

CareDx, Inc.  
Form 10-Q  
November 13, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO 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: 001-36536**

**CareDx, Inc.**

**(Exact name of registrant as specified in its charter)**

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

**94-3316839**  
**(I.R.S. Employer**  
**Identification Number)**

**3260 Bayshore Boulevard**  
**Brisbane, California 94005**

**(Address of principal executive offices and zip code)**

**(415) 287-2300**

**(Registrant's telephone number, including area code)**

**N/A**

**(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.

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 in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

There were 11,902,363 shares of the registrant's Common Stock issued and outstanding as of October 31, 2015.



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**CareDx, Inc.**

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. UNAUDITED CONDENSED FINANCIAL STATEMENTS****CareDx, Inc.****Condensed Balance Sheets****(Unaudited)****(In thousands, except share and per share data)**

	<b>September 30, 2015</b>	<b>December 31, 2014 (Note 2)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,954	\$ 36,431
Accounts receivable	2,241	2,687
Inventory	814	686
Prepaid and other assets	960	542
<b>Total current assets</b>	<b>37,969</b>	<b>40,346</b>
Property and equipment, net	2,571	1,968
Intangible assets, net	6,650	6,650
Goodwill	12,005	12,005
Restricted cash	147	147
Other noncurrent assets		25
<b>Total assets</b>	<b>\$ 59,342</b>	<b>\$ 61,141</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 1,949	\$ 1,128
Accrued payroll liabilities	2,192	1,684
Accrued and other liabilities	2,331	1,616
Accrued royalties	252	241
Deferred revenue	136	505
Current portion of long-term debt	3,594	5,961
<b>Total current liabilities</b>	<b>10,454</b>	<b>11,135</b>
Deferred rent, net of current portion	1,490	1,684
Deferred revenue, net of current portion	724	471
Long-term debt, net of current portion	12,125	5,451
Contingent consideration	618	1,074

Other liabilities	28	28
Total liabilities	25,439	19,843
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at September 30, 2015 and December 31, 2014; no shares issued and outstanding at September 30, 2015 and December 31, 2014		
Common stock: \$0.001 par value; 100,133,900 and 100,000,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 11,892,518 and 11,803,970 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	12	12
Additional paid-in capital	202,213	200,661
Accumulated deficit	(168,322)	(159,375)
Total stockholders' equity	33,903	41,298
Total liabilities and stockholders' equity	\$ 59,342	\$ 61,141

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

**Table of Contents****CareDx, Inc.****Condensed Statements of Operations****(Unaudited)****(In thousands, except share and per share data)**

	<b>Three Months Ended September 30, 2015</b>		<b>Nine Months Ended September 30, 2014</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Revenue:</b>				
Testing revenue	\$ 7,007	\$ 6,601	\$ 21,147	\$ 19,145
Collaboration and license revenue	144	53	349	209
<b>Total revenue</b>	<b>7,151</b>	<b>6,654</b>	<b>21,496</b>	<b>19,354</b>
<b>Operating expenses:</b>				
Cost of testing	2,568	1,772	7,786	6,337
Research and development	2,698	1,036	6,629	2,548
Sales and marketing	2,062	1,753	6,453	4,837
General and administrative	3,361	1,976	8,553	6,087
Change in estimated fair value of contingent consideration	(345)	(1,276)	(456)	(1,276)
<b>Total operating expenses</b>	<b>10,344</b>	<b>5,261</b>	<b>28,965</b>	<b>18,533</b>
(Loss) income from operations	(3,193)	1,393	(7,469)	821
Interest expense, net	(251)	(535)	(1,334)	(1,727)
Other (expense) income, net	(45)	355	(142)	192
(Loss) income before income taxes	(3,489)	1,213	(8,945)	(714)
Income tax benefit				1,500
<b>Net (loss) income</b>	<b>(\$ 3,489)</b>	<b>\$ 1,213</b>	<b>(\$ 8,945)</b>	<b>\$ 786</b>
<b>Net (loss) income per share (Note 3):</b>				
Basic	(\$ 0.29)	\$ 0.13	(\$ 0.76)	\$ 0.21
Diluted	(\$ 0.29)	\$ 0.12	(\$ 0.76)	\$ 0.11
<b>Shares used to compute net (loss) income per share:</b>				
Basic	11,890,057	9,279,649	11,846,921	3,798,559
Diluted	11,890,057	11,219,377	11,846,921	8,298,903

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



**Table of Contents****CareDx, Inc.****Condensed Statements of Cash Flows****(Unaudited)****(In thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities:</b>		
Net (loss) income	(\$ 8,945)	\$ 786
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	575	354
Stock-based compensation	1,028	350
Amortization of deferred revenue	(115)	(26)
Amortization of debt discount and non-cash interest expense	204	792
Revaluation of contingent consideration to estimated fair value	(456)	(1,276)
Revaluation of warrants to estimated fair value		14
Gain on remeasurement of embedded derivative		(239)
Non-cash income tax benefit		(1,500)
Changes in operating assets and liabilities:		
Accounts receivable	446	521
Inventory	(129)	22
Prepaid and other assets	(393)	(461)
Accounts payable	791	204
Accrued payroll liabilities	508	17
Accrued and other liabilities	699	321
Accrued royalties	11	(2,507)
Net cash used in operating activities	(5,776)	(2,628)
<b>Investing activities:</b>		
Purchase of property and equipment	(1,123)	(333)
Payment for acquisition, net of cash acquired (Note 11)		(406)
Net cash used in investing activities	(1,123)	(739)
<b>Financing activities:</b>		
Proceeds from initial public offering, net of underwriters discount		39,246
Payment of initial public offering costs		(3,716)
Proceeds from debt, net of issuance costs	15,625	4,982
Proceeds from exercise of stock options	45	5
Principal payments on debt and capital leases	(11,451)	(3,230)
Issuance of common stock under employee stock purchase plan	203	0

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Net cash provided by financing activities	4,422	37,287
Net (decrease) increase in cash and cash equivalents	(2,477)	33,920
Cash and cash equivalents at beginning of period	36,431	5,128
Cash and cash equivalents at end of period	\$ 33,954	\$ 39,048

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

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**CareDx, Inc.**

**Notes to Unaudited Condensed Financial Statements**

**1. ORGANIZATION**

CareDx, Inc., ( CareDx or the Company ) is a commercial stage company that develops, markets and delivers diagnostic surveillance solutions for organ transplant recipients to help clinicians make personalized treatment decisions throughout a transplant patient's lifetime. The Company's one commercialized testing solution, the AlloMap heart transplant molecular test ( AlloMap ), an FDA-cleared test, is a blood-based test used to monitor for acute cellular rejection in heart transplant recipients. The Company was incorporated in Delaware in December 1998, as Hippocratic Engineering, Inc. In April 1999, the Company changed its name to BioCardia, Inc., in June 2002 to Expression Diagnostics, Inc., in July 2007 to XDx, Inc. and in March 2014 to CareDx, Inc. The Company's operations are based in Brisbane, California and it operates in one segment.

