any, who controls such Holders within the meaning of Section 15 of the Act or Section 20 (a) of the Securities Exchange Act of 1934, as amended (“**Exchange Act**”), against all loss, claim, damage, expense or liability (including all reasonable attorneys’ fees and other out-of-pocket expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which any of them may become subject under the Act, the Exchange Act or otherwise, arising from such registration statement but only to the same extent and with the same effect as the provisions pursuant to which the Company has agreed to indemnify Dawson contained in Section 9 of the Placement Agency Agreement between Dawson and the Company, dated as of December 5, 2017. The Holder(s) of the Registrable Securities to be sold pursuant to such registration statement, and their successors and assigns, shall severally, and not jointly, indemnify the Company, against all loss, claim, damage, expense or liability (including all reasonable attorneys’ fees and other expenses reasonably incurred in investigating, preparing or defending against any claim whatsoever) to which they may become subject under the Act, the Exchange Act or otherwise, arising from information furnished by or on behalf of such Holders, or their successors or assigns, in writing, for specific inclusion in such registration statement to the same extent and with the same effect as the provisions contained in Section 9 of the Placement Agency Agreement pursuant to which Dawson has agreed to indemnify the Company.

4.3 Exercise of Purchase Warrants. Nothing contained in this Purchase Warrant shall be construed as requiring the Holder(s) to exercise their Purchase Warrants prior to or after the initial filing of any registration statement or the effectiveness thereof.

4.4 Documents Delivered to Holders. The Company shall deliver promptly to each Holder participating in the offering requesting the correspondence and memoranda described below, copies of all correspondence between the Commission and the Company, its counsel or auditors and all memoranda relating to discussions with the Commission or its staff with respect to the registration statement and permit each Holder and underwriter to do such investigation, upon reasonable advance notice, with respect to information contained in or omitted from the registration statement as it deems reasonably necessary to comply with applicable securities laws or rules of FINRA. Such investigation shall include access to books, records and properties and opportunities to discuss the business of the Company with its officers and independent auditors, all to such reasonable extent and at such reasonable times, during normal business hours, as any such Holder shall reasonably request.

4.5 Underwriting Agreement. The Holders shall be parties to any underwriting agreement relating to a Piggyback Registration. Such Holders shall not be required to make any representations or warranties to or agreements with the Company or the underwriters except as they may relate to such Holders, their Shares and their intended methods of distribution.

4.6 Documents to be Delivered by Holder(s). Each of the Holder(s) participating in any of the foregoing offerings shall furnish to the Company a completed and executed questionnaire provided by the Company requesting information customarily sought of selling security holders.

4.7 Damages. Should the Company fail to comply with such provisions, the Holder(s) shall, in addition to any other legal or other relief available to the Holder(s), be entitled to obtain specific performance or other equitable (including injunctive) relief against the threatened breach of such provisions or the continuation of any such breach, without the necessity of proving actual damages and without the necessity of posting bond or other security.

5. New Purchase Warrants to be Issued.

5.1 Partial Exercise or Transfer. Subject to the restrictions in Section 3 hereof, this Purchase Warrant may be exercised or assigned in whole or in part. In the event of the exercise or assignment hereof in part only, upon surrender of this Purchase Warrant for cancellation, together with the duly executed exercise or assignment form and funds sufficient to pay any Exercise Price and/or transfer tax if exercised pursuant to Section 2.1 hereto, the Company shall cause to be delivered to the Holder without charge a new Purchase Warrant of like tenor to this Purchase Warrant in the name of the Holder evidencing the right of the Holder to purchase the number of Shares purchasable hereunder as to which this Purchase Warrant has not been exercised or assigned.

5.2 Lost Certificate. Upon receipt by the Company of evidence satisfactory to it of the loss, theft, destruction or mutilation of this Purchase Warrant and of reasonably satisfactory indemnification or the posting of a bond, the Company shall execute and deliver a new Purchase Warrant of like tenor and date. Any such new Purchase Warrant executed and delivered as a result of such loss, theft, mutilation or destruction shall constitute a substitute contractual obligation on the part of the Company.

6. Adjustments.

6.1 Adjustments to Exercise Price and Number of Securities. The Exercise Price and the number of Shares underlying the Purchase Warrant shall be subject to adjustment from time to time as hereinafter set forth:

6.1.1 Share Dividends; Split Ups. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is increased by a stock dividend payable in Shares or by a split up of Shares or other similar event, then, on the effective day thereof, the number of Shares purchasable hereunder shall be increased in proportion to such increase in outstanding Shares, and the Exercise Price shall be proportionately decreased.

