

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission file number: 001-36284

**Biocept, Inc.**

(Exact name of registrant as specified in its charter)

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

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

**5810 Nancy Ridge Drive, San Diego, California**  
(Address of principal executive offices)

**92121**  
(Zip Code)

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

**Not Applicable**  
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes  No

As of November 4, 2016, there were 17,499,397 shares of the Registrant's common stock outstanding.

**BIOCEPT, INC.**  
**FORM 10-Q**  
**FOR THE QUARTERLY PERIOD ENDED**  
**September 30, 2016**

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## IMPORTANT NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

*Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in our other filings with the Securities and Exchange Commission, or the SEC. Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made except as required by law. Readers should, however, review the factors and risks we describe in the reports and registration statements we file from time to time with the SEC.*

## Item 1. Financial Statements

**Biocept, Inc.**  
**Condensed Balance Sheets**

	<u>December 31,</u> <u>2015</u>	<u>September 30,</u> <u>2016</u> (unaudited)
<b>Current assets:</b>		
Cash and cash equivalents	\$ 8,821,329	\$ 678,855
Accounts receivable	34,200	85,664
Inventories, net	349,271	497,517
Prepaid expenses and other current assets	435,938	499,133
Total current assets	9,640,738	1,761,169
Fixed assets, net	946,180	1,521,380
<b>Total assets</b>	<b>\$ 10,586,918</b>	<b>\$ 3,282,549</b>
<b>Current liabilities:</b>		
Accounts payable	\$ 632,538	\$ 1,700,383
Accrued liabilities	966,899	1,143,863
Supplier financings	42,369	48,880
Current portion of equipment financings	110,924	255,605
Current portion of credit facility	1,588,058	1,896,718
Total current liabilities	3,340,788	5,045,449
Non-current portion of equipment financings, net	291,189	572,096
Non-current portion of credit facility, net	2,638,487	1,593,220
Non-current portion of interest payable	153,547	209,914
Non-current portion of deferred rent	470,172	418,028
<b>Total liabilities</b>	<b>6,894,183</b>	<b>7,838,707</b>
<b>Commitments and contingencies (see Note 11)</b>		
<b>Shareholders' equity/(deficit):</b>		
Common stock, \$0.0001 par value, 40,000,000 authorized; 6,556,685 issued and outstanding at December 31, 2015; 150,000,000 authorized; 8,399,397 issued and outstanding at September 30, 2016.	656	840
Additional paid-in capital	158,928,627	164,891,998
Accumulated deficit	(155,236,548)	(169,448,996)
<b>Total shareholders' equity/(deficit)</b>	<b>3,692,735</b>	<b>(4,556,158)</b>
<b>Total liabilities and shareholders' equity/(deficit)</b>	<b>\$ 10,586,918</b>	<b>\$ 3,282,549</b>

*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,	
	2015	2016	2015	2016
Revenues:	\$ 164,856	\$ 1,047,280	\$ 391,626	\$ 1,931,509
Costs and expenses:				
Cost of revenues	1,159,710	1,876,288	3,320,467	5,020,649
Research and development expenses	677,729	600,613	2,073,391	2,044,968
General and administrative expenses	1,630,608	1,919,843	4,281,883	4,924,731
Sales and marketing expenses	1,055,653	1,278,455	2,616,218	3,875,063
Total costs and expenses	<u>4,523,700</u>	<u>5,675,199</u>	<u>12,291,959</u>	<u>15,865,411</u>
Loss from operations	(4,358,844)	(4,627,919)	(11,900,333)	(13,933,902)
Other income/(expense):				
Interest expense, net	(175,562)	(154,869)	(494,235)	(393,029)
Other income	38,412	38,412	64,020	115,236
Gain on sale of fixed assets	—	1,300	—	1,300
Total other income/(expense):	<u>(137,150)</u>	<u>(115,157)</u>	<u>(430,215)</u>	<u>(276,493)</u>
Loss before income taxes	(4,495,994)	(4,743,076)	(12,330,548)	(14,210,395)
Income tax expense	(199)	—	(1,478)	(2,053)
Net loss and comprehensive loss	<u>\$ (4,496,193)</u>	<u>\$ (4,743,076)</u>	<u>\$ (12,332,026)</u>	<u>\$ (14,212,448)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	<u>6,242,604</u>	<u>8,370,691</u>	<u>5,245,303</u>	<u>7,549,663</u>
Diluted	<u>6,242,604</u>	<u>8,370,691</u>	<u>5,245,303</u>	<u>7,549,663</u>
Net loss per common share:				
Basic	<u>\$ (0.72)</u>	<u>\$ (0.57)</u>	<u>\$ (2.35)</u>	<u>\$ (1.88)</u>
Diluted	<u>\$ (0.72)</u>	<u>\$ (0.57)</u>	<u>\$ (2.35)</u>	<u>\$ (1.88)</u>

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

**Biocept, Inc.**  
**Condensed Statements of Cash Flows**  
**(Unaudited)**

	For the nine months ended September 30,	
	2015	2016
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (12,332,026)	\$ (14,212,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	188,120	248,164
Inventory reserve	(20,277)	(40,708)
Stock-based compensation	1,016,266	1,164,979
Non-cash interest expense related to credit facility and other financing activities	93,454	60,951
Gain on sale of fixed assets	—	(1,300)
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable	(29,760)	(51,464)
Inventories	(93,000)	(107,538)
Prepaid expenses and other current assets	(181,284)	501,532
Accounts payable	142,028	991,846
Accrued liabilities	218,468	152,860
Accrued interest	96,295	58,684
Deferred rent	5,614	(22,839)
Net cash used in operating activities	(10,896,102)	(11,257,281)
<b>Cash Flows from Investing Activities:</b>		
Proceeds from sale of fixed assets	—	1,300
Purchases of fixed assets	(118,896)	(392,496)
Net cash used in investing activities	(118,896)	(391,196)
<b>Cash Flows from Financing Activities:</b>		
Net proceeds from issuance of common stock and warrants	8,830,057	4,798,576
Proceeds from exercise of common stock warrants	9,697,660	—
Payments on equipment financings	(54,007)	(86,336)
Payments on supplier and other third party financings	(33,674)	(427,934)
Payments on line of credit	(247,701)	(778,303)
Net cash provided by financing activities	18,192,335	3,506,003
Net increase (decrease) in Cash and Cash Equivalents	7,177,337	(8,142,474)
Cash and Cash Equivalents at Beginning of Period	5,364,582	8,821,329
Cash and Cash Equivalents at End of Period	<u>\$ 12,541,919</u>	<u>\$ 678,855</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	<u>\$ 309,324</u>	<u>\$ 282,142</u>
Taxes	<u>\$ 2,054</u>	<u>\$ 2,053</u>

**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 3). 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, (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, 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 3). 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 4).

