

**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, 2015

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 2, 2015, there were 18,806,903 shares of the Registrant's common stock outstanding.

BIOCEPT, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED
September 30, 2015

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IMPORTANT NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (“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 (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>2014</u>	<u>September 30,</u> <u>2015</u> <u>(unaudited)</u>
Current assets:		
Cash and cash equivalents	\$ 5,364,582	\$ 12,541,919
Accounts receivable	10,600	40,360
Inventories, net	188,728	302,005
Prepaid expenses and other current assets	338,721	456,894
Total current assets	5,902,631	13,341,178
Fixed assets, net	662,422	855,208
Total assets	\$ 6,565,053	\$ 14,196,386
Current liabilities:		
Accounts payable	\$ 641,406	\$ 766,436
Accrued liabilities	699,903	916,730
Supplier financings	33,674	—
Current portion of equipment financings	55,800	125,920
Current portion of credit facility	—	1,556,909
Current portion of deferred rent	—	24,752
Total current liabilities	1,430,783	3,390,747
Non-current portion of equipment financings, net	68,801	244,612
Non-current portion of credit facility, net	4,731,322	3,020,166
Non-current portion of interest payable	54,537	131,543
Non-current portion of deferred rent	500,179	481,041
Total liabilities	6,785,622	7,268,109
Commitments and contingencies (see Note 10)		
Shareholders' equity/(deficit):		
Common stock, \$0.0001 par value, 40,000,000 authorized; 4,449,603 issued and outstanding at December 31, 2014; 18,766,903 issued and outstanding at September 30, 2015 (see Note 2)	445	1,877
Additional paid-in capital	138,066,008	157,545,448
Accumulated deficit	(138,287,022)	(150,619,048)
Total shareholders' equity/(deficit)	(220,569)	6,928,277
Total liabilities and shareholders' equity/(deficit)	\$ 6,565,053	\$ 14,196,386

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,	
	2014	2015	2014	2015
Revenues:	\$ 10,274	\$ 164,856	\$ 57,794	\$ 391,626
Costs and expenses:				
Cost of revenues	538,181	1,159,710	1,555,861	3,320,467
Research and development expenses	1,310,905	677,729	3,427,513	2,073,391
General and administrative expenses	1,060,812	1,630,608	3,970,579	4,281,883
Sales and marketing expenses	812,005	1,055,653	1,246,507	2,616,218
Total costs and expenses	3,721,903	4,523,700	10,200,460	12,291,959
Loss from operations	(3,711,629)	(4,358,844)	(10,142,666)	(11,900,333)
Other income/(expense):				
Interest expense, net	(151,491)	(176,120)	(1,640,045)	(494,596)
Change in fair value of warrant liability	3,326	558	(200,994)	361
Other income	—	38,412	—	64,020
Total other income/(expense):	(148,165)	(137,150)	(1,841,039)	(430,215)
Loss before income taxes	(3,859,794)	(4,495,994)	(11,983,705)	(12,330,548)
Income tax expense	—	(199)	(800)	(1,478)
Net loss & comprehensive loss	<u>\$ (3,859,794)</u>	<u>\$ (4,496,193)</u>	<u>\$ (11,984,505)</u>	<u>\$ (12,332,026)</u>
Weighted-average shares outstanding used in computing net loss per share attributable to common shareholders:				
Basic	4,449,603	18,727,806	3,845,540	15,735,907
Diluted	4,449,603	18,727,806	3,845,540	15,735,907
Net loss per common share:				
Basic	<u>\$ (0.87)</u>	<u>\$ (0.24)</u>	<u>\$ (3.12)</u>	<u>\$ (0.78)</u>
Diluted	<u>\$ (0.87)</u>	<u>\$ (0.24)</u>	<u>\$ (3.12)</u>	<u>\$ (0.78)</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,	
	2014	2015
Cash Flows From Operating Activities:		
Net loss	\$ (11,984,505)	\$ (12,332,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	177,516	188,120
Inventory reserve	(9,616)	(20,277)
Stock-based compensation	1,506,586	1,016,266
Non-cash interest expense related to convertible debt, credit facility and other financing activities	1,428,324	93,454
Change in fair value of warrant liability	200,994	(361)
Increase/(decrease) in cash resulting from changes in:		
Accounts receivable	(3,245)	(29,760)
Inventory	(46,201)	(93,000)
Prepaid expenses and other current assets	(528,988)	(181,284)
Other non-current assets	500	—
Accounts payable	(992,399)	142,028
Accrued liabilities	(1,177,510)	218,829
Accrued interest	38,304	96,295
Deferred rent	33,238	5,614
Net cash used in operating activities	<u>(11,357,002)</u>	<u>(10,896,102)</u>
Cash Flows From Investing Activities:		
Purchases of fixed assets	<u>(201,835)</u>	<u>(118,896)</u>
Net cash used in investing activities	<u>(201,835)</u>	<u>(118,896)</u>
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock	17,390,240	8,830,057
Proceeds from exercise of common stock warrants	—	9,697,660
Payments on equipment financings	(9,300)	(54,007)
Payments on supplier and other third party financings	(163,411)	(33,674)
Payments on line of credit	(2,346,000)	(247,701)
Proceeds from borrowings on line of credit	365,000	—
Proceeds from issuance of convertible notes and warrants	175,000	—
Net proceeds from borrowings on credit facility and warrants	4,898,002	—
Net cash provided by financing activities	<u>20,309,531</u>	<u>18,192,335</u>
Net increase in Cash and Cash Equivalents	8,750,694	7,177,337
Cash and Cash Equivalents at Beginning of Period	69,178	5,364,582
Cash and Cash Equivalents at End of Period	<u>\$ 8,819,872</u>	<u>\$ 12,541,919</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	<u>\$ 298,381</u>	<u>\$ 309,324</u>
Taxes	<u>\$ 800</u>	<u>\$ 2,054</u>

Non-cash Investing and Financing Activities:

During the nine months ended September 30, 2014, the Company replaced its private company directors and officers liability insurance policy financed during the year ended December 31, 2013 with a public company policy. The previously financed premium balance of \$44,559 was cancelled and a partial refund of \$10,955 was received.

During the nine months ended September 30, 2014, common stock warrants with an estimated aggregate grant date fair value of \$135,222 were issued in conjunction with guarantees on the Company's additional borrowings under its line of credit and additional borrowings made under its convertible notes issued in 2013, and were recorded as a discount to outstanding debt at the date of issuance.

An initial public offering ("IPO") of the Company's common stock was effected on February 5, 2014, the closing of which occurred on February 10, 2014 (see Note 2). On February 4, 2014, as contemplated by the registration statement covering the IPO, 69,421,047 shares of outstanding Series A Convertible Preferred Stock were automatically converted into 1,652,851 shares of common stock. In connection with the closing of the IPO on February 10, 2014, (i) the underwriters of the IPO were granted a 45 day option from the closing date to purchase up to 285,000 shares of common stock at \$9.30 per share to cover over-allotments with a grant date fair value of \$202,143, which was recorded as an offset to additional paid-in capital within common stock issuance costs, (ii) certain designees of the representative of the underwriters were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock at \$12.50 per share with a term of five years and a grant date fair value of \$544,116, and was recorded as an offset to additional paid-in capital within common stock issuance costs, (iii) underwriter IPO costs and discounts of \$279,760 and \$1,330,000, respectively, were netted against the proceeds from the IPO and are reflected as an offset to additional paid-in capital, (iv) the \$1,400,000 principal amount and \$233,982 of accrued interest related to the convertible note issued in 2008 were converted at \$10.00 per share into a total of 163,399 shares of common stock, (v) the \$5,165,000 principal amount and \$313,017 of accrued interest related to the convertible notes issued in 2013 were converted at \$10.00 per share into a total of 548,803 shares of common stock, (vi) derivative warrant liabilities of \$2,475,620 associated with an aggregate of 387,152 common stock warrants related to the convertible notes issued in 2013 and line of credit were reclassified to additional paid-in capital when their underlying exercise price was fixed at \$10.00 per share, and (vii) additional costs associated with the IPO of \$932,136 were reclassified from prepaid expenses and other current assets to additional paid-in capital.