**Reverse Stock Split, and Increase in Authorized Shares**

On July 1, 2014, the Company's Board of Directors approved an amendment to the Company's Certificate of Incorporation to reflect a 1 for 6.85 reverse stock split (the Reverse Stock Split ) of the Company's outstanding common stock and convertible preferred stock. The Reverse Stock Split became effective July 14, 2014. The par value per share was not adjusted as a result of the Reverse Stock Split. All authorized, issued and outstanding shares of common stock, convertible preferred stock, options and warrants to purchase common or preferred stock and related per share amounts contained in the financial statements have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

**Initial Public Offering**

On July 22, 2014, the Company closed its initial public offering ( IPO ) of 4,000,000 shares of its common stock, and issued an additional 220,000 shares of common stock on August 13, 2014 pursuant to the exercise of the over-allotment option granted to its underwriters. The public offering price of the shares sold in the offering was \$10.00 per share. The total proceeds from the offering to the Company, net of underwriting discounts and commissions of \$3.0 million, were \$39.2 million. After deducting offering expenses payable by the Company of \$3.7 million, net proceeds to the Company were \$35.5 million. Upon the closing of the IPO, all shares of convertible preferred stock then outstanding converted into 6,048,220 shares of common stock, and a subordinated convertible note previously issued by the Company in the principal amount of \$5.0 million converted into 510,777 shares of common stock. In addition, all of our convertible preferred stock warrants were converted into warrants to purchase common stock.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( U.S. GAAP ), and follow the requirements of the Securities and Exchange Commission ( SEC ) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the

Company's financial information. The condensed balance sheet as of December 31, 2014 has been derived from audited financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three and nine months ended September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

The accompanying unaudited condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K filed on March 31, 2015 with the SEC.

### **Use of Estimates**

The preparation of unaudited condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the unaudited condensed financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to (i) revenue recognition, (ii) the differences between amounts billed and estimated receipts from payers, (iii) the determination of the accruals for clinical studies, (iv) the determination of refunds to be requested by third-party payers, (v) the fair value of assets and liabilities as applicable, (vi) the valuation of warrants to purchase convertible preferred stock, (vii) the determination of fair value of the Company's common stock, (viii) the fair value of contingent consideration in a business acquisition, (ix) the fair value of the embedded features associated with the subordinated convertible note, (x) the fair value of the embedded features associated with long-term debt, (xi) measurement of stock-based compensation expense, (xii) the determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (xiii) any impairment of long-lived assets including in-process technology and goodwill and (xiv) legal contingencies. Actual results could differ from those estimates.

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**Table of Contents****Concentrations of Credit Risk and Other Risks and Uncertainties**

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents and accounts receivable. The Company's policy is to invest its cash and cash equivalents in money market funds, obligations of U.S. government agencies and government-sponsored entities, commercial paper, and various bank deposit accounts. These financial instruments were held in Company accounts at two financial institutions. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing. The Company is exposed to credit risk in the event of default by the financial institutions to the extent of amounts recorded on the balance sheets which may be in excess of insured limits.

The Company is also subject to credit risk from its accounts receivable which are derived from revenue earned from AlloMap tests provided for patients located in the U.S. and billed to various third-party payers. For the nine months ended September 30, 2015 and 2014, approximately 50% of testing revenue was derived from Medicare. No other payers represented more than 10% of testing revenue for these periods. At September 30, 2015 and December 31, 2014 approximately 34% and 78%, respectively, of accounts receivable was from Medicare. At September 30, 2015, approximately 16% of accounts receivable was from Aetna. No other payer represented more than 10% of accounts receivable at September 30, 2015 and December 31, 2014.

**Reimbursement and Regulatory Risk**

The Company is also subject to reimbursement and regulatory risk. We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance. On September 25, 2015, Centers for Medicare and Medicaid Services (CMS) announced proposed changes in reimbursement policies for a number of established molecular diagnostic tests, including AlloMap. Under the current proposed fee schedule, AlloMap reimbursement would be reduced by 77% effective January 1, 2016. For additional information, see Risk Factors section in Part II of this Form 10-Q.

**Cash Equivalents**

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consist primarily of amounts invested in money market funds and checking accounts.

**Impairment of Long-lived Assets**

The Company evaluates its long-lived assets for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. The Company then compares the carrying amounts of the assets with the future net undiscounted cash flows expected to be generated by such asset. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value determined using discounted estimates of future cash flows. The Company has not identified any such impairment losses to date.

**Fair Value of Financial Instruments**

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which the Company would transact, and it takes into consideration the assumptions that market participants would use when pricing the asset or liability. The Company's

assessment of the significance of a particular input to the fair value measurement of an asset or liability requires management to make judgments and to consider specific characteristics of that asset or liability.

The carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The carrying amounts of the convertible preferred stock warrant liability and contingent consideration liability represent their fair values.

### **Testing Revenue**

The Company recognizes revenue for tests delivered when the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery has occurred or services rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured.

The first criterion is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with the Company for the test. The second criterion is satisfied when the Company performs the test and delivers the test result to the ordering

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physician. The third criterion is satisfied if the third-party payer's coverage decision or reimbursement contract specifies a price for the test. The fourth criterion is satisfied based on management's judgments regarding the collectability of the fees charged under the arrangement. Such judgments include review of past payment history. AlloMap testing may be considered investigational by some payers and not covered under their reimbursement policies. Others may cover the test, but not pay a set or determinable amount. As a result, in the absence of a reimbursement agreement or sufficient payment history, collectability cannot reasonably be assured so revenue is not recognized at the time the test is delivered.

If all criteria set forth above are met, revenue is recognized. When the first, third or fourth criteria are not met but third-party payers make a payment to the Company for tests performed, the Company recognizes revenue on the cash basis in the period in which the payment is received.

Revenue is recognized on the accrual basis net of adjustments for differences between amounts billed and the estimated receipts from payers. The amount the Company expects to collect may be lower than the agreed upon amount due to several factors, such as the amount of patient co-payments, the existence of secondary payers and claim denials. Estimated receipts are based upon historical payment practices of payers. Differences between estimated and actual cash receipts are recorded as an adjustment to revenue, which have been immaterial to date.

During the three and nine months ended September 30, 2015, the Company changed its revenue recognized from one and four of its payers, respectively, from cash to accrual basis based on the Company's revenue recognition criteria being met. The impact of this change in accounting estimate is to increase revenues by \$47,000 and \$187,000 for the three and nine months ended September 30, 2015, respectively. The impact to net loss per share is less than one cent for the three and nine months ended September 30, 2015.

Taxes assessed by governmental authorities on revenue, including sales and value added taxes, are excluded from revenue in the statements of operations.

## **Collaboration and License Revenue**

The Company generates revenue from collaboration and license agreements. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. The Company's performance obligations under the collaborations may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration partners. The Company makes judgments that affect the periods over which it recognizes revenue. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis.

## **Cost of Testing**

Cost of testing reflects the aggregate costs incurred in delivering the Company's AlloMap test results to clinicians. The components of cost of testing are materials and service costs, direct labor costs, including stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation and utilities and royalties. Costs associated with performing tests (except royalties) are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of

testing as a percentage of revenue may vary significantly from period to period because we do not recognize all revenue in the period in which the associated costs are incurred. Royalties for licensed technology, calculated as a percentage of test revenues, are recorded as license fees in cost of testing at the time the test revenues are recognized.

### **Business Combinations**

In accordance with ASC 805, *Business Combinations*, the Company determines and allocates the purchase price of an acquired business to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the business combination date, including identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill.



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Goodwill and indefinite-lived intangible assets including acquired in-process technology are reviewed for impairment on an annual basis during the fourth quarter of each fiscal year or more frequently if events or circumstances indicate that goodwill or indefinite-lived intangible assets may be impaired. The Company's assessment of goodwill uses both quantitative and qualitative factors to determine if its sole reporting unit's fair value is more likely than not to exceed its carrying value. In the event the Company determines that it is more likely than not that its reporting unit's fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair value. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, then the Company would calculate the potential impairment loss by comparing the implied fair value of goodwill with the carrying value. If the implied fair value of goodwill is less than the carrying value, then an impairment charge would be recorded. For indefinite-lived intangible assets, if the fair value exceeds the carrying value, without consideration of any recoverability test, then there is no impairment. The Company has not identified any impairment losses to date.