6.1.2 Aggregation of Shares. If, after the date hereof, and subject to the provisions of Section 6.3 below, the number of outstanding Shares is decreased by a consolidation, combination or reclassification of Shares or other similar event, then, on the effective date thereof, the number of Shares purchasable hereunder shall be decreased in proportion to such decrease in outstanding Shares, and the Exercise Price shall be proportionately increased.

6.1.3 Replacement of Securities upon Reorganization, etc. In case of any reclassification or reorganization of the outstanding Shares other than a change covered by Section 6.1.1 or 6.1.2 hereof or that solely affects the par value of such Shares, or in the case of any share reconstruction or amalgamation or consolidation or merger of the Company with or into another corporation (other than a consolidation or share reconstruction or amalgamation or merger in which the Company is the continuing corporation and that does not result in any reclassification or reorganization of the outstanding Shares), or in the case of any sale or conveyance to another

corporation or entity of the property of the Company as an entirety or substantially as an entirety in connection with which the Company is dissolved, the Holder of this Purchase Warrant shall have the right thereafter (until the expiration of the right of exercise of this Purchase Warrant) to receive upon the exercise hereof, for the same aggregate Exercise Price payable hereunder immediately prior to such event, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, share reconstruction or amalgamation, or consolidation, or upon a dissolution following any such sale or transfer, by a Holder of the number of Shares of the Company obtainable upon exercise of this Purchase Warrant immediately prior to such event; and if any reclassification also results in a change in Shares covered by Section 6.1.1 or 6.1.2, then such adjustment shall be made pursuant to Sections 6.1.1, 6.1.2 and this Section 6.1.3. The provisions of this Section 6.1.3 shall similarly apply to successive reclassifications, reorganizations, share reconstructions or amalgamations, or consolidations, sales or other transfers.

6.1.4 Changes in Form of Purchase Warrant. This form of Purchase Warrant need not be changed because of any change pursuant to this Section 6.1, and Purchase Warrants issued after such change may state the same Exercise Price and the same number of Shares as are stated in the Purchase Warrants initially issued pursuant to this Agreement. The acceptance by any Holder of the issuance of new Purchase Warrants reflecting a required or permissive change shall not be deemed to waive any rights to an adjustment occurring after the Commencement Date or the computation thereof.

6.2 Substitute Purchase Warrant. In case of any consolidation of the Company with, or share reconstruction or amalgamation or merger of the Company with or into, another corporation (other than a consolidation or share reconstruction or amalgamation or merger which does not result in any reclassification or change of the outstanding Shares), the corporation formed by such consolidation or share reconstruction or amalgamation shall execute and deliver to the Holder a supplemental Purchase Warrant providing that the holder of each Purchase Warrant then outstanding or to be outstanding shall have the right thereafter (until the stated expiration of such Purchase Warrant) to receive, upon exercise of such Purchase Warrant, the kind and amount of shares of stock and other securities and property receivable upon such consolidation or share reconstruction or amalgamation, by a holder of the number of Shares of the Company for which such Purchase Warrant might have been exercised immediately prior to such consolidation, share reconstruction or amalgamation or merger, sale or transfer. Such supplemental Purchase Warrant shall provide for adjustments which shall be identical to the adjustments provided for in this Section 6. The above provision of this Section shall similarly apply to successive consolidations or share reconstructions or amalgamations or mergers.

6.3 Elimination of Fractional Interests. The Company shall not be required to issue certificates representing fractions of Shares upon the exercise of the Purchase Warrant, nor shall it be required to issue scrip or pay cash in lieu of any fractional interests, it being the intent of the parties that all fractional interests shall be eliminated by rounding any fraction up or down, as the case may be, to the nearest whole number of Shares or other securities, properties or rights.

7. Reservation. The Company shall at all times reserve and keep available out of its authorized Shares, solely for the purpose of issuance upon exercise of the Purchase Warrants, such number of Shares or other securities, properties or rights as shall be issuable upon the exercise thereof. The Company covenants and agrees that, upon exercise of the Purchase Warrants and payment of the Exercise Price therefor, in accordance with the terms hereby, all Shares and other securities issuable upon such exercise shall be duly and validly issued, fully paid and non-assessable and not subject to preemptive rights of any shareholder.