During the nine months ended September 30, 2014, a common stock warrant with an estimated grant date fair value of \$233,107 was issued in conjunction with borrowings made under the Company's April 2014 credit facility with Oxford Finance LLC (the "April 2014 Credit Facility"), and was recorded as a discount to outstanding debt at the date of issuance (see Note 6).

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 2). In connection with the closing of this offering, (i) warrants were issued to buy (in the aggregate) up to 8,000,000 shares of common stock at a price of \$1.56 per share with a term of five years and an estimated grant date fair value of \$7,690,395 (see Note 4), 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 the offering to purchase up to 1,200,000 additional shares of common stock at a price of \$1.25 per share and/or additional warrants to purchase up to 1,200,000 shares of common stock at a price of \$0.0001 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any, with an aggregate estimated grant date fair value of \$1,627,396 (see Note 4) 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.

Fixed assets purchased totaling \$4,775 and \$3,190 during the nine months ended September 30, 2014 and 2015, respectively, were unpaid as of each reporting date, and are excluded from cash purchases in the Company's unaudited condensed statements of cash flows.

Fixed assets purchased totaling \$140,267 and \$279,008 during the nine months ended September 30, 2014 and 2015, respectively, are recorded as equipment financing obligations and are excluded from cash purchases in the Company's unaudited condensed statements of cash flows.

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 ("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 ("GAAP") to be included in a full set of financial statements. The balance sheet at December 31, 2014 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, 2014, filed with the SEC with our Annual Report on Form 10-K on March 11, 2015 include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Certain prior period amounts have been reclassified to conform to the current period presentation. Additionally, a total of \$318,565 of revenue-generating costs previously allocated to research and development expenses during the six months ended June 30, 2015 were reclassified to cost of revenues in the current period presentation of the unaudited condensed statement of operations and comprehensive loss for the nine months ended September 30, 2015.

The Company and Business Activities

Biocept, Inc. (the "Company") was founded in California in May 1997 and is a commercial-stage cancer diagnostics company developing and commercializing proprietary circulating tumor cell ("CTC") and circulating tumor DNA ("ctDNA") 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 ("CEE") 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, the Financial Standards Accounting Board (the "FASB") issued authoritative guidance that requires entities to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. This proposed guidance has been deferred and would be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. 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 does not expect adoption of this guidance to have a material impact on its 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 April 2015, the FASB issued authoritative guidance requiring debt issuance costs to be presented in the balance sheet as a direct deduction from the associated debt liability. This guidance is effective on a retrospective basis for the annual reporting period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early adoption is permitted. The Company early adopted this guidance on a retrospective basis for the interim reporting period ended March 31, 2015. A balance of \$23,194 of such costs were reclassified from other non-current assets, net to non-current portion of credit facility, net in the Company's balance sheet as of December 31, 2014. A total of \$15,093 of such costs remain unamortized and recorded as an offset to non-current portion of credit facility, net in the Company's unaudited condensed balance sheet at September 30, 2015.

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 August 2015, the FASB issued amendments to SEC paragraphs referenced in authoritative guidance around the presentation and subsequent measurement of debt issuance costs associated with line-of-credit arrangements. These amendments state that the SEC staff would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit arrangement. The Company's adoption of these amendments upon issuance did not have a material impact on its financial statements or disclosures.

2. Public Offerings

Pursuant to an underwriting agreement dated February 4, 2014 between the Company and Aegis Capital Corp. ("Aegis"), as representative of the several underwriters named therein, an IPO of 1,900,000 shares of common stock at \$10.00 per share was effected on February 5, 2014. The closing of the sale of these shares to the underwriters occurred on February 10, 2014. The Company received, after deducting underwriting discounts and additional costs paid to the underwriters, \$17.4 million of net cash proceeds from the sale of these 1,900,000 shares. The total increase in capital as a result of the sale of these shares was \$16.5 million after deducting \$0.9 million of additional non-underwriter costs incurred that were netted against these proceeds under applicable accounting guidance. Additionally, the underwriters were granted a 45 day option from the closing date of the IPO to purchase up to 285,000 shares of common stock at \$9.30 per share to cover overallocments with an estimated grant date fair value of \$0.2 million, which was not exercised. In addition, designees of Aegis were issued warrants to buy (in the aggregate) up to 95,000 shares of common stock at \$12.50 per share with a term of five years and an estimated grant date fair value of \$0.5 million.

On February 4, 2014, as contemplated by the registration statement covering the IPO, 69,421,047 shares of outstanding Series A Convertible Preferred Stock with a par value of \$0.0001 per share were converted into 1,652,851 shares of common stock and the Company's certificate of incorporation was amended to provide for an authorized capitalization of 40,000,000 shares of common stock and 5,000,000 shares of preferred stock. There were no shares of preferred stock issued or outstanding as of December 31, 2014 or September 30, 2015.

In connection with the closing of the IPO on February 10, 2014, (i) the \$1.4 million principal amount and \$0.2 million of accrued interest related to the convertible note issued in 2008 were converted at \$10.00 per share into a total of 163,399 shares of common stock, (ii) the \$5.2 million principal amount and \$0.3 million of accrued interest related to the convertible notes issued in 2013 were converted at \$10.00 per share into a total of 547,794 shares of common stock, (iii) the exercise price of the warrants associated with the convertible notes issued in 2013 was fixed at \$10.00 per share for an aggregate 258,249 shares of common stock, (iv) the exercise price of the warrants associated with the \$2.6 million of collateral provided to secure the Company's line of credit was fixed at \$10.00 per share for an aggregate 128,903 shares of common stock, (v) 73,151 shares of common stock vested as settlement of certain restricted stock units (which were previously expressed in shares of preferred stock) and became issuable subsequent to the expiration of the 180 day lock-up period following the IPO, (vi) the Company's Executive Chairman ceased to be an employee and continues to serve as non-executive Chairman, (vii) the number of shares of common stock covered by the Company's 2013 Equity Incentive Plan increased by 800,000, (viii) all but 1,587 of the preferred warrants previously outstanding were canceled due to early termination clauses associated with the IPO, (ix) derivative warrant liabilities of \$2.5 million associated with the aggregate of 387,152 common stock warrants related to the convertible notes issued in 2013 and line of credit were reclassified to additional paid-in capital when

their underlying exercise price was fixed, (x) unamortized discounts of \$1.0 million related to the warrants associated with the convertible notes issued in 2013 and line of credit were reclassified to interest expense, and (xi) offering costs associated with the IPO of \$0.9 million were reclassified from prepaid expenses and other current assets to additional paid-in capital, while additional underwriter IPO costs and discounts of \$0.3 million and \$1.3 million, respectively, were netted against the proceeds from the IPO and are reflected as an offset to additional paid-in capital.