In those circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under ASC 480, *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

Transaction costs associated with these acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

## **Stock-based Compensation**

The Company uses the Black-Scholes option pricing model ( Black-Scholes Model ), which requires the use of estimates such as stock price volatility and expected option lives, to value employee stock options. The Company estimates the expected option lives using historical data, volatility using data of similar companies in the diagnostics industry, risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected option lives, and dividend yield based on the Company's expectations and historical data.

The Company uses the straight-line attribution method for recognizing compensation expense. Compensation expense is recognized on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on the Company's historical experience.

Compensation expense for stock options issued to nonemployees is recorded over the service performance period. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

## **Warrants**

The Company had freestanding warrants enabling counterparties to purchase shares of its convertible preferred stock which were converted to warrants to purchase common stock on the Company's IPO date.

In accordance with the accounting guidance regarding distinguishing liabilities from equity, freestanding warrants for convertible preferred stock that are contingently redeemable are classified as liabilities on the balance sheet and recorded at their estimated fair value. These warrants are remeasured at each balance sheet date and any change in

estimated fair value is recognized in other (expense) income, net, on the statements of operations.

Upon the completion of the Company's IPO in July 2014, preferred stock warrants were converted into warrants to purchase common stock or expired, and, accordingly, the liability was reclassified to equity and became no longer subject to remeasurement.

The Company has issued warrants to purchase shares of its common stock in connection with financing activities (see Note 9). The Company accounts for these warrants as equity at fair value on the date the warrants are issued. The fair value of the outstanding warrants is estimated using the Black-Scholes Model. The Black-Scholes Model requires inputs such as the expected term of the warrants, expected volatility and risk-free interest rate. Certain of these inputs are subjective and require significant analysis and judgment to develop. For the estimate of the expected term, the Company uses the full remaining contractual term of the warrant.

### **Comprehensive Loss**

Net loss and comprehensive loss are the same for all periods presented.

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**Table of Contents****Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ( ASU 2014-09 ), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled to when products are transferred to customers. On July 9, 2015, the FASB decided to delay the effective date of the new standard by one year. The standard would become effective for us beginning in the first quarter of 2018. Early application is permitted as early as the first quarter of 2017 and is required by the first quarter of 2018 . Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company is currently evaluating the impact of adopting the new revenue standard on its financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ( ASU 2015-03 ). This ASU requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is applicable to the Company beginning January 1, 2016. However, early adoption of ASU 2015-03 is permitted and the Company adopted ASU 2015-03 as of January 1, 2015 using the retrospective method as required. Debt discount and issuance costs, current, as of September 30, 2015 and December 31, 2014 were \$170,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of September 30, 2015 and December 31, 2014 were \$177,000 and \$11,000, respectively. There is no impact from the adoption of ASU 2015-03 on the unaudited condensed statements of operations or in the net (loss) income per share calculations.

In April 2015, the FASB issued ASU 2015-05 *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40) ( ASU 2015-05 ). This ASU provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. This ASU will be effective for annual periods, including interim periods beginning after December 15, 2015. Early adoption is permitted. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. The Company is currently evaluating the impact of adopting ASU 2015-05 on its financial statements.

**3. NET (LOSS) INCOME PER SHARE**

Basic net (loss) income per share has been computed by dividing the net (loss) income by the weighted-average number of common shares outstanding during the period.

For the three and nine months ended September 30, 2014, common share equivalents have been included in diluted net income per share, as the effect to net income per share is dilutive. For the three and nine months ended September 30, 2015, all common share equivalents have been excluded from diluted net loss per share as the effect to net loss per share would be antidilutive. Our common share equivalents include (i) options and warrants to purchase common stock; (ii) options and warrants to purchase convertible preferred stock prior to their conversion into options and warrants to purchase common stock upon the IPO on July 22, 2014; and (iii) convertible preferred stock and the

subordinated convertible note prior to their conversion into common stock upon the IPO. Common share equivalents for convertible preferred stock and the subordinated convertible note are determined using the if-converted method. Common share equivalents for options and warrants to purchase common and convertible preferred stock are determined using the treasury-stock method.

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The following tables set forth the computation of the Company's basic and diluted net (loss) income per share (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
<b>Numerator:</b>				
Net (loss) income	\$ (3,489)	\$ 1,213	\$ (8,945)	\$ 786
Add: interest expense related to subordinated convertible note		231		364
Less: gain on change in fair value of derivative related to subordinated convertible note				(118)
Less: gain on extinguishment of derivative related to subordinated convertible note		(120)		(120)
Net (loss) income attributable to common stockholders	\$ (3,489)	\$ 1,324	\$ (8,945)	\$ 912
<b>Denominator:</b>				
Weighted-average shares used to compute basic net (loss) income per common share	11,890,057	9,279,649	11,846,921	3,798,559
Effect of potentially dilutive securities:				
Employee stock options		371,273		347,108
Convertible preferred stock		1,446,313		3,973,622
Subordinated convertible note		122,142		179,614
Weighted-average shares used to compute diluted net (loss) income per common share	11,890,057	11,219,377	11,846,921	8,298,903
<b>Net (loss) income per share:</b>				
Net (loss) income per common share - basic	\$ (0.29)	\$ 0.13	\$ (0.76)	\$ 0.21
Net (loss) income per common share - diluted	\$ (0.29)	\$ 0.12	\$ (0.76)	\$ 0.11

The following potentially dilutive securities have been excluded from diluted net (loss) income per share, because their effect would be antidilutive:

	<b>Three Months Ended September 30,</b>	<b>2015</b>	<b>2014</b>	<b>Nine Months Ended September 30,</b>	<b>2015</b>	<b>2014</b>
Shares of common stock subject to outstanding options	1,510,479	514,370	1,510,479	514,370		
Shares of common stock subject to outstanding common stock warrants	576,096	266,586	576,096	266,586		
Restricted stock units	110,300	110,300				
Total common stock equivalents	2,196,875	780,956	2,196,875	780,956		

#### 4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value except for its debt, which is recorded at amortized cost. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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The following table sets forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis, as of September 30, 2015 and December 31, 2014 (in thousands):

	<b>September 30, 2015</b>			<b>Total Balance</b>
	<b>Fair Value Measured Using</b>			
	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>	
<b>Assets</b>				
Money market funds	\$ 31,622	\$	\$	\$ 31,622
<b>Liabilities</b>				
Contingent consideration	\$	\$	\$ 618	\$ 618

  

	<b>December 31, 2014</b>			<b>Total Balance</b>
	<b>Fair Value Measured Using</b>			
	<b>(Level 1)</b>	<b>(Level 2)</b>	<b>(Level 3)</b>	
<b>Assets</b>				
Money market funds	\$ 36,779	\$	\$	\$ 36,779
<b>Liabilities</b>				
Contingent consideration	\$	\$	\$ 1,074	\$ 1,074

The following table presents the issuances, changes in fair value and reclassifications of the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

	<b>Level 3</b>			<b>Total</b>
	<b>Contingent Consideration Liability</b>	<b>Warrants to Purchase Convertible Preferred Stock</b>	<b>Derivative Liability Related to Subordinated Convertible Note</b>	
Balance as of December 31, 2013	\$	\$ 525	\$	\$ 525
Issuance of financial instruments	2,313		239	2,552
Change in estimated fair value	(1,239)	14	(239)	(1,464)
Reclassification to stockholders' equity		(539)		(539)
Balance as of December 31, 2014	1,074			1,074
Change in estimated fair value	(456)			(456)
Balance as of September 30, 2015	\$ 618	\$	\$	\$ 618

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers between Level 1, Level 2 and Level 3 categories during the periods presented.