## 8. Certain Notice Requirements.

8.1 Holder's Right to Receive Notice. Nothing herein shall be construed as conferring upon the Holders the right to vote or consent or to receive notice as a shareholder for the election of directors or any other matter, or as having any rights whatsoever as a shareholder of the Company. If, however, at any time prior to the expiration of the Purchase Warrants and their exercise, any of the events described in Section 8.2 shall occur, then, in one or more of said events, the Company shall give written notice of such event at least ten (10) days prior to the date fixed as a record date or the date of closing the transfer books for the determination of the shareholders entitled

to such dividend, distribution, conversion or exchange of securities or subscription rights. Such notice shall specify such record date or the date of the closing of the transfer books, as the case may be. Notwithstanding the foregoing, the Company shall deliver to each Holder a copy of each notice given to the other shareholders of the Company at the same time and in the same manner that such notice is given to the shareholders.

8.2 Events Requiring Notice. The Company shall be required to give the notice described in this Section 8 upon one or more of the following events: (i) if the Company shall take a record of the holders of its Shares for the purpose of entitling them to receive a dividend or distribution payable otherwise than in cash, or a cash dividend or distribution payable otherwise than out of retained earnings, as indicated by the accounting treatment of such dividend or distribution on the books of the Company, or (ii) the Company shall offer to all the holders of its Shares any additional shares of capital stock of the Company or securities convertible into or exchangeable for shares of capital stock of the Company, or any option, right or warrant to subscribe therefor.

8.3 Notice of Change in Exercise Price. The Company shall, promptly after an event requiring a change in the Exercise Price pursuant to Section 6 hereof, send notice to the Holders of such event and change ("**Price Notice**"). The Price Notice shall describe the event causing the change and the method of calculating same.

8.4 Transmittal of Notices. All notices, requests, consents and other communications under this Purchase Warrant shall be in writing and shall be deemed to have been duly made when hand delivered, or mailed by express mail or private courier service: (i) if to the registered Holder of the Purchase Warrant, to the address of such Holder as shown on the books of the Company, or (ii) if to the Company, to following address or to such other address as the Company may designate by notice to the Holders:

If to the Holder:

Dawson James Securities, Inc.  
1 North Federal Highway – 5th Floor  
Boca Raton, FL 33432  
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Schiff Hardin LLP  
901 K Street, NW, Suite 700  
Washington, DC 20001  
Attn: Ralph V. De Martino, Esq.  
Fax No.: (202) 778-6460

If to the Company:

Biocept Inc.  
Michael W. Nall  
Chief Executive Officer and President  
Biocept, Inc.  
5810 Nancy Ridge Drive  
San Diego, CA 92121

## 9. Miscellaneous.

9.1 Amendments. The Company and Dawson may from time to time supplement or amend this Purchase Warrant without the approval of any of the Holders in order to cure any ambiguity, to correct or supplement any provision contained herein that may be defective or inconsistent with any other provisions herein, or to make any other provisions in regard to matters or questions arising hereunder that the Company and Dawson may deem necessary or desirable and that the Company and Dawson deem shall not adversely affect the interest of the Holders. All other modifications or amendments shall require the written consent of and be signed by (i) the Company and (ii) the Holder(s) of Purchase Warrants then-exercisable for at least a majority of the Shares then-exercisable pursuant to all then-outstanding Purchase Warrants.

9.2 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Purchase Warrant.

9.3. Entire Agreement. This Purchase Warrant (together with the other agreements and documents being delivered pursuant to or in connection with this Purchase Warrant) constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.4 Binding Effect. This Purchase Warrant shall inure solely to the benefit of and shall be binding upon, the Holder and the Company and their permitted assignees, respective successors, legal representative and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Purchase Warrant or any provisions herein contained.

9.5 Governing Law; Submission to Jurisdiction; Trial by Jury. This Purchase Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Purchase Warrant shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 8 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company and the Holder agree that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and the Holder hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.6 Waiver, etc. The failure of the Company or the Holder to at any time enforce any of the provisions of this Purchase Warrant shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Purchase Warrant or any provision hereof or the right of the Company or any Holder to thereafter enforce each and every provision of this Purchase Warrant. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Purchase Warrant shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

9.7 Exchange Agreement. As a condition of the Holder's receipt and acceptance of this Purchase Warrant, Holder agrees that, at any time prior to the complete exercise of this Purchase Warrant by Holder, if the Company and Dawson enter into an agreement ("**Exchange Agreement**") pursuant to which they agree that all outstanding Purchase Warrants will be exchanged for securities or cash or a combination of both, then Holder shall agree to such exchange and become a party to the Exchange Agreement.

**[Signature Page Follows]**

IN WITNESS WHEREOF, the Company has caused this Purchase Warrant to be signed by its duly authorized officer as of the 7<sup>th</sup> day of December, 2017.