Subsequent to December 31, 2013, the maximum amount of the Company's line of credit was increased to approximately \$2.6 million and common stock warrants were issued to four shareholders in conjunction with their guarantees on the Company's additional borrowings under the line of credit. On February 10, 2014, the current outstanding balance under the line of credit of approximately \$2.3 million plus accrued interest of \$27,043 was paid in full using the net proceeds from the IPO.

On February 13, 2014, the Compensation Committee of the Company's Board of Directors approved payments of approximately \$1.0 million for deferred salary obligations, including contractual interest, to current and former executive officers pursuant to previously existing agreements, which was fully disbursed by April 2014 using the net proceeds from the IPO. An additional \$344,883 in deferred salary obligations and interest thereon was paid to former employees other than executive officers. Also on February 13, 2014, in connection with the closing of the IPO and pursuant to a director compensation policy adopted by the Company's Board of Directors in 2013, the Company's Board of Directors approved annual cash retainers to non-employee directors, and granted 238,500 stock options under the Company's 2013 Equity Incentive Plan to non-employee directors. These option awards vest in equal annual installments over 3 years from the date of grant with a 10 year term, subject to continuing service requirements. Subsequently in February 2014, the Company's Board of Directors approved grants of 54,298 stock options as a result of the closing of the IPO pursuant to the terms of underlying employment agreements. Included in the stock options granted pursuant to the terms of underlying employment agreements were 53,108 option awards granted to the Company's non-executive Chairman, which vested fully on the date of grant.

Under the terms of certain employment agreements with executive officers, the Company incurred additional cash compensation expense of \$150,000 immediately, and \$225,000 annually, upon the closing of its IPO. All payments required under these agreements as a result of the closing of the IPO on February 10, 2014 were subsequently made in February and March 2014, using the net proceeds from the IPO.

During the year ended December 31, 2014, the Company repaid in full the remaining amounts outstanding of approximately \$70,000 due for laboratory equipment under financing agreements with a supplier, which is a business owned by a member of the Company's board of directors, using the net proceeds from the IPO.

Pursuant to an underwriting agreement dated February 9, 2015 between the Company, Aegis and Feltl and Company, as underwriters named therein, a public offering of 8,000,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 8,000,000 shares of common stock was effected at a combined offering price of \$1.25. 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 (see Note 4). Each of the members of the Company's Board of Directors participated in this offering, purchasing an aggregate 142,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 142,000 shares of its common stock for a total purchase price of \$177,500. All warrants sold in this offering have a per share exercise price of \$1.56, 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 1,200,000 additional shares of common stock at a price of \$1.25 per share and/or additional warrants to purchase up to 1,200,000 shares of common stock at a price of \$0.0001 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any, which was not exercised. The estimated grant date fair value of the over-allotment 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 (see Note 4). Underwriter costs and discounts of \$0.2 million and \$0.7 million, respectively, as well as additional non-underwriter costs associated with the 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 and through November 2, 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 \$0.9 million of underwriter costs and discounts and \$0.3 million of additional non-underwriter costs incurred, which were netted against these proceeds under applicable accounting guidance.

3. Liquidity & Going Concern Uncertainty

These unaudited condensed financial statements have been prepared and presented on a basis assuming the Company will continue as a going concern. The factors below raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

At December 31, 2014 and September 30, 2015, the Company had accumulated deficits of \$138.3 million and \$150.6 million, respectively. For the year and nine month periods ended December 31, 2014 and September 30, 2015, the Company incurred net losses of \$15.9 million and \$12.3 million, respectively. The Company borrowed a total of \$0.5 million during the year ended December 31, 2014 under note agreements with certain shareholders and a line of credit. In addition, the Company borrowed \$5.0 million during the year ended December 31, 2014 under a credit facility entered into in April 2014. 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 in 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 clinical laboratory testing through contracted partners. 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 net revenues to achieve and sustain income from operations.

As of September 30, 2015, cash and cash equivalents totaled \$12.5 million. On February 13, 2015, the Company 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 the follow-on public offering on February 13, 2015 and through November 2, 2015, additional cash proceeds of \$9.8 million have been received from the exercise of warrants sold in such offering. Management expects that the Company will need additional financing in the future to execute on its current or future business strategies beyond June 2016. Until the Company can generate significant cash from operations, including assay revenues, the Company expects to continue to fund its operations with the 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.

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. As of September 30, 2015, the Company had not sold any securities under this shelf registration statement. The specific terms of future offerings, if any, under this shelf registration statement would be established at the time of such offerings.

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, other than warrant liability, approximate their estimated fair values due to the short-term maturities of these financial instruments. The estimated fair value of the Company's credit facility at September 30, 2015 approximated carrying value, which was determined using a discounted cash flow analysis. The analysis considered interest rates of instruments with similar maturity dates, which involved the use of significant unobservable Level 3 inputs.

In connection with the closing of the Company's public offering on February 13, 2015, warrants were issued to buy (in the aggregate) up to 8,000,000 shares of common stock with an estimated grant date fair value of \$7,690,395, which was recorded as an offset to additional paid-in capital within common stock issuance costs. Also in connection with the closing of the Company's follow-on public offering on February 13, 2015, the underwriters were granted a 45 day option from the closing date of the offering to purchase up to 1,200,000 additional shares of common stock at a price of \$1.25 per share and/or additional warrants to purchase up to 1,200,000 shares of common stock at a price of \$0.0001 per warrant, less underwriting discounts and commissions, to cover over-allotments, if any. The estimated aggregate grant date fair value of these over-allotment options and warrants of \$1,627,396 was also recorded to common stock issuance costs as a component of additional paid-in capital. The fair values of these over-allotment options and all common stock warrants issued in this offering were estimated using Black-Scholes valuation models with the following assumptions:

	Over-allotment Options	Warrants
Stock price	\$ 1.41	\$ 1.41
Exercise price	\$ 1.25	\$ 1.56
Expected dividend yield	0.00%	0.00%
Discount rate-bond equivalent yield	0.02%	1.53%
Expected life (in years)	0.12	5.00
Expected volatility	168.1%	90.0%

5. Balance Sheet Details

The following provides certain balance sheet details:

	December 31, 2014	September 30, 2015
Fixed Assets		
Machinery and equipment	\$ 2,922,303	\$ 2,997,676
Furniture and office equipment	209,844	212,659
Computer equipment and software	681,508	756,365
Leasehold improvements	506,328	514,614
Financed equipment	878,447	1,157,455
Construction in process	72,172	12,739
	<u>5,270,602</u>	<u>5,651,508</u>
Less accumulated depreciation and amortization	4,608,180	4,796,300
Total fixed assets, net	<u>\$ 662,422</u>	<u>\$ 855,208</u>
Accrued Liabilities		
Accrued interest	\$ 33,125	\$ 31,484
Accrued payroll	82,241	216,154
Accrued vacation	276,574	286,125
Accrued bonuses	302,763	286,557
Accrued sales commissions	—	63,167
Warrant liability	1,070	709
Other	4,130	32,534
Total accrued liabilities	<u>\$ 699,903</u>	<u>\$ 916,730</u>