Fixed assets purchased totaling \$279,008 and \$631,232 during the nine months ended September 30, 2015 and 2016, 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, a financing agreement underlying a fixed asset with a remaining net book value of \$126,811, which was previously recorded as an equipment financing obligation, was cancelled.

The amount of unpaid fixed asset purchases excluded from cash purchases in the Company's unaudited condensed statements of cash flows decreased from \$19,546 at December 31, 2014 to \$3,190 at September 30, 2015. 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.

During the nine months ended September 30, 2016, the Company financed insurance premiums of \$434,475 through third party financings.

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 13). 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, and a corresponding total of approximately \$5.2 million was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering. Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of \$1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of \$0.0009 per warrant to cover overallocments, if any. Through the date that these unaudited condensed financial statements were available to be issued, 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. 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. As of September 30, 2016, a total of \$130,252 of costs directly associated with this offering were accrued and recorded in prepaid expenses and other current assets, of which none were paid as of September 30, 2016 and thus excluded from changes in both prepaid expenses and other current assets and accounts payable in the Company's unaudited condensed statement of cash flows, and which were also subsequently reclassified to common stock issuance costs as an offset to additional paid in capital upon the closing of this offering.

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

## NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

**1. Basis of Presentation****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, 2015 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, 2015, filed with the SEC with our Annual Report on Form 10-K on March 10, 2016 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.

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. 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, which was not affected by the one-for-three reverse stock split.

**The Company and Business Activities**

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

The Company operates a clinical laboratory that is CLIA-certified (under the Clinical Laboratory Improvement Amendment of 1988) and CAP-accredited (by the College of American Pathologists), and manufactures 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.

**Recent Accounting Pronouncements**

In May 2014, and as subsequently updated and amended from time to time, the Financial Accounting Standards Board, or 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 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. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. The Company is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

In June 2014, the FASB issued authoritative guidance requiring share-based payments with a performance target which affects vesting and that could be achieved after the requisite service period be treated as a performance condition. This guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2015. The Company adopted this guidance for the interim



reporting period ended September 30, 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 is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and 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 does not expect adoption of this guidance to have a material impact on its 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 does not expect adoption of this guidance to have a material impact on its financial statements or disclosures.

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 is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

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 is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and 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 is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and 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 is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and 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. Early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of this guidance on its financial statements and disclosures.

## **2. Liquidity and Going Concern Uncertainty**

As of September 30, 2016, cash and cash equivalents totaled \$0.7 million and the Company had an accumulated deficit of \$169.4 million. For the year and nine month periods ended December 31, 2015 and September 30, 2016, the Company incurred net losses of \$16.9 million and \$14.2 million, respectively. At September 30, 2016, the Company had aggregate gross interest-bearing indebtedness of approximately \$5.3 million, of which approximately \$2.2 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 \$2.8 million of other non-interest bearing 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 (see Note 11). These factors raise substantial doubt about the Company's ability to continue as a going concern. 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.

Subsequent to the closing of a follow-on public offering on February 13, 2015, cash proceeds of approximately \$9.8 million have been received by the Company from the exercise of warrants sold in such offering, while approximately \$2.7 million in gross warrant proceeds remain outstanding and available to be exercised at \$4.68 per share until their expiration in February 2020. In May 2015, the SEC declared effective a shelf registration statement filed by the Company. The shelf registration statement allows the Company to issue any combination of its common stock, preferred stock, debt securities and warrants from time to time for an aggregate initial offering price of up to \$50 million, subject to certain limitations for so long as the Company's public float is less than \$75 million. A public offering of the Company's common stock and warrants to purchase its common stock was effected under this shelf registration statement on April 29, 2016, the closing of which occurred on May 4, 2016, pursuant to which the Company received net cash proceeds of approximately \$4.3 million (see Note 3). Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in such 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. Following this offering and through the date that the Company's September 30, 2016 unaudited condensed financial statements are available to be issued, given the limitations that apply for so long as the Company's public float is less than \$75 million, no additional common stock, preferred stock, debt securities or warrants may be sold by the Company under this shelf registration statement. 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. 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 for total gross proceeds to the Company of approximately \$10.0 million (see Note 13).

## **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**

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 underwriting discounts and additional costs paid to the underwriters, \$9.1 million of net cash proceeds. The total increase in capital as a result of the sale of these shares and warrants was \$8.8 million after deducting \$0.3 million of additional non-underwriter costs incurred. 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 overallocation 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. Underwriter costs and discounts of \$0.2 million and \$0.7 million, respectively, as well as additional non-underwriter costs associated with this offering of \$0.3 million, were also recorded to common stock issuance costs upon closing. 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 such offering. As such, the aggregate total increase in capital related to this offering has been \$18.6 million, after deducting the \$0.9 million of underwriter costs and discounts and \$0.3 million of additional non-underwriter costs incurred, which were offset against these proceeds under applicable accounting guidance.

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 the placement agent's fees and non-accountable expense reimbursements paid to Wainwright, as well as advisory service fees paid to Roth Capital Partners, LLC and certain other transactional fees paid to third parties, approximately \$4.6 million of net cash proceeds. The total increase in capital as a result of the sale of these shares and warrants was approximately \$4.3 million after deducting an estimated \$0.3 million of additional third party costs incurred in connection with this offering. An aggregate balance of approximately \$0.7 million related to placement agent's fees, advisory service expenses and non-placement agent costs associated with this offering was recorded to common stock issuance costs upon closing under applicable accounting guidance. Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in such 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. Following this offering and through the date that the Company's September 30, 2016 unaudited condensed financial statements are available to be issued, given the limitations that apply for so long as the Company's public float is less than \$75 million, no additional common stock, preferred stock, debt securities or warrants may be sold by the Company under this shelf registration statement. 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 (see Note 13). 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. Under the common stock purchase agreement, on any trading day selected by the Company, the Company had the right, in its sole discretion, to present a purchase notice directing Aspire Capital to purchase up to 33,333 shares of the Company's common stock per business day, up to \$15.0 million of common stock in the aggregate at a per share price equal to the lesser of either (i) the lowest sale price of the Company's common stock on the purchase date, or (ii) the arithmetic average of the three lowest closing sale prices for the Company's common stock during the 10 consecutive trading days ending on the trading day immediately preceding the purchase date. In addition, on any date on which the Company submitted a purchase notice to Aspire Capital in an amount equal to 33,333 shares and the Company's stock price was not less than \$1.50 per share, the Company also had the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the its principal market on the next trading day, subject to a maximum number of shares the Company could determine. The purchase price per share pursuant to such volume-weighted average price purchase notice was generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the volume-weighted average purchase date. The purchase price was to be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the