In determining fair value, the Company uses various valuation approaches within the fair value measurement framework. The valuation methodologies used for the Company's instruments measured at fair value and their classification in the valuation hierarchy are summarized below:

*Money market funds* - Investments in money market funds are classified within Level 1. At September 30, 2015 and December 31, 2014, money market funds were included on the balance sheets in cash and cash equivalents.

*Contingent consideration* - As of September 30, 2015, the Company had a contingent obligation to issue 227,845 shares of the Company's common stock to the former owners of ImmuMetrix, Inc. ( IMX ) in conjunction with the Company's acquisition of IMX (see Note 11). IMX was a privately held development stage company working in new technologies using cell-free donor DNA ( cfDNA ) technology for the diagnosis, treatment and management of transplant rejection, immune disorders and diseases, including the development of a new, non-invasive test designed to detect the early stages of solid organ transplant rejection. The issuance will occur if the Company completes 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients in the United States by June 10, 2020. The Company recorded its estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual conditions that would result in the payment of the contingent consideration. The fair value of the contingent consideration was estimated using the fair value of the shares to be paid if the contingency is met multiplied by management's 65% estimate at September 30, 2015 and December 31, 2014 of the probability of success. The significant input in the Level 3 measurement not supported by market activity is the Company's probability assessment of the milestone being met. The value of the liability is subsequently remeasured to fair value each reporting date, and the change in estimated fair value is recorded to a component of operating expenses until the milestone contingency is paid, expires or is no longer achievable. Increases (decreases) in the estimation of the probability percentage result in a directionally similar impact to the fair value measurement of the contingent consideration liability.



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*Debt* We determined the estimated fair value of our debt using the present value of payments discounted at an average borrowing rate of a peer group of public companies, which is a Level 2 observable input.

*Warrants to purchase convertible preferred stock* Prior to the Company's IPO, the Company's warrants to purchase convertible preferred stock were classified as Level 3 because they were valued based on unobservable inputs and management's judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. These assumptions are inherently subjective and involve significant management judgment. The significant unobservable input used in the fair value measurement of the warrant liability was the fair value of the underlying convertible preferred stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying stock would result in a directionally similar impact to the fair value measurement of the preferred stock warrants. Any change in estimated fair value is recognized in other income or expense on the statements of operations. Upon the Company's IPO in July 2014, certain warrants to purchase convertible preferred stock were converted into warrants to purchase common stock and were reclassified to equity, while other warrants to purchase preferred stock expired pursuant to their terms.

*Derivative liability related to subordinated convertible note* On April 17, 2014, the Company issued a \$5.0 million subordinated convertible promissory note to Illumina, Inc. that had some features that constituted embedded derivatives. The Company determined that the optional conversion or repayment upon a change of control is an equity call option with a potentially variable value to be received and meets the definition of a derivative which was required to be bifurcated. The estimated fair value of this embedded derivative was affected by the estimated probability assigned to the various scenarios for the host instrument. As of April 17, 2014, management estimated repayment upon a change in control within the loan term at a 10% probability. The estimated fair value of the embedded derivative liability of \$239,000 as of April 17, 2014 was included in accrued and other liabilities. Upon the Company's IPO in July 2014, the subordinated convertible note was converted into common stock, and so the embedded conversion option was extinguished. Accordingly, the fair value of the derivative became \$0, and a gain of \$239,000 was recorded in other (expense) income, net. The significant unobservable input used in the fair value measurement of the derivative liability was the probability assigned to the various scenarios. Generally, increases (decreases) in the probability of the factors primarily impacting the valuation would result in a directionally similar impact to the fair value measurement of the derivative liability. Changes in estimated fair value were recognized in other (expense) income, net on the statements of operations.

The Company's liabilities classified as Level 3 were valued based on unobservable inputs and management's judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of the financial instruments.

**5. INVENTORY**

The following table summarizes the Company's inventories (in thousands):

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Finished Goods	\$ 341	\$ 277
Raw Materials	473	409
<b>Total Inventory</b>	<b>\$ 814</b>	<b>\$ 686</b>

**Table of Contents****6. ACCRUED AND OTHER LIABILITIES**

The following table represents the components of accrued and other liabilities (in thousands):

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Professional fees	\$ 431	\$ 273
Test sample processing fees	413	318
Accrued overpayments and refunds	144	146
Clinical Studies	523	144
Deferred rent current portion	244	202
Capital leases current portion	76	70
Other accrued expenses	500	463
 Total accrued and other liabilities	 \$ 2,331	 \$ 1,616

**7. COMMITMENTS AND CONTINGENCIES****Royalty Commitments**

In November 2004, the Company entered into a license agreement with Roche Molecular Systems, Inc., or Roche, that grants the Company the right to use certain Roche technology relating to polymerase chain reaction, or PCR, and quantitative real-time PCR, in clinical laboratory services, including in connection with AlloMap. This is a non-exclusive license agreement in the United States covering claims in multiple Roche patents. The Company had disputed the combination services percentage Roche sought to apply under the agreement. The combination service percentage is a multiplier used to calculate royalties where licensed services are sold in combination with other services. From July 2011 through September 2014, the Company withheld payment of such royalties pending resolution of the matter. On February 11, 2014, Roche filed a demand for arbitration with the American Arbitration Association seeking a declaration that the Company had materially breached the Roche license agreement by failing to report and pay royalties owing to Roche in respect of licensed services performed by the Company after July 1, 2011. Since July 1, 2011, the Company fully accrued the unpaid royalties on the balance sheets, and the amount of the unpaid royalties has been reflected as an expense in the Company's condensed statements of operations in the periods revenue was recorded to which the royalties relate. In September 2014, the Company entered into a settlement and mutual release agreement with Roche whereby: (i) for the period beginning July 1, 2011 through June 30, 2014, the Company agreed to pay the amount of \$2,827,220 in settlement of past royalties due; (ii) for the period beginning July 1, 2014 through September 30, 2014, the Company agreed to pay royalties based on the same combination services percentage used to determine the past royalties due; (iii) for the period beginning October 1, 2014 through September 30, 2017, Roche and the Company agreed to a downward adjustment of the combination services percentage used to determine the portion of the AlloMap testing revenue that is royalty bearing under the terms of the license; (iv) the Company agreed to report and pay quarterly royalties within 45 days of the end of each calendar quarter; (v) Roche agreed that, subject to the Company's timely payment of all applicable royalties through such date, no further royalties will be payable by the Company for periods after September 30, 2017; (vi) the Company and Roche agreed to mutually release all claims under the license agreement through the settlement date; and (vii) Roche agreed to dismiss the arbitration claims. For all time periods, the contractual royalty rate in the license agreement was or will be applied to the applicable combination services percentage to determine the royalties payable for the AlloMap service.

Under the license agreement, the Company incurs royalty expenses as a percentage of combination services revenue and classifies those expenses as a component of cost of testing in the statements of operations. For the three months ended September 30, 2015 and 2014, royalty expenses in connection with the Roche agreement were \$252,000 and \$296,000, respectively. For the nine months ended September 30, 2015 and 2014, royalty expenses in connection with the Roche agreement were \$761,000 and \$408,000, respectively. For the nine months ended September 30, 2014, the Company's settlement with Roche in 2014 resulted in a one-time credit to royalty expenses.