6. April 2014 Credit Facility

On April 30, 2014, the Company received net cash proceeds of approximately \$4,927,000 pursuant to the execution of its April 2014 Credit Facility with Oxford Finance LLC. A second term loan of up to a principal amount of \$5 million will be funded at the Company's request prior to December 31, 2015, subject to the achievement of product and services revenues of at least \$9 million for the trailing six months, with such six-month period ending no later than November 30, 2015. Upon the entry into the April 2014 Credit Facility, the Company was required to pay the lenders a facility fee of \$50,000 in conjunction with the funding of the first term loan. Another \$50,000 facility fee will be due and payable to the lenders on the funding date of the second term loan (if such date occurs). The April 2014 Credit Facility is secured by substantially all of the Company's personal property other than its intellectual property. Each 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 applicable term loan, plus (b) 7.71%, such rate to be fixed at the time of borrowing. The first term loan bears interest at an annual rate

of 7.95%. The Company was required to make interest-only payments on the first term loan through August 1, 2015. If the Company requests and the lenders fund the second term loan, the Company is required to make interest-only payments on the second term loan through the seventh month following the funding date of the second term loan. All outstanding term loans under the April 2014 Credit Facility will begin amortizing at the end of the applicable interest-only period, with monthly payments of principal and interest being made by the Company to the lenders in consecutive monthly installments following such interest-only period. The first term loan under the April 2014 Credit Facility matures on July 1, 2018, and the second term loan matures on the first day of the 29th month following the end of the applicable interest-only period. Upon repayment of each term loan, the Company is also required to make a final payment to the lenders equal to 5.5% of the original principal amount of such term loan funded. At its option, the Company may prepay the outstanding principal balance of the term loans in whole but not in part, subject to a prepayment fee of 2% of the amount prepaid if the prepayment occurs prior to April 30, 2016, and 1% of any amount prepaid after April 30, 2016.

The April 2014 Credit Facility includes affirmative and negative covenants applicable to the Company and any subsidiaries the Company creates 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 the Company's 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 loans under the April 2014 Credit Facility, including foreclosure against the Company's properties securing the April 2014 Credit Facility, including the Company's 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, the Company's 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 52,966 shares of the Company's common stock at an exercise price of \$4.72 per share with a term of 10 years was issued to Oxford Finance LLC on April 30, 2014. The estimated fair value of the warrant issued of \$233,107 was recorded as a discount to outstanding debt as of the closing date. Additional warrants to purchase shares of the Company's common stock will be issued upon execution of the second term loan under the April 2014 Credit Facility in an amount equal to 5.0% of the funded amount divided by the exercise price, which will be equal to the lower of (i) the closing price per share of the Company's common stock on the NASDAQ on the date prior to the funding date of the second term loan or (ii) the ten-day average closing price per share prior to the funding date of the second term loan. The effective annual interest rate associated with the April 2014 Credit Facility was 10.81% at December 31, 2014 and 11.50% at September 30, 2015.

7. Stock-based Compensation

Equity Incentive Plans

On January 1, 2015, the number of shares of common stock covered by the Company's 2013 Equity Incentive Plan automatically increased by 222,480 shares, or 5% of the number of common shares then outstanding, to a total of 1,426,051 shares. At the Company's annual meeting of stockholders held on June 16, 2015, the stockholders approved the Company's Amended and Restated 2013 Equity Incentive Plan ("2013 Plan"), which included (i) an increase in the number of shares of common stock authorized for issuance under the 2013 Plan by 1,500,000 shares, and (ii) a provision that shares available for grant under the Company's 2007 Equity Incentive Plan ("2007 Plan") become available for issuance under the 2013 Plan and are no longer available for issuance under the 2007 Plan. As of September 30, 2015, under all plans, a total of 3,104,622 shares were authorized for issuance, 2,131,603 stock options and restricted stock units ("RSUs") had been issued and were outstanding, and 836,082 shares were available for grant.

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, 2015 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, 2014	901,882	\$ 6.28	8.9
Outstanding at December 31, 2014	906,194	\$ 6.29	9.0
Granted	1,194,871	\$ 2.07	
Exercised	—	—	
Cancelled/forfeited/expired	(46,727)	\$ 4.33	
Outstanding at September 30, 2015	2,054,338	\$ 3.88	9.1
Vested and unvested expected to vest, September 30, 2015	1,899,759	\$ 4.01	9.0

The intrinsic values of options outstanding and options vested and unvested expected to vest at September 30, 2015 were \$313,095 and \$287,631, respectively.

The fair values of option awards granted during the nine months ended September 30, 2015 were estimated using a Black-Scholes pricing model with the following assumptions:

Stock and exercise prices	\$2.01 - \$3.38
Expected dividend yield	0.00%
Discount rate-bond equivalent yield	1.52% – 1.93%
Expected life (in years)	5.23 – 6.08
Expected volatility	70.0% – 100.0%

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, 2015 was \$1.35 per share.

On August 31, 2015, the Company's Board of Directors approved the issuance of 100,000 stock options with an estimated grant date fair value of \$1.47 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 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:

Target	Percentage of Overall Stock Option Grant Subject to Vesting
Minimum number of accessions processed, billed and collected in fiscal 2016	25%
Minimum revenues from contracts with pharmaceutical companies in fiscal 2016	20%
Attainment of a sustainable positive GAAP gross margin by December 31, 2016	25%
Minimum operating cash on-hand at December 31, 2016, with no more than one interim dilutive equity financing event	30%
Total	100%

Further information about the options outstanding and exercisable at September 30, 2015 is as follows:

	Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)	Total Shares Exercisable
\$	2.01	1,079,637	9.9	-
\$	2.65	152,734	9.6	1,000
\$	4.51	79,526	8.0	46,192
\$	5.12	406,643	8.1	297,977
\$	7.50	43,000	8.5	16,125
\$	8.88	238,500	8.4	79,497
\$	9.11	54,298	8.4	54,298
		<u>2,054,338</u>		<u>495,089</u>

The intrinsic value of options exercisable at September 30, 2015 was zero.

Restricted Stock

At September 30, 2015, there were 150,418 RSUs outstanding, of which 121,829 shares were vested and unvested expected to vest. The intrinsic values of RSUs outstanding and RSUs vested and unvested expected to vest at September 30, 2015 were \$345,961 and \$280,207, respectively.

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 statement of operations and comprehensive loss during the periods presented:

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2014	2015	2014	2015
<u>Stock Options</u>				
Cost of revenues	\$ -	\$ 15,029	\$ -	\$ 48,839
Research and development expenses	35,569	20,910	149,626	65,835
General and administrative expenses	236,769	257,404	908,490	706,026
Sales and marketing expenses	27,834	31,888	46,762	93,989
Total expenses related to stock options	300,172	325,231	1,104,878	914,689
<u>RSUs</u>				
Research and development expenses	7,500	1,625	22,500	10,724
General and administrative expenses	13,750	12,515	379,208	90,853
Total stock-based compensation	\$ 321,422	\$ 339,371	\$ 1,506,586	\$ 1,016,266

Stock-based compensation expense was recorded net of estimated forfeitures of 0% - 5% and 0% - 4% per annum during the three and nine months ended September 30, 2014 and 2015, respectively. As of September 30, 2015 total unrecognized stock-based compensation expense related to unvested stock option and RSU awards, adjusted for estimated forfeitures, was approximately \$2,993,000 and \$17,000, respectively, and is expected to be recognized over a weighted-average period of 2.7 years and 0.3 years, respectively.