purchase price. The Company could have delivered multiple purchase notices and volume-weighted average price purchase notices to Aspire Capital from time to time during the term of the common stock purchase agreement, so long as the most recent purchase had been completed. The common stock purchase agreement provided that the Company and Aspire Capital would not effect any sales on any purchase date where the closing sale price of the Company's common stock was less than \$1.50. There were no trading volume requirements or restrictions under the common stock purchase agreement, and the Company controlled the timing and amount of sales of its common stock to Aspire Capital. Aspire Capital had no right to require any sales by the Company, but was obligated to make purchases from the Company as directed by the Company in accordance with the common stock purchase agreement. There were no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the 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 common stock purchase agreement could have been terminated by the Company at any time, at its discretion, without any cost to the Company. Aspire Capital had agreed that neither it nor any of its agents, representatives and affiliates were to engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the common stock purchase agreement. The proceeds received by the Company under the common stock purchase agreement were used for working capital and general corporate purposes. During the nine months ended September 30, 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 \$83,000 during the year ended December 31, 2015 and nine months ended September 30, 2016, respectively, were also recorded to common stock issuance costs under applicable accounting guidance, and as such, the aggregate total increase in capital related to this transaction was 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 for total gross proceeds to the Company of approximately \$10.0 million (see Note 13).

#### 4. Fair Value Measurement

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

#### Other Fair Value Measurements

As of the closing of the Company's public offering in May 2016, 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 such 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%

The estimated fair value of the April 2014 Credit Facility at September 30, 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.

## 5. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2015	September 30, 2016
<b>Fixed Assets</b>		
Machinery and equipment	\$ 2,518,158	\$ 2,707,601
Furniture and office equipment	143,726	143,726
Computer equipment and software	577,898	617,802
Leasehold improvements	514,614	517,968
Financed equipment	914,179	1,457,377
Construction in process	70,815	118,280
	4,739,390	5,562,754
Less accumulated depreciation and amortization	3,793,210	4,041,374
Total fixed assets, net	<u>\$ 946,180</u>	<u>\$ 1,521,380</u>
<b>Accrued Liabilities</b>		
Accrued interest	\$ 28,981	\$ 23,825
Accrued payroll	128,753	301,988
Accrued vacation	307,845	313,825
Accrued bonuses	376,100	318,237
Accrued sales commissions	76,574	97,844
Current portion of deferred rent	31,170	60,475
Accrued other	17,476	27,669
Total accrued liabilities	<u>\$ 966,899</u>	<u>\$ 1,143,863</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. If on or before September 30, 2016 the Company received unrestricted net cash proceeds of at least \$7.0 million from the issuance and sale its equity securities, or the Company received a signed letter of intent relating to a sale or merger of the Company, in form and substance satisfactory to the lender, the Company could have been required to make interest-only payments on the term loan through December 31, 2016, and the amount of the additional final payment to the lender upon repayment would have increased to \$75,000, which did not occur. 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 Company's 2014 Credit Facility was accounted for as a modification of debt under applicable accounting guidance.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to 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 recorded as a discount to outstanding debt as of the closing date. The discounts and other issuance costs are amortized to interest expense utilizing the effective interest method over the underlying term of the loan. The effective annual interest rate associated with the April 2014 Credit Facility was 11.50% and 13.87% at December 31, 2015 and September 30, 2016, respectively.

## 7. Capital Lease Obligations

The Company leases certain laboratory equipment under arrangements classified as capital leases. The leased equipment is depreciated on a straight-line basis over periods ranging from 5 to 7 years. Total gross value of fixed assets capitalized under such lease arrangements was \$914,179 and \$1,457,377 at December 31, 2015 and September 30, 2016, respectively. Total accumulated depreciation related to the leased equipment was approximately \$523,000 and \$616,000 at December 31, 2015 and September 30, 2016, respectively. Total depreciation expense for the leased equipment was approximately \$24,000 and \$40,000 for the three months ended September 30, 2015 and 2016, respectively, and was approximately \$49,000 and \$93,000 for the nine months ended September 30, 2015 and 2016, respectively. The weighted average effective annual interest rates related to the lease obligations are 13.35% and the maturity dates on outstanding arrangements range from July 2017 to May 2023.

The following schedule sets forth the future minimum lease payments, as well as corresponding laboratory equipment maintenance obligations that are not recorded as part of the leased equipment balances within fixed assets or capital lease obligations, outstanding under capital leases and due within each respective year ending December 31, and the present value of the minimum lease payments as of September 30, 2016:

	Minimum Lease Payments	Maintenance Obligation Payments
2016	\$ 68,754	\$ 6,375
2017	238,287	25,440
2018	190,333	25,434
2019	155,388	24,676
2020	151,400	24,608
Thereafter	374,005	59,471
Total payments	1,178,167	166,004
Less amount representing interest	350,466	—
Present value of payments	<u>\$ 827,701</u>	<u>\$ 166,004</u>

At September 30, 2016, the present value of minimum lease payments due within one year was \$255,605.

## 8. Stock-based Compensation

On September 27, 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 January 1, 2015.

### 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 27, 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 September 30, 2016, under all plans, a total of 1,022,955 non-inducement shares were authorized for issuance, 978,358 non-inducement stock options and restricted stock units, or RSUs, had been issued and were outstanding, and 3,115 non-inducement shares were available for grant. As of September 30, 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

A summary of stock option activity for option awards granted under the 2013 Plan and 2007 Plan for the nine months ended September 30, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Vested and unvested expected to vest, December 31, 2015	646,900	\$ 15.48	9.0
Outstanding at December 31, 2015	713,659	\$ 11.23	9.0
Granted	276,628	\$ 2.60	
Exercised	—		
Cancelled/forfeited/expired	(63,679)	\$ 8.08	
Outstanding at September 30, 2016	926,608	\$ 8.87	8.7
Vested and unvested expected to vest, September 30, 2016	838,037	\$ 9.37	8.1

The intrinsic values of options outstanding and options vested and unvested expected to vest at September 30, 2016 were both zero. The intrinsic value of options exercisable at September 30, 2016 was zero.

The fair values of option awards granted during the nine months ended September 30, 2016 were estimated using a Black-Scholes pricing model with the following assumptions:

Stock and exercise prices	\$1.57 - \$4.02
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	0.99% - 1.39%
Expected life (in years)	5.13 - 6.08
Expected volatility	80.0% - 90.0%

Using the assumptions described above, with stock and exercise prices being equal on date of grant, the weighted-average estimated fair value of options granted in the nine months ended September 30, 2016 was \$1.86 per share.