### **Contingencies**

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, or results of operations.

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**8. COLLABORATION AND LICENSING AGREEMENTS**

**Laboratory Corporation of America Holdings ( LabCorp )**

In April 2012, CareDx and LabCorp entered into a collaboration and license agreement ( 2012 Agreement ) to develop a lupus flare predictor test. The agreement provided for CareDx to license technology to LabCorp. Of the total arrangement consideration, the fair value of the license was assessed to be \$1.0 million. The license term in the 2012 Agreement was the later of 10 years from the date of the agreement or the expiration of the last-to-expire patents and patent applications included in the CareDx technology licensed to LabCorp, unless the license was terminated by mutual agreement. The agreement provided that CareDx and LabCorp would share equally the costs of developing the lupus flare predictor test; however LabCorp's share of the development cost was subject to certain limits at each stage of the arrangement.

Under the agreement, in 2012 LabCorp paid the Company a nonrefundable and non-creditable upfront license fee payment of \$1,000,000, and a nonrefundable and non-creditable payment of \$250,000 for certain lupus samples. The Company was to receive royalties in the high single digits from LabCorp on net sales of the commercialized flare predictor test or other tests developed using the samples sold.

Phase 1 of the project was completed in the first quarter of 2014.

On September 18, 2014, CareDx and LabCorp terminated the 2012 agreement. The termination agreement provides that:

CareDx transfer and assign to LabCorp, 300 SAGE I clinical samples and related clinical data and documentation that CareDx obtained from patients during the discovery phase of the collaboration;

CareDx grant a perpetual, non-exclusive worldwide, fully paid, sublicensable, royalty-free license to use any collaboration intellectual property and data for any and all purposes; and

LabCorp pay \$500,000 to CareDx within 30 days of CareDx's delivery of the clinical samples and clinical data and documentation. No further royalties, milestone fees or other fees will be payable by LabCorp after the termination date.

During the three months ended December 31, 2014, the Company delivered the clinical samples and the related clinical data and documentation to LabCorp, and accordingly recognized the \$500,000 termination fee and the remaining \$611,000 previously unrecognized license fee.

During the three and nine months ended September 30, 2014, the Company recognized \$0 and \$31,000, respectively, in revenue under this arrangement, which consisted of amortization of the upfront license fee of \$0 and \$15,000, respectively, and reimbursement of research and development expenses of \$0 and \$16,000, respectively. Such revenues are included in collaboration and license revenue on the unaudited condensed statements of operations. No revenues were earned in the three and nine months ended September 30, 2015.

Included in research and development expenses were \$0 and \$32,000 for the three and nine months ended September 30, 2014, respectively, for development costs associated with the 2012 Agreement. No research and

development expenses were recorded in the three and nine months ended September 30, 2015.

**Diaxonhit ( DHT )**

In June 2013, the Company entered into an exclusive Distribution and Licensing Agreement with DHT, a French public company, whereby DHT will have the AlloMap test performed in a European laboratory and commercialize the test in the European Economic Area ( EEA ). The agreement will expire at the later of the last-to-expire patent in the EEA or ten years from the first commercial sale of the test in the EEA, which occurred in 2014.

Consideration under the agreement includes an upfront cash payment of approximately 387,500 (\$503,000) that is designated to offset royalties earned by the Company in the first three years following the first commercial sale. The Company is entitled to receive royalties from DHT as a percent of net sales, as defined in the agreement, of AlloMap tests in the mid to high teens. Approximately 250,000 (\$344,000) of the upfront payments is refundable under certain circumstances. Upon confirmation that the CE mark was in place, the Company also received an equity payment of DHT common stock with a value of 387,500 (\$503,000). The CE mark is a mandatory conformity marking for certain products sold within the EEA. These shares were promptly sold by the Company in July 2013 for total consideration of \$467,000.

Other consideration that may be earned by the Company includes agreed-upon per unit pricing for the supply of AlloMap products, and additional royalties that are payable upon the achievement of various sales milestones by DHT. In this arrangement, there is one combined unit of accounting.

Commercial sales began in the EEA in June 2014. Total revenues recognized from this arrangement for the three and nine months ended September 30, 2014 were zero and \$1,000 respectively, and for the three and nine months ended September 30, 2015 were \$8,000 and \$41,000, respectively.

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**Table of Contents****CardioDx, Inc. ( CDX )**

In 2005, the Company entered into a services agreement with CDX, whereby the Company provided CDX with biological samples and related data and performed laboratory services on behalf of CDX. Each company granted the other a worldwide license under certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company of a low single-digit percentage of the cash collected from sales of CDX licensed products. In 2009, CDX terminated the services portion of this agreement, however, the royalty obligation from CDX continues until the tenth anniversary of the first commercial sale of a CDX licensed product. The first commercial sale of such product by CDX occurred in 2009, therefore the royalty obligation to the Company continues until 2019. Royalty revenues, recorded when earned, were \$96,000 and \$49,000 for the three months ended September 30, 2015 and 2014, respectively, and were \$275,000 and \$166,000 for the nine months ended September 30, 2015 and 2014, respectively, and are included in collaboration and license revenue on the condensed statements of operations. The Company had receivable balances from CDX of \$185,000 and \$54,000 at September 30, 2015 and December 31, 2014, respectively.

**9. DEBT**

On January 30, 2015, the Company entered into a Loan and Security Agreement (the **Loan Agreement**) which provides a secured term loan facility in an aggregate principal amount of up to \$20.0 million. The Company borrowed the first advance of \$16.0 million (**Draw A**) on January 30, 2015. Under the terms of the Loan Agreement, following a six month period from the closing date and until any time before December 31, 2015, the Company may, at its option, borrow from the lender a second advance of \$4.0 million (**Draw B**), subject to the Company's satisfaction of certain conditions described in the Loan Agreement. Draw A was used to payoff the Company's existing term debt of \$11.3 million. A loss on extinguishment of \$0.6 million from the pay-off of the existing term loan was recognized as interest expense during the nine months ended September 30, 2015. Draw A and Draw B each bear interest at a daily floating rate equal to 2.00%, plus the greater of (i) 3.25% or (ii) the prime rate published by the lender.

The maturity date of the loan is December 1, 2018. Principal pay-down of the loan begins on January 1, 2016 with the loan being payable in 36 equal monthly installments. The principal pay-down of the loan may be delayed to July 1, 2016 with the loan being payable in 30 equal monthly installments, if on December 31, 2015, the Company has achieved certain net product revenue milestones as described in the Loan Agreement.

A fully non-refundable commitment fee of \$160,000 was paid on January 30, 2015 when Draw A for \$16 million was received. An additional \$40,000 loan fee will be payable if Draw B for \$4 million is received. The loan has no prepayment penalty. Commitment fees are included in debt issuance costs which are amortized to interest expense using the effective interest method over the term of the loan. Debt discount and issuance costs, current, as of September 30, 2015 and December 31, 2014 were \$170,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of September 30, 2015 and December 31, 2014 were \$177,000 and \$11,000, respectively.