BIOCEPT INC.

By: /s/ Timothy Kennedy  
Name: Timothy Kennedy  
Title: CFO, SVP Operations



Date: \_\_\_\_\_, 20 \_\_\_\_

The undersigned hereby elects irrevocably to exercise the Purchase Warrant for \_\_\_\_\_ shares of common stock, par value \$0.0001 per share (the “**Shares**”), of Biocept Inc., a Delaware corporation (the “**Company**”), and hereby makes payment of \$\_\_\_\_\_ (at the rate of \$\_\_\_\_\_ per Share) in payment of the Exercise Price pursuant thereto. Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been exercised.

or

The undersigned hereby elects irrevocably to convert its right to purchase \_\_\_\_\_ Shares of the Company under the Purchase Warrant for \_\_\_\_\_ Shares, as determined in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where,

- X = The number of Shares to be issued to Holder;
- Y = The number of Shares for which the Purchase Warrant is being exercised;
- A = The fair market value of one Share which is equal to \$\_\_\_\_\_ ; and
- B = The Exercise Price which is equal to \$\_\_\_\_\_ per share

The undersigned agrees and acknowledges that the calculation set forth above is subject to confirmation by the Company and any disagreement with respect to the calculation shall be resolved by the Company in its sole discretion.

Please issue the Shares as to which this Purchase Warrant is exercised in accordance with the instructions given below and, if applicable, a new Purchase Warrant representing the number of Shares for which this Purchase Warrant has not been converted.

Signature \_\_\_\_\_

Signature Guaranteed \_\_\_\_\_

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INSTRUCTIONS FOR REGISTRATION OF SECURITIES

Name: \_\_\_\_\_  
(Print in Block Letters)

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

NOTICE: The signature to this form must correspond with the name as written upon the face of the Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

ASSIGNMENT

(To be executed by the registered Holder to effect a transfer of the within Purchase Warrant):

FOR VALUE RECEIVED, \_\_\_\_\_ does hereby sell, assign and transfer unto the right to purchase shares of Common Stock, par value \$0.0001 per share, of Biocept Inc., a Delaware corporation (the “**Company**”), evidenced by the Purchase Warrant and does hereby authorize the Company to transfer such right on the books of the Company.

Dated: \_\_\_\_\_, 20\_\_\_\_

Signature \_\_\_\_\_

Signature Guaranteed \_\_\_\_\_

NOTICE: The signature to this form must correspond with the name as written upon the face of the within Purchase Warrant without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank, other than a savings bank, or by a trust company or by a firm having membership on a registered national securities exchange.

**SECOND AMENDMENT TO  
EMPLOYMENT AGREEMENT**

**THIS SECOND AMENDMENT TO EMPLOYMENT AGREEMENT** (the “Amendment”) is entered by and between Biocept, Inc., a Delaware corporation (the “**Company**”), and Michael W. Nall (“**Executive**”) and shall be effective as of November 1, 2017 (the “**Amendment Effective Date**”).

**WHEREAS**, the Company and Executive are parties to that certain Employment Agreement, effective August 26, 2013 and amended effective November 6, 2015 (collectively the “**Employment Agreement**”); and

**WHEREAS**, the Company and Executive now desire to amend the Employment Agreement as set forth herein;

**NOW THEREFORE**, in consideration of the foregoing and the mutual promises herein contained, the parties agree as follows (capitalized terms used but not defined herein shall have the meaning set forth in the Employment Agreement):

**1. AMENDMENT TO SECTION 4 (C) “EXPENSES.”** The parties mutually agree that the Agreement is amended as of the Amendment Effective Date, by amending Section 4 (c) to delete the last sentence.

**2. UNCHANGED TERMS/CONFLICT.** Except as expressly modified by this Amendment, the Agreement shall remain unmodified and in full force and effect. Should there be any conflict between the terms and conditions of this Amendment and the terms and conditions of the Agreement, the parties agree that the terms and conditions of this Amendment shall control/prevail.

**IN WITNESS WHEREOF**, the parties have executed this Amendment as of the date first set forth above.

**BIOCEPT, INC.**

**EXECUTIVE**

By: /s/ David F. Hale

David F. Hale

Chairman of the Board

/s/ Michael W. Nall

Michael W. Nall

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

As independent registered public accountants, we hereby consent to the use in this Amendment No. 2 to Form S-1 Registration Statement and related Prospectus, of our report dated March 28, 2017, relating to the financial statements of Biocept, Inc., as of and for the years ended December 31, 2016 and 2015 (which report includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern). 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  
January 22, 2018