8. Common Warrants Outstanding

A summary of equity-classified common stock warrant activity for the nine months ended September 30, 2015 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Average Remaining Contractual Term in Years
Outstanding at December 31, 2014	609,187	\$ 9.93	3.8
Issued	9,200,000	\$ 1.56	
Exercised	(6,216,449)	\$ 1.56	
Expired	(1,200,000)	\$ 1.56	
Outstanding at September 30, 2015	2,392,738	\$ 3.69	4.0

Further information about equity-classified common stock warrants outstanding and exercisable at September 30, 2015 is as follows:

Weighted Average Exercise Price	Total Shares Outstanding	Weighted Average Contractual Life (in years)
\$ 1.56	1,783,551	4.4
\$ 4.72	52,966	8.6
\$ 10.00	461,221	2.4
\$ 12.50	95,000	3.4
	2,392,738	

The intrinsic value of equity-classified common stock warrants outstanding and exercisable at September 30, 2015 was \$1,319,828.

9. Net Loss per Common Share

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted-average common shares outstanding during the period. Because there is a net loss attributable to common shareholders for the three and nine months ended September 30, 2014 and 2015, 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.

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,	
	2014	2015
Preferred warrants outstanding (number of common stock equivalents)	1,587	1,587
Preferred share RSUs (number of common stock equivalents)	73,151	73,151
Common warrants outstanding	609,187	2,392,738
Common share RSUs	178,467	77,267
Common options outstanding	875,042	2,054,338
Total anti-dilutive common share equivalents	1,737,434	4,599,081

10. 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.

The Company's former Vice President of Operations filed an administrative proceeding against the Company with the California Labor Commissioner in April 2013, seeking damages for alleged unpaid wages and penalties. A hearing was held on August 19, 2013 which resulted in a finding against the Company for approximately \$65,000, of which \$40,000 was paid during the year ended December 31, 2013 and \$25,000 was accrued as of December 31, 2013. On February 25, 2014, the aforementioned administrative proceeding filed with the California Labor Commissioner by the Company's former Vice President of Operations was settled in full following payment of the remaining \$25,000 due.

11. Related Party Transactions

Each of the members of the Company's Board of Directors participated in its public offering in February 2015, purchasing an aggregate of 142,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 142,000 shares of its common stock for a total purchase price of \$177,500 (see Note 2).

Pursuant to a sublease agreement dated March 30, 2015, the Company rented 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 member of the Company's management is the controlling person of Aegea Biotechnologies, Inc. ("Aegea"). On September 2, 2012, the Company entered into an Assignment and Exclusive Cross-License Agreement (the "Cross-License Agreement") with Aegea. The Company received payments totaling \$25,763 from Aegea as reimbursements for shared patent costs under the Cross-License Agreement.

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.

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, 2014 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, 2014, filed with the Securities and Exchange Commission on March 11, 2015. Past operating results are not necessarily indicative of results that may occur in future periods.

We are an early-stage molecular oncology diagnostics company that develops and commercializes proprietary circulating tumor cell ("CTC") and circulating tumor DNA ("ctDNA") assays utilizing a standard blood sample, or "liquid biopsy." Our current breast, lung and gastric cancer 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 based on better, timelier and more-detailed data on the characteristics of their patients' tumors.

Our current breast, lung and gastric cancer assays and our planned future assays utilize our CEE technology for the enumeration and analysis of CTCs, and our Target-Selector™ technology for the detection and analysis of ctDNA from plasma, each performed on a standard blood sample. The CEE technology is an internally developed and patented, microfluidics-based CTC capture and analysis platform, with enabling features that change how CTC testing can be used by clinicians by providing real-time biomarker monitoring with only a standard blood sample. The Target-Selector technology enables mutation detection with enhanced sensitivity and specificity and is applicable to nucleic acid from CTCs or other sample types, such as blood plasma for ctDNA. We believe the Target-Selector technology could someday be used as a stand-alone test for molecular biomarkers, screening and monitoring.

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

We are continuing to commercialize our first assays: OncoCEE-BR™ for breast cancer, OncoCEE-LU™ for both non-small cell lung cancer ("NSCLC") and small cell lung cancer ("SCLC"), OncoCEE-ME™ for melanoma, and OncoCEE-GA™ for gastric cancer. These assays utilize our CEE technology platform and provide CTC enumeration as well as biomarker analysis from a standard blood sample. In the case of the OncoCEE-BR and OncoCEE-GA assays, biomarker analysis involves fluorescence in situ hybridization ("FISH") for the detection and quantitation of the human epidermal growth factor receptor 2 ("HER2") gene copy number as well as immunocytochemical analysis of estrogen receptor ("ER") protein, which is currently commercially available. We plan to include immunocytochemical analysis of progesterone receptor proteins in the OncoCEE-BR assay during 2015. A patient's HER2 status provides the physician with information about the appropriateness of therapies such as Herceptin® or Tykerb®. Estrogen receptor and progesterone receptor ("PR") status provides the physician with information about the appropriateness of endocrine therapies such as tamoxifen and aromatase inhibitors.

The OncoCEE-LU assay's biomarker analysis currently includes FISH testing for ALK and ROS1 gene rearrangements and mutation analysis of the T790M, Deletion 19, and L858R mutations of the epidermal growth factor receptor ("EGFR") gene as well as B-RAF and K-RAS using our Target-Selector platform. We plan to add FISH testing for RET gene analysis. The L858R mutation of the EGFR gene and Exon 19 deletions as activators of EGFR kinase activity are linked to the drugs Tarceva®, Gilotrif® and Iressa®. The codon 12 and 13 mutations of the K-RAS gene are found in patients whose tumors are unlikely to respond to the EGFR kinase inhibitors such as Erbitux® and Vectibix®. Our OncoCEE-LU assay is performed on a standard blood sample.

For lung cancer, we also offer a resistance panel assay consisting of the biomarkers MET, HER2 (both of which we perform using our OncoCEE technology for CTCs) and T790M which is performed using Target-Selector 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.

Fibroblast growth receptor 1 ("FGFR1") amplification is offered for CTC testing utilizing our OncoCEE 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 B-RAF gene are linked to Zelboraf® and Tafinlar®, which are both approved for melanoma and are in clinical trials for lung cancer. We offer testing for B-RAF on blood using our CEE-Selector platform.

We plan to add other biomarker analyses on blood samples to our current assays and our planned future OncoCEE assays as their relevance is demonstrated in clinical trials, for example, RET proto-oncogene gene fusions in NSCLC, which may indicate a particular course of therapy, and N-RAS genes for melanoma, which may predict therapy resistance. In addition, we are developing a series of other CTC and ctDNA assays for different solid tumor types, including colorectal cancer, prostate cancer, gastric cancer and melanoma, each incorporating treatment-associated biomarker analyses specific to that cancer, planned to be launched as noted in the table below.