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 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 to its Chief Executive Officer pursuant to the 2013 Plan. Vesting of these stock options may occur based on the Company's achievement of specified objectives by December 31, 2016 as determined by the Company's Board of Directors, or a committee of the Company's Board of Directors, in its sole discretion, as follows:

<b>Target</b>	<b>Percentage of Overall Stock Option Grants Subject to Vesting</b>
Minimum number of accessions processed, billed and collected	13%
Minimum revenues from contracts with pharmaceutical companies	10%
Attainment of a sustainable positive GAAP gross margin	12%
Minimum operating cash on-hand with no more than one interim dilutive equity financing event	15%
Achievement of the Company's 2016 corporate goals	25%
Completion of a Board-approved strategic transaction	25%
Total	<u>100%</u>

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 to purchase up to (i) 66,666 shares of the Company's common stock with an estimated grant date fair value of \$1.45 per share, 25% of which will vest on the one-year anniversary of the commencement of the CFO's employment with the Company, and remainder of which will vest in equal monthly installments over the following three years, and (ii) 33,333 shares of the Company's common stock with an estimated grant date fair value of \$1.26 per share, which vest upon the Company's achievement of specified corporate goals for 2016 and the consummation of a specified financing transaction.

### Restricted Stock

A summary of RSU activity for awards granted under the 2013 Plan and 2007 Plan for the nine months ended September 30, 2016 is as follows:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Vested and unvested expected to vest, December 31, 2015	<u>15,369</u>	\$ 14.49
Outstanding at December 31, 2015	<u>25,752</u>	\$ 15.12
Granted	165,829	\$ 1.96
Vested and issued	(4,449)	\$ 16.05
Forfeited	(10,383)	\$ 16.05
Outstanding at September 30, 2016	<u>176,749</u>	\$ 2.70
Vested and unvested expected to vest, September 30, 2016	<u>172,550</u>	\$ 2.71

The RSUs granted during the nine months ended September 30, 2016 vest fully on the one year anniversary of the date of grant, subject to continuing service by the holders of such RSUs. At September 30, 2016, the intrinsic values of RSUs outstanding and RSUs unvested and expected to vest were \$277,496 and \$270,904, respectively.

On June 12, 2014, the Company's Board of Directors granted an RSU award for 14,832 shares 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 the Compensation Committee of the Board of Directors, as follows:



<b>Target</b>	<b>Percentage of Overall RSU Grant Subject to Vesting</b>
Minimum revenue	25%
Maximum EBITDA loss	15%
Attainment of financial plan for fiscal 2015	20%
Minimum value of strategic agreements	20%
Implementation of four new diagnostic test panels	20%
<b>Total</b>	<b>100%</b>

During the nine months ended September 30, 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 this award and the remaining 10,383 shares underlying this RSU were forfeited.

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 unaudited condensed statements of operations and comprehensive loss during the periods presented:

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2015	2016	2015	2016
<u>Stock Options</u>				
Cost of revenues	\$ 15,029	\$ 34,119	\$ 48,839	\$ 89,606
Research and development expenses	20,910	28,189	65,835	87,153
General and administrative expenses	257,404	292,381	706,026	829,516
Sales and marketing expenses	31,888	51,924	93,989	91,164
Total expenses related to stock options	325,231	406,613	914,689	1,097,439
<u>RSUs</u>				
Cost of revenues	—	14,918	—	16,834
Research and development expenses	1,625	14,131	10,724	15,583
General and administrative expenses	12,515	6,668	90,853	7,676
Sales and marketing expenses	—	22,939	—	27,447
Total stock-based compensation	\$ 339,371	\$ 465,269	\$ 1,016,266	\$ 1,164,979

Stock-based compensation expense was recorded net of estimated forfeitures of 0% - 4% and 0% - 8% per annum during the three and nine months ended September 30, 2015 and 2016, respectively. As of September 30, 2016, total unrecognized stock-based compensation expense related to unvested stock options and RSUs, adjusted for estimated forfeitures, was approximately \$2,081,000 and is expected to be recognized over a weighted-average period of 2.1 years.

### 9. Common Stock Warrants Outstanding

On September 27, 2016, the Company effected a one-for-three reverse stock split of all common shares outstanding. The summary of equity-classified common stock warrant activity has been adjusted for this reverse stock split as if it had occurred on December 31, 2015.

A summary of equity-classified common stock warrant activity for the nine months ended September 30, 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2015	784,234	\$ 11.19	3.8
Issued	1,163,526	\$ 3.90	
Exercised	—		
Expired	(50,904)	\$ 30.00	
Outstanding at September 30, 2016	1,896,856	\$ 6.21	4.1

The intrinsic value of equity-classified common stock warrants outstanding and exercisable at September 30, 2016 was zero.

## 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 nine months ended September 30, 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 27, 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 January 1, 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,	
	2015	2016
Preferred warrants outstanding (number of common stock equivalents)	529	529
Preferred share RSUs (number of common stock equivalents)	24,384	—
Common warrants outstanding	797,579	1,896,856
Common share RSUs	25,752	176,749
Common options outstanding	684,779	926,608
Total anti-dilutive common share equivalents	1,533,023	3,000,742

## 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, 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.

## 12. 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 of 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 gross proceeds of \$177,500 (see Note 3).

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 a payment of \$19,047 during the nine months ended September 30, 2016 from Aegea as reimbursement 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 is subject to renewal on a month-to-month basis thereafter. A total of \$64,020 and \$115,236 in rental income was recorded to other income in the Company's unaudited condensed statements of operations and comprehensive loss during the nine months ended September 30, 2015 and 2016, 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 the Company's major stockholder, 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 3).

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.

### 13. Subsequent Events

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 for total gross proceeds to the Company of approximately \$10.0 million. The estimated grant date fair value of these warrants of approximately \$0.57 per share, or a total of approximately \$5.2 million, was recorded as an offset to additional paid-in capital within common stock issuance upon the closing of this offering. Additionally, the underwriters were granted a 30-day option to purchase up to 1,365,000 additional shares of common stock at a price of \$1.0331 per share, net of the underwriting discount, and/or additional warrants to purchase up to 1,365,000 shares of common stock at a price of \$0.0009 per warrant to cover overallocments, if any. Through the date that these unaudited condensed financial statements were available to be issued, 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. 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 fair values of these overallocation options and all warrants issued in the October 2016 offering were estimated using Black-Scholes valuation models with the following assumptions:

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

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 the Company's major shareholder, 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. The closing of the sale of these securities to the underwriters occurred on October 19, 2016, when the Company received, after deducting \$0.6 million of underwriters' discount and additional costs paid to the underwriters, \$9.4 million of net cash proceeds. Subsequent to the closing of this offering on October 19, 2016 and through the date that these unaudited condensed financial statements were available to be issued, no additional cash proceeds had been received from the exercise of warrants sold in such offering. As such, the total increase in capital as a result of the sale of these shares and warrants is \$8.8 million after deducting the \$0.6 million of underwriter fees and costs and the estimated additional \$0.6 million of non-underwriter costs incurred, which were offset against these proceeds under applicable accounting guidance.