In connection with the Loan Agreement, the Company agreed to issue to the lender detachable warrants to purchase shares of the Company's common stock upon the drawdown of each advance in an amount equal to 1.5% of the amount drawn, divided by the exercise price per share for that tranche. The fair value of the warrants are reflected as a discount to the debt. As a result of Draw A, the Company issued to the lender a warrant to purchase an aggregate of 34,483 shares of the Company's common stock, at an exercise price equal to \$6.96 per share. The fair value of the warrants was estimated to be \$90,000 on January 30, 2015, using the Black-Scholes Model with the following assumptions: expected volatility of 39.83%, a contractual term of 5 years, risk-free interest rate of 1.18%, underlying common stock price of \$7.06, and dividend yield of 0%. The warrants are included in stockholders' equity with the offset to debt discount that is amortized over the term of the loan using the effective interest method. The warrants are not subject to remeasurement.

The Loan Agreement requires collateral by a security interest in all of the Company's assets except intellectual property and contains customary affirmative and negative covenants including financial maintenance covenants, and also includes standard events of default, including payment defaults. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. At September 30, 2015, the Company was in compliance with all loan covenants.

## **10. STOCKHOLDER S EQUITY**

### **Common Stock**

On August 10, 2015, the Company filed a registration statement on Form S-3 ( Shelf Filing ) with the Securities and Exchange Commission which will allow the Company to raise up to \$75.0 million of common stock, preferred stock, depository shares, warrants, debt securities and/or units in one or more offerings and in any combination. In addition, on August 10, 2015 the Company



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entered into an At The Market Issuance Sales Agreement (the "2015 ATM Agreement"), with Cantor Fitzgerald and Company ("Cantor") under which it may sell shares of its common stock from time to time in an aggregate amount not to exceed \$19 million per year per the 2015 ATM Agreement and not to exceed \$75 million in total per the Shelf Filing. Cantor may sell the shares by any method permitted by law deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act, including without limitation sales made directly on The NASDAQ Global Market, on any other existing trading market for the Company's common stock or to or through a market maker. Cantor also may sell the shares in privately negotiated transactions, subject to the Company's prior approval. The Company will pay Cantor a commission equal to 3% of the gross proceeds of the sales price of all shares sold through it as sales agent under the 2015 ATM Agreement. Approximately \$0.3 million of costs associated with this Shelf Filing and 2015 ATM Agreement are included in general and administrative expenses for the three and nine months ending September 30, 2015.

**Stock Option Plans**

Prior to its IPO, the Company had one active stock option plan, the 2008 Equity Incentive Plan ("2008 Plan"), one assumed stock option plan, the ImmuMetrix 2014 Equity Incentive Plan, and one terminated stock option plan, the 1998 Stock Plan.

Upon its IPO, the Company reserved 838,695 shares of common stock for issuance under a new 2014 Equity Incentive Plan ("2014 Plan"). The shares reserved for issuance under the 2014 Plan also include shares returned to the 2008 Plan as the result of expiration or termination of options, provided that the maximum number of shares that may be added to the 2014 Plan thereby is limited to a maximum of 865,252 shares. The number of shares available for issuance under the 2014 Plan also includes an annual increase on the first day of each year equal to the lesser of:

357,075 shares

4.0% of the outstanding shares of common stock as of the last day of the immediately preceding year; or

such other number of shares as the Company's board of directors may determine.

The following table summarizes option activity and related information:

		<b>Stock Options Outstanding</b>	<b>Weighted- average Exercise Price</b>
Balance	December 31, 2014	1,031,804	\$ 7.36
Granted		558,578	6.36
Exercised		(23,284)	1.94
Forfeited		(55,450)	7.81
Expired		(1,169)	12.40
Balance	September 30, 2015	1,510,479	\$ 7.05

There were 434,255 shares available for the granting of stock options, restricted stock units and restricted stock from the 2014 Plan as of September 30, 2015.

Options outstanding and exercisable that have vested or are expected to vest as of September 30, 2015 are as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Value (In thousands)</b>
Vested	629,151	\$ 5.52	7.34	\$ 834
Expected to Vest	881,328	8.13	9.10	127
<b>Total</b>	<b>1,510,479</b>			<b>\$ 961</b>

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The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at September 30, 2015 for stock options that were in-the-money. The fair market value of the Company's common stock as of September 30, 2015 was \$4.17 per share.

The weighted-average grant-date fair value of options granted during the three and nine months ended September 30, 2015 using the Black-Scholes Model was \$2.81 and \$2.63 per share, respectively.

**Valuation Assumptions**

The fair value of stock-based awards was estimated using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected term (in years)	6.0	6.0	6.0	5.3
Expected volatility	39.10%	43.81%	40.74%	42.30%
Risk-free interest rate	1.90%	2.05%	1.87%	1.76%
Expected dividend yield				

**2014 Employee Stock Purchase Plan**

Our board of directors adopted our 2014 Employee Stock Purchase Plan (the "ESPP") in March 2014 and our stockholders approved the ESPP in July 2014. However, our ESPP was not made available to our employees until January 1, 2015. The first offering period of the ESPP began on January 1, 2015 and ended June 30, 2015. Under the first offering period, 36,696 shares were purchased under the ESPP. At September 30, 2015, the proceeds from the issuance of shares were \$0.2 million and a total of 186,473 shares of our common stock is available for sale under the ESPP.

The option price per share of common stock to be paid by a participant upon exercise of the participant's option on the applicable exercise date for an offering period shall be equal to 85% of the lesser of the fair market value of a share of common stock on (a) the applicable grant date or (b) the applicable exercise date.

**Restricted Stock Units**

The Company's 2014 Plan allows restricted stock units ("RSUs") to be granted in addition to stock options. The RSUs vest annually over four years in equal increments. RSUs were granted by the Company for the first time in March 2015.

Unvested RSU activity for the nine months ended September 30, 2015 is summarized below:

	<b>Weighted Average Grant-Date Fair Value</b>
<b>Number of Shares</b>	

Unvested balance at December 31, 2014		
Granted	114,400	\$ 6.49
Vested		
Forfeited	(4,100)	6.49
Unvested balance at September 30, 2015	110,300	\$ 6.49

**Non-Employee Director Equity-Based Compensation**

For the three and nine months ended September 30, 2015, the Company paid a portion of its non-employee directors compensation through the award of common shares. The stock awards are classified as equity-based compensation expense. Expenses associated with the awards were \$60,000 and \$183,000 for the three and nine months ended September 30, 2015, respectively, and are included

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in general and administrative expense in the condensed statement of operations. The shares issued and associated expenses were as follows:

<b>Service Period Three Months Ended</b>	<b>Number of Shares Issued</b>	<b>Fair Market Value per Share at Date of Issuance</b>	<b>Fair Value of Shares Issued (In Thousands)</b>
March 31, 2015	8,663	\$ 5.56	\$ 48
June 30, 2015	11,628	6.48	75
September, 30 2015	9,553	\$ 4.23	40
Total	29,844		\$ 163

The shares issued at each date were for services performed during the three-month period that ended one day prior to the date of issuance. The Company's results of operations include expense relating to employee and nonemployee stock-based payment awards from stock options and RSUs as follows (in thousands):

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Cost of testing	\$ 22	\$ 6	\$ 91	\$ 15
Research and development	79	35	215	57
Sales and marketing	37	13	93	22
General and administrative	198	111	629	256
	\$ 336	\$ 165	\$ 1,028	\$ 350

At September 30, 2015, there was approximately \$3.4 million of total unrecognized stock-based compensation from stock option and RSU grants, net of estimated forfeitures, related to non-vested stock option and RSUs granted that will be recognized on a straight-line basis over the remaining average vesting period of 2.9 years.