Assay Name/ Solid Tumor Type	Biomarkers	Status of Assay or Project	Actual or Targeted Quarter of Availability for Commercialization
OncoCEE-BR / Breast Cancer	Enumeration, HER2 by FISH	Currently available	Launched 2011 Q3
	ER	Currently available	Launched 2014 Q2
	FGFR by FISH	Currently available	Launched 2015 Q3
	PR	Validation	2015 Q4
	ESR1	Development	2016 Q1
OncoCEE-LU / Lung Cancer	Enumeration, ALK	Currently available	Launched 2014 Q4
	ROS1 by FISH	Currently available	Launched 2015 Q1
	T790M, L858R and Del19 EGFR mutations	Currently available	Launched 2015 Q1
	MET by FISH	Currently available	Launched 2015 Q2
	FGFR by FISH	Currently available	Launched 2015 Q3
	B-RAF by Target-Selector	Currently available	Launched 2015 Q3
	K-RAS by Target-Selector	Currently available	Launched 2015 Q3
	ALK mutations by Target-Selector	Development and Validation	2016 Q2

<u>Assay Name/ Solid Tumor Type</u>	<u>Biomarkers</u>	<u>Status of Assay or Project</u>	<u>Actual or Targeted Quarter of Availability for Commercialization</u>
OncoCEE-GA / Gastric Cancer	Enumeration, HER2, MET by FISH	Currently available	Launched 2015 Q2
OncoCEE-CR™ / Colorectal Cancer	Enumeration	Currently available	Launched 2015 Q3
	B-RAF by Target-Selector	Currently available	Launched 2015 Q3
	K-RAS by Target-Selector	Currently available	Launched 2015 Q3
OncoCEE-PR™ / Prostate Cancer	Enumeration	Currently available	Launched 2011 Q3
	PTEN deletion by FISH and AR by ICC	Development and Validation	2015 Q4
OncoCEE-ME™ / Melanoma	B-RAF by Target-Selector	Currently available	Launched 2015 Q3
	Enumeration	Development	2015 Q4
	PDL-1 by ICC	Validation	2015 Q4
	N-RAS mutations by Target-Selector	Development	2016 Q2
CEE-Selector / Next Generation Sequencing application for multiple cancer types	K-RAS, B-RAF, EGFR and other mutations detected in plasma.	Development	2016 Q1/Q2

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.

We accessioned 482 commercial cases during the three months ended September 30, 2015 as compared to 96 commercial cases for the same period in 2014, an increase of 386 cases, or 402%. We accessioned 1,065 commercial cases during the nine months ended September 30, 2015 as compared to 110 commercial cases for the same period in 2014, an increase of 955 cases, or 868%. 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 all cases accessioned, the minimum amount expected to be collected is based upon the applicable reimbursement rate according to either the Medicare Physician Fee Schedule or Clinical Lab Fee Schedule. Currently, Medicare reimbursement rates for our assays range from approximately \$370 per case for enumeration-only samples without biomarker assays to over \$1,700 per case for lung cancer samples with all biomarker assays. For cases accessioned during the first nine months of 2015, we estimate that the weighted-average amount expected to be collected will range from approximately \$750 to \$800 per case, depending on the mix of biomarker assays performed in each sample, although such reimbursement experience has not yet been achieved. Relatively higher reimbursement rates are expected to be achieved for cases billed to private payers.

Results of Operations

Three Months Ended September 30, 2014 and 2015

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

	Three Months Ended September 30,		Change	
	2014	2015	\$	%
<i>(dollars in thousands)</i>				
Revenues	\$ 10	\$ 165	\$ 155	1,550%
Cost of revenues	538	1,160	622	116%
Research and development expenses	1,311	678	(633)	(48%)
General and administrative expenses	1,061	1,630	569	54%
Sales and marketing expenses	812	1,056	244	30%
Loss from operations	(3,712)	(4,359)	(647)	17%
Interest expense, net	(151)	(176)	(25)	17%
Change in fair value of warrant liability	3	1	(2)	(67%)
Other income	—	38	38	—
Loss before income taxes	(3,860)	(4,496)	(636)	16%
Income tax expense	—	—	—	—
Net loss	\$ (3,860)	\$ (4,496)	\$ (636)	16%

Revenues

Revenues were approximately \$165,000 for the three months ended September 30, 2015, compared with approximately \$10,000 for the same period in 2014, an increase of \$155,000, or 1,550%. The increase was due to an increase of approximately \$139,000 in commercial assay revenues resulting primarily from an increase in commercial assay collections, as well as an increase of approximately \$16,000 in development services revenues with 49 development services assays performed during the three months ended September 30, 2015 as compared to 3 assays during the same period in 2014.

Costs and Expenses

Cost of Revenues. Cost of revenues was approximately \$1,160,000 for the three months ended September 30, 2015, compared with approximately \$538,000 for the three months ended September 30, 2014, an increase of \$622,000, or 116%. The increase was primarily attributable to an increase of approximately \$614,000 related to the greater proportion of laboratory costs charged to cost of revenues as a result of increased sample volume that related to revenue-generating activities relative to the total number of samples processed during the three months ended September 30, 2015 as compared to the same period in 2014, as well as an increase of approximately \$64,000 in materials costs and other direct costs primarily related to higher assay volume, partially offset by a decrease of approximately \$58,000 in allocated facilities costs.

Research and Development Expenses. Research and development expenses were approximately \$678,000 for the three months ended September 30, 2015, compared with approximately \$1,311,000 for the three months ended September 30, 2014, a decrease of \$633,000, or 48%. The decrease was primarily attributable to a decrease of approximately \$614,000 associated with the lower proportion of laboratory costs charged to research and development as a result of decreased sample volume that related to research and development activities relative to the total number of samples processed during the three months ended September 30, 2015 as compared to the same period in 2014, in addition to a decrease of approximately \$101,000 in materials and sample costs related to reduced validation activities as new assay panels and biomarkers have been brought to market, partially offset by an increase of approximately \$110,000 in personnel costs attributable primarily to the increase in the average number of employees in the research and development function from 6 employees during the three months ended September 30, 2014 to 9 employees during the same period in 2015.

General and Administrative Expenses. General and administrative expenses were approximately \$1,630,000 for the three months ended September 30, 2015, compared with approximately \$1,061,000 for the three months ended September 30, 2014, an increase of \$569,000, or 54%. The increase was primarily due to an increase of approximately \$284,000 in consulting, billing, and other service provider costs and legal fees associated with expanded commercial activities and being a publicly traded company, an increase of approximately \$166,000 in personnel costs primarily associated with non-recurring severance, and an increase of approximately \$139,000 in allocated facilities costs.

Sales and Marketing Expenses. Sales and marketing expenses were approximately \$1,056,000 for the three months ended September 30, 2015, compared with approximately \$812,000 for the three months ended September 30, 2014, an increase of \$244,000, or 30%. The increase was primarily due to an increase of approximately \$127,000 in personnel costs and travel expenses associated with an increase in the average number of employees included in the sales and marketing function from 9 employees during the three months ended September 30, 2014 to 12 employees during the same period in 2015, as well as an increase of approximately \$109,000 in consulting and other 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. We estimate that if such a change did occur, the federal and state net operating loss carryforwards and research and development credits that can be utilized in the future will be significantly limited.

Nine Months Ended September 30, 2014 and 2015

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

	Nine Months Ended September 30,		Change	
	2014	2015	\$	%
<i>(dollars in thousands)</i>				
Revenues	\$ 58	\$ 392	\$ 334	576%
Cost of revenues	1,556	3,321	1,765	113%
Research and development expenses	3,428	2,073	(1,355)	(40%)
General and administrative expenses	3,971	4,282	311	8%
Sales and marketing expenses	1,246	2,616	1,370	110%
Loss from operations	(10,143)	(11,900)	(1,757)	17%
Interest expense, net	(1,640)	(495)	1,145	(70%)
Change in fair value of warrant liability	(201)	—	201	(100%)
Other income	—	64	64	—
Loss before income taxes	(11,984)	(12,331)	(347)	3%
Income tax expense	(1)	(1)	—	—
Net loss	\$ (11,985)	\$ (12,332)	\$ (347)	3%

Revenues

Revenues were approximately \$392,000 for the nine months ended September 30, 2015, compared with approximately \$58,000 for the same period in 2014, an increase of \$334,000, or 576%. The increase was due to an increase of approximately \$334,000 in commercial assay revenues resulting primarily from an increase in commercial assay collections, as development services revenues remained consistent with 141 development services assays performed during the nine months ended September 30, 2015 as compared to 104 assays during the same period in 2014.