Over the past several years the Company has generated operating losses in all jurisdictions in which it may be subject to income taxes. As a result, the Company has accumulated significant net operating losses and other deferred tax assets. Because of the Company's history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized.

The Company does not expect to report a provision for income taxes until it has a history of earnings, if ever, that would support the realization of its deferred tax assets.

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

On November 4, 2016, the Company voluntarily terminated the common stock purchase agreement that the Company entered into on December 21, 2015, with Aspire Capital. Pursuant to this common stock purchase agreement, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was 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.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission on March 10, 2016. Past operating results are not necessarily indicative of results that may occur in future periods. The share numbers in the following discussion reflect a one-for-three reverse common stock split that we effected on September 27, 2016.*

We are an early stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell, or CTC, and circulating tumor DNA, or ctDNA, assays utilizing a standard blood sample, or "liquid biopsy." Our assays provide, and our planned future assays would 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 timelier and more contemporaneous data on the characteristics of their patients' tumors.

Our current assays and our planned future assays focus on key solid tumor indications utilizing our Target-Selector™ CTC offering for the biomarker analysis of CTCs and ctDNA from a standard blood sample. The Target-Selector CTC offering is based on an internally developed and patented, microfluidics-based capture and analysis platform, with enabling features that change how CTC testing is used by clinicians. The Target-Selector platforms provide both biomarker detection as well as monitoring capabilities, and require only a blood sample. Our patent pending Target-Selector ctDNA technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood, plasma, or cerebrospinal fluid. We believe the Target-Selector technology can someday be used as a stand-alone test for molecular biomarker screening, marked as in vitro diagnostics kits.

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

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

In the case of our breast and gastric cancer offering, biomarker analysis involves fluorescence in situ hybridization, or FISH, for the detection and quantitation of the human epidermal growth factor receptor 2, or HER2, gene copy number as well as immunocytochemical analysis of estrogen receptor, or ER, protein, as well as androgen receptor, or AR, protein, which are currently commercially available. We plan to include immunocytochemical analysis of progesterone receptor, or PR, proteins as part of the Target-Selector CTC menu in 2017. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. ER and PR status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

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

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

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

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

We plan to add other biomarker analyses, such as ESR1 and NRAS, on blood samples to our current assays and our planned future Target-Selector CTC assays as their relevance is demonstrated in clinical trials and/or included in guidelines used by physicians to make treatment decisions.

We continue to execute on our strategies of expanding our business globally as well as engaging with pharmaceutical companies on clinical trials and assay development. We have executed distribution agreements in Mexico with Quest Diagnostics to support testing for a large pharmaceutical partner, as well as an agreement with Progenetics to market our assays in Israel for clinical testing.

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

Our revenue generating efforts are focused in three areas:

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

The following tables set forth certain information concerning our commercial cases accessioned for the periods shown:

	<b>Three Months Ended September 30,</b>		<b>Change</b>	
	<b>2015</b>	<b>2016</b>	<b>#</b>	<b>%</b>
Commercial cases accessioned	443	1,023	580	131%
	<b>Nine Months Ended September 30,</b>		<b>Change</b>	
	<b>2015</b>	<b>2016</b>	<b>#</b>	<b>%</b>
Commercial cases accessioned	1,024	2,727	1,703	166%

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 nine months ended September 30, 2015 and 2016, the average number of tests performed increased from 2.4 tests per accession to 3.8 tests per accession, respectively. For commercial accessions received from January 1, 2016 through September 30, 2016, the expected price to be collected at 2016 Medicare schedule rates ranged from less than \$200 per accession to over \$5,000 per accession, and the weighted-average expected price to be collected is approximately \$1,185 per accession, although such reimbursement experience has not yet been achieved. Relatively higher reimbursement rates are expected to be achieved for cases billed to certain private payors where we have agreements. Approximately 47% of the number of commercial accessions billed from January 1, 2016 through September 30, 2016 were subject to Medicare reimbursement rates, and approximately 50% and 45% of commercial revenues and total revenues, respectively, during the nine months ended September 30, 2016 were associated with Medicare reimbursement. 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 also managing an external “out-sourced” billing company. Additionally, a significant amount of our non-Medicare business (private payors) has historically not been contracted, and reimbursement for this business has historically not been at “in network” rates and has therefore been inconsistent. We did begin to contract private payor networks in 2015 and continue to do so in 2016, and our number of accessions treated as “in network” increased and reimbursement is improving. We are currently contracted with eight Preferred Provider Organization networks, one large health plan, 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.

## Results of Operations

### Three Months Ended September 30, 2015 and 2016

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

	Three Months Ended September 30,		Change	
	2015	2016	\$	%
<i>(dollars in thousands)</i>				
Revenues	\$ 165	\$ 1,047	\$ 882	535%
Cost of revenues	1,160	1,876	716	62%
Research and development expenses	678	601	(77)	(11%)
General and administrative expenses	1,630	1,920	290	18%
Sales and marketing expenses	1,056	1,278	222	21%
<b>Loss from operations</b>	<b>(4,359)</b>	<b>(4,628)</b>	<b>(269)</b>	<b>6%</b>
Interest expense, net	(175)	(154)	21	(12%)
Other income	38	38	—	—
Gain on sale of fixed assets	—	1	1	—
<b>Loss before income taxes</b>	<b>(4,496)</b>	<b>(4,743)</b>	<b>(247)</b>	<b>5%</b>
Income tax expense	—	—	—	—
<b>Net loss</b>	<b>\$ (4,496)</b>	<b>\$ (4,743)</b>	<b>\$ (247)</b>	<b>5%</b>

### Revenues

Revenues were approximately \$1,047,000 for the three months ended September 30, 2016, compared with approximately \$165,000 for the same period in 2015, an increase of \$882,000, or 535%. The increase was due to an increase of approximately \$840,000 in commercial assay revenues resulting primarily from increases in both commercial accession volume and collections made thereon, as well as an increase of approximately \$42,000 in development services revenues with 156 development services accessions received during the three months ended September 30, 2016 as compared to 88 accessions received during the same period in 2015.