**11. BUSINESS COMBINATION**

On June 10, 2014, in accordance with an agreement and plan of merger, the Company acquired ImmuMetrix, Inc. (IMX), a privately held development stage company working in new technologies using cell-free donor DNA (cfDNA) technology for the diagnosis, treatment and management of transplant rejection, immune disorders and diseases, including the development of a new, non-invasive test designed to detect the early stages of solid organ transplant rejection. The Company acquired all IMX assets associated with transplant diagnostics, including related immune repertoire and infectious diseases. An IMX successor company retained the limited assets not associated with transplant diagnostics. The acquisition was structured as a tax-free reorganization.

The Company acquired all of the issued and outstanding capital stock of IMX for the total estimated purchase price of \$17.2 million consisting of \$600,000 in cash; 911,364 shares of the Company's Series G convertible preferred stock

with an estimated fair value of \$14.2 million, including 23,229 shares of the Company's Series G convertible preferred stock with an estimated fair value of \$369,000 as a result of the Company's assumption of IMX outstanding stock options; and an additional payment of 227,845 shares of CareDx Series G convertible preferred stock if a future milestone is achieved. The Agreement provides that the milestone will be achieved if the Company completes 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients in the United States no later than six years after the closing date of the acquisition. All shares of Series G Preferred Stock and options to acquire Series G Preferred Stock converted into common stock and options to acquire common stock, respectively, immediately prior to the closing of the Company's initial public offering. The additional shares to be paid for the achievement of the milestone will also be issued in common stock. The fair value of this contingent consideration was \$2.3 million at the acquisition date, \$1.1 million at December 31, 2014, and \$618,000 at September 30, 2015. The intellectual property acquired includes an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. The license provides for the Company to pay royalties to Stanford University on sales of the Company's cfDNA tests.

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IMX's post-acquisition results of operations for the three and nine months ending September 30, 2015 are included in the Company's condensed statement of operations.

**Pro Forma Impact of the Acquisition of IMX**

The following table presents pro forma results of operations and gives effect to the IMX transaction as if the transaction had been consummated on January 1, 2013. The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or operating efficiencies resulting from combining the two companies (in thousands, except per share data):

	<b>Nine Months Ended September 30, 2014</b>	
Net revenue	\$	19,354
Net loss	\$	(1,075)
Net loss per common share - basic and diluted	\$	0.28

The unaudited pro forma financial information was prepared using the acquisition method of accounting and is based on the historical financial information of the Company and IMX, reflecting the Company's and IMX's results of operations for the nine month period ended September 30, 2014. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated financial information reflects: (a) the removal of acquisition-related costs of \$1.7 million incurred by both CareDx and IMX for the nine months ended September 30, 2014 including the removal of \$0.2 million of IMX stock-based compensation expense that resulted from modifications to options in anticipation of the acquisition; (b) the removal of a \$1.5 million tax benefit for the nine months ended September 30, 2014 that resulted from the acquisition; and (c) the addition of salaries, benefits and fees for IMX employees and consultants retained after the acquisition. Acquisition related expenses are primarily included in general and administrative expenses.

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**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 together with the unaudited condensed financial statements and related notes included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on March 31, 2015.*

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q 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 contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words believe, may, will, potentially, estimate, continue, anticipate, intend, could, would, project, plan, expect and the negative and plural forms of the similar expressions are intended to identify forward-looking statements.

These forward-looking statements may include, but are not limited to, statements concerning the following:

our ability to generate revenue from sales of AlloMap and future solutions, if any, and our ability to increase the commercial success of AlloMap;

our plans and ability to develop and commercialize new solutions, including cell-free DNA, or cfDNA, solutions for the surveillance of heart and kidney transplant recipients;

our ability to achieve, maintain and expand reimbursement coverage from payers for AlloMap and future solutions, if any;

the outcome or success of our clinical trial collaborations and observational studies;

our compliance with federal, state and foreign regulatory requirements;

the favorable review of AlloMap and our future solutions, if any, in peer-reviewed publications;

our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us;





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our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;

anticipated trends and challenges in our business and the markets in which we operate; and

our ability to comply with the requirements of being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, 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 we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this report and the documents that we reference in this report and have filed with the SEC as exhibits with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all forward-looking statements by these cautionary statements.

## **Overview and Recent Developments**

We are a commercial stage company that develops, markets and delivers diagnostic surveillance solutions for organ transplant recipients to help clinicians make personalized treatment decisions throughout a patient's lifetime. Our one commercialized testing solution, the AlloMap heart transplant molecular test, is a blood-based test used to monitor heart transplant recipients for moderate or acute cellular rejection. We believe the use of AlloMap, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant. In particular, we believe AlloMap can improve patient care by helping healthcare providers to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We believe that there is a significant unmet need for post-transplant surveillance solutions and are applying our expertise in transplantation towards the development of additional solutions for other organ transplant recipients, including recipients of kidney transplants.

Since the launch of AlloMap in January 2005 we have performed more than 75,000 commercial AlloMap tests, including 9,793 tests during the first nine months of 2015, in our Brisbane, California laboratory. During 2015, the test was used in 115 of the approximately 129 heart transplant management centers in the U.S. We believe that there is an opportunity for AlloMap outside of the U.S. and through recent partnerships we have expanded the AlloMap offering

to Europe and Canada. We believe that we are not currently capacity constrained and that our current facility can support a substantial increase in AlloMap testing volume.

On August 10, 2015, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission which will allow the Company to raise up to \$75 million from the capital markets.

Centers for Medicare and Medicaid Services ( CMS ) recently announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the current proposed fee schedule, AlloMap reimbursement from the Medicare program would be reduced by 77%. The draft fee schedule is subject to an open comment period and has not yet been adopted as final guidance, but if the current proposal is adopted, that could require us to discontinue testing for Medicare patients. Given the significant portion of payments represented by Medicare, the remaining test revenue may be insufficient to sustain our operations. Additionally, some hospitals may reduce the use of AlloMap if it is not available to all patients, and only to non-Medicare recipients.

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**Table of Contents****Financial Operations Overview*****Testing Revenue***

Our testing revenue is derived from AlloMap tests which represented 98% of our total revenues for the three and nine months ended September 30, 2015, and 99% for the three and nine months ended September 30, 2014. Our testing revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenue on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; (v) our ability to expand into markets outside of the United States; and (vi) how quickly we can successfully commercialize new product offerings.

We currently market AlloMap to healthcare providers through our direct sales force that targets transplant centers and their physicians, coordinators and nurse practitioners. The healthcare providers that order the tests and on whose behalf we provide our testing services are generally not responsible for the payment of these services. As of September 30, 2015, the list price of AlloMap was \$3,600 per test. However, amounts actually received by us vary from payer to payer based on each payer's internal coverage practices and policies. We generally bill third-party payers upon delivery of an AlloMap score report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

As of September 30, 2015 and 2014, the number of tests for which results were delivered and billed, but for which the associated revenue had not been recognized because our revenue recognition criteria were not met, and taking into account claim status and possibility of collection, was approximately 3,600 and 3,500, respectively. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected.

***Collaboration and License Revenue***

Revenue from our collaboration and license agreements was not more than 2% of total revenues for each period presented. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Our performance obligations under the collaboration and license agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated periods of performance on a prospective basis.

***Cost of Testing***

Cost of testing reflects the aggregate costs incurred in delivering our AlloMap test results to clinicians. The components of our cost of testing are materials and service costs, direct labor costs, including stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation and utilities and royalties. Costs associated with performing tests (except royalties) are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. Royalties incurred for licensed technology, calculated as a percentage of test revenues, are

recorded as license fees in cost of testing at the time the test revenues are recognized.