Costs and Expenses

Costs of Revenues. Cost of revenues was approximately \$3,321,000 for the nine months ended September 30, 2015, compared with approximately \$1,556,000 for the nine months ended September 30, 2014, an increase of \$1,765,000, or 113%. The increase was primarily attributable to an increase of approximately \$1,262,000 related to the greater proportion of laboratory costs charged to cost of revenues as a result of increased sample volume that related to revenue-generating activities relative to the total number of samples processed during the nine months ended September 30, 2015 as compared to the same period in 2014, as well as an increase of approximately \$776,000 in personnel, materials and other direct costs mainly related to higher assay volume, partially offset by a

decrease of approximately \$158,000 in allocated facilities costs and a decrease of approximately \$111,000 in non-recurring stock-based compensation and other personnel costs triggered by our initial public offering in February 2014.

Research and Development Expenses. Research and development expenses were approximately \$2,073,000 for the nine months ended September 30, 2015, compared with approximately \$3,428,000 for the nine months ended September 30, 2014, a decrease of \$1,355,000, or 40%. The decrease was primarily attributable to a decrease of approximately \$1,262,000 related to the lower proportion of laboratory costs charged to research and development as a result of decreased sample volume associated with research and development activities relative to the total number of samples processed during the nine months ended September 30, 2015 as compared to the same period in 2014, a decrease of approximately \$145,000 in non-recurring personnel costs triggered by our initial public offering in February 2014, and a decrease of approximately \$98,000 in allocated facilities costs, partially offset by an increase of approximately \$162,000 in personnel costs attributable primarily to the increase in the average number of employees in the research and development function from 7 employees during the nine months ended September 30, 2014 to 8 employees during the same period in 2015.

General and Administrative Expenses. General and administrative expenses were approximately \$4,282,000 for the nine months ended September 30, 2015, compared with approximately \$3,971,000 for the nine months ended September 30, 2014, an increase of \$311,000, or 8%. The increase was primarily due to an increase of approximately \$344,000 in consulting, billing, and other service provider costs associated with expanded commercial activities and being a publicly traded company, an increase of approximately \$331,000 in allocated facilities costs, and an increase of approximately \$241,000 in personnel costs attributable primarily to the increase in the average number of general and administrative employees from 6 employees during the nine months ended September 30, 2014 to 8 employees during the same period in 2015, partially offset by a decrease of approximately \$581,000 in non-recurring stock-based compensation and other personnel costs triggered by our initial public offering in February 2014.

Sales and Marketing Expenses. Sales and marketing expenses were approximately \$2,616,000 for the nine months ended September 30, 2015, compared with approximately \$1,246,000 for the nine months ended September 30, 2014, an increase of \$1,370,000, or 110%. The increase was primarily due to an increase of approximately \$1,108,000 in personnel costs and travel expenses associated with an increase in the average number of employees included in the sales and marketing function from 6 employees during the nine months ended September 30, 2014 to 12 employees during the same period in 2015, as well as an increase of approximately \$256,000 in consulting and other service provider costs associated with expanded commercial activities.

Interest Expense

Interest expense was approximately \$495,000 during the nine months ended September 30, 2015, compared with approximately \$1,640,000 for the nine months ended September 30, 2014, a decrease of \$1,145,000, or 70%. The decrease was due to amortization and write-offs of discounts to convertible notes payable that were converted into common stock and our revolving line of credit that was repaid in February 2014, partially offset by an increase of approximately \$185,000 in cash interest expense primarily associated with the April 2014 Credit Facility.

Change in Fair Value of Warrant Liability

The decrease in the non-cash loss of approximately \$201,000 for the nine months ended September 30, 2015 as compared to the same period in 2014 is primarily due to a fewer number of estimated average warrants outstanding, as the majority of the outstanding liability-classified warrants were reclassified to equity upon the closing of our initial public offering in February 2014.

Income Taxes

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

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

Liquidity and Capital Resources

Cash Flows

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

	Nine Months Ended	
	September 30,	
	2014	2015
<i>(dollars in thousands)</i>		
Cash provided by (used in):		
Operating activities	\$ (11,357)	\$ (10,896)
Investing activities	(202)	(119)
Financing activities	20,310	18,192
Net increase in cash and cash equivalents	<u>\$ 8,751</u>	<u>\$ 7,177</u>

Cash Used in Operating Activities. Net cash used in operating activities was \$10.9 million for the nine months ended September 30, 2015, compared to net cash used in operating activities of \$11.4 million for the nine months ended September 30, 2014. In all periods the primary use of cash was to fund our net loss. The decrease of \$0.5 million in cash used in operating activities for the nine months ended September 30, 2015 as compared to the same period in 2014 also includes a decrease of \$2.8 million in cash used to fund operating assets and liabilities, primarily related to the payment of deferred salaries, interest and taxes thereon as well as initial public offering costs, which was partially offset by a \$2.0 million decrease in non-cash operating expenses during the nine months ended September 30, 2015 as compared to the same period in 2014. The decrease in non-cash operating expenses was mainly due to non-recurring costs triggered by our initial public offering in February 2014, including interest expense associated with amortization and write-offs of discounts to convertible notes payable that were converted into common stock and our revolving line of credit that was repaid, as well as stock-based compensation expense, in addition to a decrease in non-cash loss related to outstanding liability-classified warrants that were reclassified to equity upon the closing of our initial public offering.

Cash Used in Investing Activities. Cash used in investing activities of approximately \$119,000 and \$202,000 during the nine months ended September 30, 2015 and 2014, respectively, was related to the acquisition of fixed assets.

Cash Provided by Financing Activities. Net cash provided by financing activities was \$18.2 million for the nine months ended September 30, 2015, compared to net cash provided by financing activities of \$20.3 million for the nine months ended September 30, 2014. Our primary source of financing in the nine months ended September 30, 2014 consisted of proceeds from our initial public offering. Our primary sources of financing in the nine months ended September 30, 2015 consisted of proceeds from our follow-on public offering and the exercise of common stock warrants sold in that offering.

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 offering and our revenues from operations to hire sales and marketing personnel, support increased sales and marketing activities, fund further research and development, clinical utility studies and future enhancements of our 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 being a public company. We may also use a portion of the net proceeds of our follow-on public offering 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, 2015, our cash and cash equivalents totaled \$12.5 million, and our outstanding indebtedness totaled \$5.4 million (including \$0.2 million of interest accrued thereon, and excluding \$0.3 million of associated debt discounts). On February 13, 2015, we received net cash proceeds of \$9.1 million as a result of the closing of our follow-on public offering, before deducting \$0.3 million of additional non-underwriting costs incurred. Between February 13, 2015 and November 2, 2015, additional cash proceeds of \$9.8 million have been received from the exercise of warrants sold in such offering. Management expects that the Company will need additional financing in the future to execute on its current or future business strategies beyond June 2016. 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.

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. As of September 30, 2015, we had not sold any securities under this shelf registration statement.

We expect that we will need additional financing in the future 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 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. 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 payers for our assays and services;
- the costs of additional general and administrative personnel, including accounting and finance, legal and human resources, as a result of becoming a public company;
- 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, 2014. 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, 2014.