### Costs and Expenses

*Cost of Revenues.* Cost of revenues was approximately \$1,876,000 for the three months ended September 30, 2016, compared with approximately \$1,160,000 for the three months ended September 30, 2015, an increase of \$716,000, or 62%. The increase was primarily attributable to an increase of approximately \$645,000 in personnel, materials, and other direct costs mainly related to higher assay volume, an increase of approximately \$49,000 in third party consulting fees, as well as an increase of approximately \$22,000 related to fewer laboratory costs charged to research and development.

*Research and Development Expenses.* Research and development expenses were approximately \$601,000 for the three months ended September 30, 2016, compared with approximately \$678,000 for the three months ended September 30, 2015, a decrease of \$77,000, or 11%. The decrease was primarily attributable to a decrease of approximately \$43,000 in materials and supplies consumed in performing research and development activities, as well as a decrease of approximately \$22,000 in laboratory costs charged to research and development.

*General and Administrative Expenses.* General and administrative expenses were approximately \$1,920,000 for the three months ended September 30, 2016, compared with approximately \$1,630,000 for the three months ended September 30, 2015, an increase of \$290,000, or 18%. The increase was primarily due to an increase of approximately \$144,000 in consulting and other third party service provider costs mainly related to expanded commercial activities, an increase of \$74,000 in third party billing fees associated with increased cash collections on commercial revenues, and an increase of approximately \$60,000 in legal fees primarily associated with patents.

*Sales and Marketing Expenses.* Sales and marketing expenses were approximately \$1,278,000 for the three months ended September 30, 2016, compared with approximately \$1,056,000 for the three months ended September 30, 2015, an increase of \$222,000, or 21%. The increase was due to approximately \$223,000 in additional personnel costs and travel expenses associated with an increase in the average number of employees included in the sales and marketing function from 12 employees during the three months ended September 30, 2015 to 15 employees during the same period in 2016.

## 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 in 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.

## Nine Months Ended September 30, 2015 and 2016

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

	Nine Months Ended September 30,		Change	
	2015	2016	\$	%
(dollars in thousands)				
Revenues	\$ 392	\$ 1,932	\$ 1,540	393%
Cost of revenues	3,321	5,021	1,700	51%
Research and development expenses	2,073	2,045	(28)	(1%)
General and administrative expenses	4,282	4,925	643	15%
Sales and marketing expenses	2,616	3,875	1,259	48%
<b>Loss from operations</b>	<b>(11,900)</b>	<b>(13,934)</b>	<b>(2,034)</b>	<b>17%</b>
Interest expense, net	(495)	(393)	102	(21%)
Other income	64	116	52	81%
Gain on sale of fixed assets	—	1	1	—
<b>Loss before income taxes</b>	<b>(12,331)</b>	<b>(14,210)</b>	<b>(1,879)</b>	<b>15%</b>
Income tax expense	(1)	(2)	(1)	100%
<b>Net loss</b>	<b>\$ (12,332)</b>	<b>\$ (14,212)</b>	<b>\$ (1,880)</b>	<b>15%</b>

## Revenues

Revenues were approximately \$1,932,000 for the nine months ended September 30, 2016, compared with approximately \$392,000 for the same period in 2015, an increase of \$1,540,000, or 393%. The increase was due to an increase of approximately \$1,428,000 in commercial assay revenues resulting primarily from increases in both commercial accession volume and collections made thereon, as well as an increase of approximately \$112,000 in development services revenues with 382 development services accessions received during the nine months ended September 30, 2016 as compared to 182 accessions received during the same period in 2015.

## Costs and Expenses

*Cost of Revenues.* Cost of revenues was approximately \$5,021,000 for the nine months ended September 30, 2016, compared with approximately \$3,321,000 for the nine months ended September 30, 2015, an increase of \$1,700,000, or 51%. The increase was primarily attributable to an increase of approximately \$1,531,000 in personnel, materials, and other direct costs mainly related to higher assay volume, an increase of approximately \$78,000 related to fewer laboratory costs charged to research and development, as well as an increase of approximately \$72,000 in third party consulting fees.

*Research and Development Expenses.* Research and development expenses were approximately \$2,045,000 for the nine months ended September 30, 2016, compared with approximately \$2,073,000 for the nine months ended September 30, 2015, a decrease of \$28,000, or 1%. The decrease was primarily attributable to a decrease of approximately \$78,000 related to fewer laboratory costs charged to research and development, a decrease of approximately \$42,000 in third party consulting fees, and a decrease of approximately \$21,000 in materials and supplies consumed in performing research and development activities, partially offset by an increase of approximately \$120,000 related to an increase in the average number of employees included in the research and development function from 8 employees during the nine months ended September 30, 2015 to 11 employees during the same period in 2016.



**General and Administrative Expenses.** General and administrative expenses were approximately \$4,925,000 for the nine months ended September 30, 2016, compared with approximately \$4,282,000 for the nine months ended September 30, 2015, an increase of \$643,000, or 15%. The increase was primarily due to an increase of approximately \$204,000 in consulting and other third party service provider costs mainly related to expanded commercial activities, an increase of \$156,000 in third party billing fees associated with increased cash collections on commercial revenues, an increase of approximately \$114,000 related to an increase in the average number of employees included in the general and administrative function from 7 employees during the nine months ended September 30, 2015 to 9 employees during the same period in 2016, an increase of approximately \$100,000 due to increased allocated facility costs and depreciation, as well as an increase of approximately \$82,000 in legal fees.

**Sales and Marketing Expenses.** Sales and marketing expenses were approximately \$3,875,000 for the nine months ended September 30, 2016, compared with approximately \$2,616,000 for the nine months ended September 30, 2015, an increase of \$1,259,000, or 48%. The increase was primarily due to an increase of approximately \$1,021,000 in personnel costs and travel expenses associated with an increase in the average number of employees included in the sales and marketing function from 12 employees during the nine months ended September 30, 2015 to 15 employees during the same period in 2016, as well as an increase of approximately \$193,000 in consulting and other third party service provider costs associated with expanded commercial activities.

### **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 in 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.

### **Liquidity and Capital Resources**

#### **Cash Flows**

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

	Nine Months Ended	
	September 30,	
	2015	2016
<i>(dollars in thousands)</i>		
Cash provided by (used in):		
Operating activities	\$ (10,896)	\$ (11,257)
Investing activities	(119)	(391)
Financing activities	18,192	3,506
Net increase (decrease) in cash and cash equivalents	\$ 7,177	\$ (8,142)

**Cash Used in Operating Activities.** Net cash used in operating activities was \$11.3 million for the nine months ended September 30, 2016, compared to net cash used in operating activities of \$10.9 million for the nine months ended September 30, 2015. The net increase of \$0.4 million of cash used in operating activities for the nine months ended September 30, 2016 as compared to the same period in 2015 was primarily related to an increase of \$1.9 million in cash used to fund our net loss, partially offset by an increase of approximately \$1.3 million of 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 and depreciation expenses.

**Cash Used in Investing Activities.** Cash used in investing activities of approximately \$391,000 and \$119,000 during the nine months ended September 30, 2016 and 2015, respectively, was related to the acquisition of fixed assets.

**Cash Provided by Financing Activities.** Net cash provided by financing activities was \$3.5 million for the nine months ended September 30, 2016, compared to net cash provided by financing activities of \$18.2 million for the nine months ended September 30, 2015. Our primary sources of cash from financing during the nine months ended September 30, 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 nine months ended September 30, 2016 consisted of \$4.3 million in net proceeds from our public offering in May 2016 and \$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 \$1.3 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 a portion of the net proceeds from our follow-on public offerings and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our 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 a portion of the net proceeds from our follow-on public offerings to acquire or invest in businesses, technologies, services or products, although we do not have any current plans to do so.

As of September 30, 2016, our cash and cash equivalents totaled \$0.7 million, and our outstanding indebtedness totaled \$5.3 million (including \$0.2 million of interest accrued thereon, and excluding \$0.7 million of associated debt discounts). 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 March 2017.

On February 13, 2015, we received net cash proceeds of \$9.1 million as a result of the closing of a follow-on public offering, before deducting \$0.3 million of additional non-underwriting costs incurred. Subsequent to the closing of this follow-on public offering on February 13, 2015, additional cash proceeds of approximately \$9.8 million have been received from the exercise of warrants sold in such 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, a public offering of 1,662,191 shares of our common stock and warrants to purchase up to an aggregate of 1,163,526 shares of common stock was effected under this registration statement at a combined offering price of \$3.00. All warrants sold in this offering have a per share exercise price of \$3.90, are exercisable immediately and expire five years from the date of issuance. The closing of the sale of these securities to the purchasers occurred on May 4, 2016, pursuant to which we received, after deducting the placement agent's fees and non-accountable expense reimbursements paid to Wainwright, as well as advisory service fees paid to Roth Capital Partners, LLC and certain other transactional fees paid to third parties, approximately \$4.6 million of net cash proceeds. The total increase in capital as a result of the sale of these shares and warrants was approximately \$4.3 million after deducting an estimated \$0.3 million of additional third party costs incurred in connection with this offering. An aggregate balance of approximately \$0.7 million related to placement agent's fees, advisory service expenses and non-placement agent costs associated with this offering was recorded to common stock issuance costs upon closing under applicable accounting guidance. Subsequent to the closing of this public offering on May 4, 2016, no warrants sold in such 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. Following this offering and through the date that our September 30, 2016 unaudited condensed financial statements are available to be issued, given the limitations that apply for so long as our public float is less than \$75 million, no additional common stock, preferred stock, debt securities or warrants may be sold by us under this shelf registration statement. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. The specific terms of additional future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

On December 21, 2015, we entered into a common stock purchase agreement with Aspire Capital, which committed to purchase up to an aggregate of \$15.0 million of shares of our common stock over the 30-month term of the common stock purchase agreement. On November 4, 2016, we voluntarily terminated this common stock purchase agreement. Upon execution of the common stock purchase agreement, we sold to Aspire Capital 208,334 shares of common stock at \$4.80 per share for gross proceeds of \$1,000,000, before deducting approximately \$0.1 million of associated costs incurred by third parties, and we concurrently also entered into a registration rights agreement with Aspire Capital, pursuant to which we filed a registration statement registering the sale of the shares of our common stock that were issued to Aspire Capital under the common stock purchase agreement. In consideration for entering into, and concurrently with the execution of, the common stock purchase agreement, we issued to Aspire Capital 55,000 shares of our common stock. During the nine months ended September 30, 2016, we submitted purchase notices to Aspire Capital for an aggregate of 173,145 shares of common stock for gross proceeds of \$544,051.

On October 19, 2016, we received net cash proceeds of approximately \$9.4 million as a result of the closing of a follow-on public offering, before deducting an estimated \$0.6 million of additional non-underwriting costs incurred. Subsequent to the closing of this public offering on October 19, 2016, the underwriters have exercised their overallotment option to purchase 627,131 option warrants for total proceeds of \$564. As such, warrants to purchase up to 9,727,131 shares of our common stock issued in connection with our October 2016 public offering were outstanding as of the date that our September 30, 2016 financial statements were available to be issued, with approximately \$10.7 million in corresponding gross warrant proceeds remaining outstanding and available to be exercised at \$1.10 per share until their expiration in October 2021.

We expect that we will need additional financing to execute on our current or future business strategies. Until we can generate significant cash from operations, including assay revenues, we expect to continue to fund operations with the proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration. For example, we have an effective shelf registration statement on file with the SEC which allows us to issue any combination of our common stock, preferred stock, debt securities and warrants from time to time with an available remaining aggregate initial offering price of up to approximately \$39.2 million, subject to certain limitations for so long as our public float is less than \$75.0 million. In connection with our public offering in May 2016, we have agreed to certain contractual terms that limit our ability to issue variable rate securities for a period of one year. We can provide no assurances that any sources of a sufficient amount of financing will be available to us on favorable terms, if at all. If we are unable to raise a sufficient amount of financing in a timely manner, we would likely need to scale back our general and administrative activities and certain of our research and development activities. Our forecast pertaining to our current financial resources and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

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

We may raise additional capital to fund our current operations and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by us could impose covenants that restrict our operations. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our 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**

For a discussion of accounting policies that we consider critical to our business operations and understanding of our results of operations, and that affect the more significant judgments and estimates used in the preparation of our financial statements, see Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” contained in our Annual Report on Form 10-K for the year ended December 31, 2015. There

have been no material changes to our critical accounting policies and estimates from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2015.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not applicable.

### **Item 4. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of September 30, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2016. There were no changes in our internal control over financial reporting that occurred during the nine months ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

For a discussion of our potential risks and uncertainties, please see the information listed below, along with the information listed in the item captioned “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015. Except as provided below, there have been no material changes to the risk factors as disclosed in the Form 10-K. You should carefully consider the risk factors discussed below and in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial position and results of operations.