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, 2015, 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, 2015. There were no changes in our internal control over financial reporting that occurred during the three months ended September 30, 2015 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, 2014. 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, 2014, 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. For further discussion of our liquidity requirements as they relate to our ability to continue as a going concern and our long-term plans, see the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

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

None.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-191323), which was declared effective by the Securities and Exchange Commission on February 4, 2014. On February 4, 2014, additional shares of our common stock were registered through a Registration Statement on Form S-1 (File No. 333-193760) filed pursuant to Rule 462(b) under the Securities Act. On February 10, 2014, a total of 1,900,000 shares of common stock were sold on our behalf at an initial public offering price of \$10.00 per share, for aggregate gross offering proceeds of \$19 million, managed by Aegis Capital Corp. We paid to the underwriters underwriting discounts totaling \$1.3 million in connection with the offering. In addition, we incurred additional costs of \$1.2 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total costs of \$2.5 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were \$16.5 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our initial public offering were invested in cash equivalents. As of September 30, 2015, we estimate that we had used all of the net proceeds from our initial public offering, with \$12.1 million used to fund the commercialization of our OncoCEE-BR, OncoCEE-LU, and OncoCEE-GA assays, research and development and other operating activities, \$3.0 million for repayments of indebtedness and purchases of fixed assets, and \$2.3 million for payments of deferred salaries, interest, and taxes thereon as well as initial public offering costs.

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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOCEPT, INC.
(Registrant)

Date: November 9, 2015

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

Date: November 9, 2015

By: /s/ Mark G. Foletta
Mark G. Foletta
Chief Financial Officer
(Principal Financial and Accounting Officer)

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).
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 lenders under the Loan and Security Agreement, dated as of April 30, 2014, by and among Biocept, Inc., Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time, including Oxford Finance LLC (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2014).
4.5	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).
10.1+	2013 Amended and Restated Equity Incentive Plan, Form of Stock Option Grant Notice, Option Agreement, and Restricted Stock Unit Agreement for use thereunder (incorporated by reference to Exhibit 99.1 of the Registrant's Registration Statement on Form S-8 (File No. 333-206347), filed with the SEC on August 13, 2015).
10.2+	Separation Agreement, between the Registrant and William Kachioff, dated August 17, 2015 (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K (File No. 001-36284), filed with the SEC on August 21, 2015).
10.3+	Employment Agreement, between the Registrant and Mark G. Foletta, dated August 18, 2015 (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 August 21, 2015).
10.4+	Employment Agreement Amendment, between the Registrant and Michael Nall, dated November 6, 2015.

Exhibit No.	Description of Exhibit
31.1	Certification of Michael Nall, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Mark Foletta, 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 Mark Foletta, 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.

EMPLOYMENT AGREEMENT AMENDMENT

THIS EMPLOYMENT AGREEMENT AMENDMENT is entered into by and between Biocept, Inc., a Delaware corporation (the "**Company**"), and Michael W. Nall ("**Executive**"), and shall be effective as of November 6, 2015 (the "**Amendment Effective Date**").

WHEREAS, the Company and Executive are parties to an Employment Agreement, effective as of August 26, 2013 (the "**Employment Agreement**"); and

WHEREAS, the Company and the Executive now desire to amend the Employment Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises herein contained, the parties agree as follows (capitalized terms used but not defined herein shall have the meaning set forth in the Employment Agreement):

1. AMENDMENT OF SECTION 4(G) "STOCK AWARD ACCELERATION". Section 4(g) of the Employment Agreement is hereby amended and restated to read in its entirety as follows:

"(g) Stock Award Acceleration

(i) In the event of a Change of Control, if the surviving corporation or acquiring corporation (or its parent company) in such Change of Control does not assume or continue Executive's then-outstanding Stock Awards or substitute similar stock awards for such Stock Awards, then all previously unvested Stock Awards shall vest and become exercisable (as applicable) immediately prior to such Change of Control, provided that Executive is providing continued service to the Company as of immediately prior to such Change of Control.

In addition, solely with respect to Executive's Stock Awards granted prior to pre-Amendment Effective Date (the "**Pre-Amendment Stock Awards**"), in the event of a Change of Control where such Pre-Amendment Stock Awards are not fully accelerated pursuant to the first sentence of this Section 4(g)(i), (A) the vesting and/or exercisability of fifty percent (50%) of the Executive's outstanding unvested Pre-Amendment Stock Awards shall be automatically accelerated on the date of a Change of Control, and (B) the remaining unvested Pre-Amendment Stock Awards shall vest and/or become exercisable on the first to occur of (1) the first anniversary of such Change of Control, or (2) the date of Executive's termination of employment as a result of Executive's discharge by the Company without Cause or by reason of Executive's resignation for Good Reason.

(ii) In the event of Executive's termination of employment as a result of Executive's discharge by the Company without Cause or by reason of Executive's resignation for Good Reason, the vesting and/or exercisability of each of Executive's outstanding Stock Awards shall be automatically accelerated on the date of Executive's termination of employment as to the number of Stock Awards that would vest over the twelve (12) month period following the date of Executive's termination of employment had Executive remained continuously employed by the Company during such period.

(iii) In the event that during the 10-day period before a Change of Control or during the 12-month period following a Change of Control, Executive's employment is terminated either as a result of Executive's discharge by the Company (or successor(s) thereto) without Cause or by reason of Executive's resignation for Good Reason, then the vesting and/or exercisability of each of Executive's outstanding Stock Awards shall be automatically accelerated on the date of Executive's termination or resignation of employment, as applicable.

(iv) The foregoing provisions of this Section 4(g) are hereby deemed to be a part of each Stock Award and to supersede any less favorable provision in any agreement or plan regarding such Stock Award."

2. AMENDMENT OF SECTION 10 "MISCELLANEOUS". A new Section 10(o) shall be added to Section 10 of the Employment Agreement as follows:

"(o) Code Section 280G.

(i) If any payment or benefit Executive will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payment (a "Payment") shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the "Reduction Method") that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

(ii) Unless Executive and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change of Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within 15 calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 10(o) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 10(o) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of clause (x) of Section 10(o), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence."

3. MISCELLANEOUS.

(a) Except as specifically provided for in this Employment Agreement Amendment, the terms of the Employment Agreement shall be unmodified and shall remain in full force and effect. In the event that any provision of this Employment Agreement Amendment and the Employment Agreement conflict, the provision of this Employment Agreement Amendment shall govern.

(b) This Employment Agreement Amendment will be effective upon the Amendment Effective Date.

(c) This Employment Agreement Amendment may be executed in counterparts, each of which when so executed shall be deemed to be an original, and such counterparts shall together constitute one and

the same instrument. This Employment Agreement Amendment shall be governed by and construed in accordance with the laws of the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. For the avoidance of doubt, the Employment Agreement Amendment shall become part of the Employment Agreement and therefore subject to its terms, including but not limited to Section 8 thereof.

(Signature Page Follows)

3.

IN WITNESS WHEREOF, the parties have executed this Employment Agreement Amendment as of the date first set forth above.

BIOCEPT, INC.

By: /s/ David F. Hale

Name: David F. Hale

Title: Chairman of the Board

EXECUTIVE

/s/ Michael W. Nall

Print Name: Michael W. Nall

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 9, 2015

/s/ Michael W. Nall

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

CERTIFICATION

I, Mark G. Foletta, 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 9, 2015

/s/ Mark G. Foletta

Mark G. Foletta

Chief Financial Officer

(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, 2015 (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 9, 2015

/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, Mark G. Foletta, 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, 2015 (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 9, 2015

/s/ Mark G. Foletta

Mark G. Foletta

Chief Financial Officer

(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.