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

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

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

If we fail to satisfy the continued listing requirements of The NASDAQ Capital Market, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum stockholders’ equity requirement, NASDAQ may take steps to de-list our common stock. For example, in May 2016, we received a letter from NASDAQ indicating that we are not in compliance with the minimum stockholders’ equity requirement of NASDAQ Listing Rule 5550(b)(1), and in June 2016, we received a letter from NASDAQ indicating that we are not in compliance with the minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2). If we fail to maintain compliance with these, or any other of the continued listing requirements of The NASDAQ Capital Market, NASDAQ may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with NASDAQ’s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, or prevent future non-compliance with NASDAQ’s listing requirements.

***We are undergoing management transitions.***

We recently hired Timothy Kennedy, who serves as our Chief Financial Officer, Senior Vice President of Operations and Secretary. We intend to recruit and hire other senior executives. Such management transitions subject us to a number of risks, including risks pertaining to coordination of responsibilities and tasks, creation of new management systems and processes, differences in management style, effects on corporate culture, and the need for transfer of historical knowledge. In addition, our Chief Executive Officer has not previously been the chief executive officer of a public or private company, and therefore his lack of experience may result in some of his time being spent acclimating to his new position and responsibilities. A lack of significant experience in being the chief executive officer of a public company could have an adverse effect on his ability to quickly respond to problems or effectively manage issues surrounding the operation of a public company.

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

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

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

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

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

We are also aware of a U.S. Patent owned by Genentech, Inc. that is relevant to one of the biomarkers we detect in our Liquid Biopsy Lung Cancer Resistance Profile Target Selector™ Assay and our Liquid Biopsy Colon Cancer Profile Target Selector™ Assay. The patent is expected to expire in 2025. Although we believe that the claims of the patent relevant to our assays would likely be held invalid, we cannot provide any assurances that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims in question is upheld upon a validity challenge, then we may be liable for past damages and would need a license in order to continue commercializing our Liquid Biopsy Lung Cancer Resistance Profile Target Selector™ Assay and our Liquid Biopsy Colon Cancer Profile Target Selector™ Assay in the United States. However, such a license may not be available on commercially reasonable terms or at all, which could 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 Test. The patent is expected to expire in 2021. At present, we believe that we will need a license to this patent to continue commercializing our Liquid Biopsy Immuno-Oncology PD-L1 Test. We are currently in discussions with Mayo and believe a license can be obtained on commercially reasonable terms. However, if we are unable to secure such a license, we may be liable for past damages, and our business could be materially and adversely affected.

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

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

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds****Unregistered Sales of Equity Securities**

None.

**Use of Proceeds**

Not applicable.

**Item 3. Defaults Upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

Not applicable.

**Item 6. Exhibits**

The exhibits listed on the accompanying index to exhibits immediately preceding the exhibits are filed as part of, or hereby incorporated by reference into, this Quarterly Report.





## Exhibit Index

The exhibits listed below are hereby filed with the SEC as part of this Quarterly Report on Form 10-Q.

### EXHIBITS

Exhibit No.	Description of Exhibit
3.1	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1.4 of the Registrant's Current Report on Form 8-K, filed with the SEC on February 14, 2014).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on September 29, 2016).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Specimen Common Stock certificate of Biocept, Inc. (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 5, 2013).
4.3	Form of Representative's Warrant, dated February 10, 2014 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), as amended, filed with the SEC on November 20, 2013).
4.4	Form of Warrant issued to the lender under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
4.5	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-201437), filed with the SEC on February 6, 2015).
4.6	Warrant to Purchase Preferred Stock, dated September 10, 2012, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.7	Warrant to Purchase Common Stock, dated September 10, 2013, issued by the Registrant in favor of ARE-SD Region No. 18, LLC (incorporated by reference to Exhibit 10.11.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.8	Warrant to Purchase Preferred Stock dated as of January 21, 2009, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.9	Warrant to Purchase Common Stock dated as of July 31, 2013, issued by the Registrant in favor of Goodman Co. Ltd. (incorporated by reference to Exhibit 10.17.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.10	Form of Warrant to Purchase Preferred Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of January 13, 2012 (incorporated by reference to Exhibit 10.19.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.11	Form of Amendment of Warrant to Purchase Preferred Stock, dated as of September 13, 2013 (incorporated by reference to Exhibit 10.19.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.12	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various investors under the Note and Warrant Purchase Agreement dated as of June 28, 2013 (incorporated by reference to Exhibit 10.20.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.13	Form of Warrant to Purchase Common Stock, issued by the Registrant in favor of various guarantors under the Reimbursement Agreement dated as of July 11, 2013 (incorporated by reference to Exhibit 10.21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.14	Amended and Restated Investor Rights Agreement, dated as of October 31, 2011, among the Registrant and certain investors named therein (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-191323), filed with the SEC on September 23, 2013).
4.15	Form of Common Stock Purchase Warrant issued to the investors under the Securities Purchase Agreement, dated April 29, 2016, by and among Biocept, Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on April 29, 2016).
4.16	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.16 of the Registrant's Post-Effective Amendment to Registration Statement on Form S-1 (File No. 333-213111), filed with the SEC on October 14, 2016).
10.1+	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 (File No. 001-36284), filed with the SEC on July 27, 2016).

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.2+	Biocept, Inc. Amended and Restated 2013 Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement, Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit agreement for use thereunder (incorporated by reference to Exhibit 99.3 of the Registrant's Current Report on Form 8-K (File No. 001-36284), filed with the SEC on July 27, 2016).
31.1	Certification of Michael Nall, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Timothy Kennedy, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Michael Nall, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Timothy Kennedy, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Indicates management contract or compensatory plan.

## CERTIFICATION

I, Michael W. Nall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biocept, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ Michael W. Nall

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

## CERTIFICATION

I, Timothy Kennedy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biocept, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2016

/s/ Timothy Kennedy

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Timothy Kennedy

Chief Financial Officer, Senior Vice President of Operations  
(Principal Financial and Accounting Officer)

## CERTIFICATION

I, Michael W. Nall, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to my knowledge, the Quarterly Report on Form 10-Q of Biocept, Inc. for the period ended September 30, 2016 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: November 10, 2016

/s/ Michael W. Nall

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

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

## CERTIFICATION

I, Timothy Kennedy, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that, to my knowledge, the Quarterly Report on Form 10-Q of Biocept, Inc. for the period ended September 30, 2016 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Biocept, Inc.

Date: November 10, 2016

/s/ Timothy Kennedy

Timothy Kennedy

Chief Financial Officer, Senior Vice President of Operations  
(Principal Financial and Accounting Officer)

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