Royalties included in cost of testing are associated with a license from Roche Molecular Systems, Inc., or Roche. In September 2014, we agreed with Roche to a downward adjustment of the combination services percentage used to determine the portion of the AlloMap service that is royalty bearing under the terms of the license with Roche. As part of this agreement no further royalties will be payable by us for periods after September 30, 2017. We expect cost of testing to increase, in absolute dollars, as the number of tests we perform increases. However, due to the fixed nature of expenses associated with direct labor, equipment and infrastructure, we expect the cost per test will decrease over time as volume increases.

### ***Research and Development Expenses***

Research and development expenses represent costs incurred to develop new surveillance solutions as well as continued efforts related to our AlloMap test. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, and certain allocated expenses as well as amounts incurred under certain collaborative agreements. Research and development costs are expensed as incurred. We record accruals for estimated study costs comprised of work performed by contract research organizations under contract terms. We expect our research and development expenses will increase in absolute dollars in future periods as we invest in research and discovery work to develop new surveillance solutions, as well as clinical outcomes studies for AlloMap.

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***Sales and Marketing Expenses***

Sales and marketing expenses represent costs incurred to sell, promote and increase awareness of our AlloMap test to both clinicians and payers, including education of patients, clinicians and payers. Sales and marketing expenses include payroll and related expenses, educational and promotional expenses, and infrastructure expenses, including allocated facility and overhead costs. Compensation related to sales and marketing includes annual salaries and eligibility for quarterly or semi-annual commissions or bonuses based on the achievement of predetermined sales goals or other management objectives.

***General and Administrative Expenses***

General and administrative expenses include costs for our executive, finance, accounting and human resources functions. Costs consist primarily of payroll and related expenses, professional service fees related to billing and collection, accounting, legal and other contract and administrative services and related infrastructure expenses, including allocated facility and overhead costs. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and The NASDAQ Global Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our general and administrative expenses will increase in absolute dollars related to anticipated testing volume and collections growth.

***Interest Expense, Net***

Interest expense, net is associated with borrowings under our loan agreements.

***Other (Expense) Income, Net***

For the three and nine months ended September 30, 2014, Other (Expense) Income, Net is primarily associated with the remeasurement of the estimated fair value of warrants to purchase shares of our convertible preferred stock which were converted to common stock warrants upon the closing of our initial public offering on July 22, 2014, and changes in the estimated fair value of derivative associated with our subordinated convertible debt. For the three and nine months ended September 30, 2015, Other (Expense) Income, Net is primarily state franchise taxes.

**Table of Contents****Results of Operations*****Comparison of the Three Months Ended September 30, 2015 and September 30, 2014******(In thousands except for Allomap results)***

	<b>Three Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Allomap results delivered	3,423	3,026
Revenue:		
Testing revenue	\$ 7,007	\$ 6,601
Collaboration and license revenue	144	53
Total revenue	7,151	6,654
Operating expenses:		
Cost of testing	2,568	1,772
Research and development	2,698	1,036
Sales and marketing	2,062	1,753
General and administrative	3,361	1,976
Change in estimated fair value of contingent consideration	(345)	(1,276)
Total operating expenses	10,344	5,261
(Loss) income from operations	(3,193)	1,393
Interest expense, net	(251)	(535)
Other (expense) income, net	(45)	355
(Loss) income before income taxes	(3,489)	1,213
Income tax benefit		
Net (loss) income	\$ (3,489)	\$ 1,213

***Testing Revenue***

Testing revenue increased by \$406,000 or 6%, for the three months ended September 30, 2015 compared to the same period of 2014. AlloMap test results delivered increased by approximately 397 or 13% for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014. The revenue mix changed such that a lower mix of test volume was recognized from payers from whom we recognize revenue on an accrual rather than a cash basis. There was also a \$47,000 increase in test revenue as we changed the revenue recognized of one payer from a cash to an accrual basis.

***Collaboration and License Revenue***

Collaboration and license revenue increased by approximately \$91,000, or 172%, for the three months ended September 30, 2015 compared to the same period in 2014 primarily due to an increase in royalties of \$47,000 from CardioDx and an increase in \$44,000 in other collaboration revenue.

*Cost of Testing*

Cost of testing increased by approximately \$800,000, or 45%. The main driver in this increase was higher royalty expenses of \$520,000 in 2015 compared to 2014 as a result of a settlement with Roche in 2014 which resulted in a one-time credit in 2014. Other drivers in the increase in cost of testing expense include increased headcount and material expenses of \$260,000, and \$20,000 in higher specimen processing and other expenses.

*Research and Development*

Research and development expenses increased by \$1.7 million, or 160%, for the three months ended September 30, 2015 compared with the same period in 2014. The increase was primarily due to an increase in headcount related expenses of \$0.6 million, increased



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expenditure of \$0.3 million in the area of cfDNA technology, an increase in clinical trial expenses of \$0.3 million and an increase of \$0.5 million in various research and development activities. We expect our research and development expenses will increase in absolute dollars in future periods as we invest in research and discovery work to develop our cell-free DNA technology, as well as clinical outcomes studies for new tests, if and when developed.

*Sales and Marketing*

Sales and marketing expenses increased by approximately \$0.3 million, or 18%, for the three months ended September 30, 2015 compared with the same period in 2014. The increase was primarily related to increased headcount and consulting expenses of \$0.4 million, partially offset by a decrease of \$0.1 million in marketing programs such as physician forums, speaker programs, advertising and other marketing expenses. We expect sales and marketing expenses to increase in the future as we continue to expand our presence in the diagnostic surveillance market.

*General and Administrative*

General and administrative expenses increased by approximately \$1.4 million, or 70%, for the three months ended September 30, 2015 compared with the same period of 2014 primarily due to increased professional fees of \$0.8 million, and increased headcount related expenses of \$0.6 million partially as a result of us in-sourcing our billing function. The increased professional fees were primarily due to the expenses associated with the filing of a registration statement on Form S-3 with the Securities and Exchange Commission which will allow the Company to raise up to \$75 million from the capital markets, and business development activities.

*Change in Fair Value of Contingent Consideration*

The consideration for our business combination with ImmuMetrix, Inc. includes a future payment that is contingent upon the achievement of a specified milestone. We recorded a contingent consideration liability at its fair value in June 2014, at the acquisition date. We revalue our contingent consideration obligation each reporting period. Changes in the fair value of our contingent consideration obligation are recognized as a component of operating expense within our condensed statements of operations.

*Interest Expense, Net*

Interest expense, net decreased by \$0.3 million for the three months ended September 30, 2015 compared with the same period of 2014. Interest expense, net in the quarter ended September 30, 2015 reflects interest expense of \$0.2 million from a term loan that the Company entered into in January 2015. Interest expense, net was \$0.5 million for the quarter ended September 30, 2014 and reflects interest associated with the \$5.0 million Illumina subordinated convertible note issued in April 2014 as well as interest expense associated with a previous term loan that was subsequently paid off in January 2015.

*Other (Expense) Income, Net*

Other (expense) income, net for the three months ended September 30, 2015 was \$(45,000) as a result of state franchise taxes. We recorded other (expense) income, net of \$0.4 million for the three months ended September 30, 2014 primarily due the remeasurement of the estimated fair value of warrants to purchase shares of our convertible preferred stock of \$0.3 million and \$0.1 million for the derivative bifurcated from our Illumina debt. Upon our July 2014 IPO, the preferred stock warrants converted into common stock warrants and the then fair value of such warrants was reclassified to additional paid-in capital. The common stock warrants are not subject to remeasurement.



**Table of Contents*****Comparison of the Nine Months Ended September 30, 2015 and September 30, 2014******(In thousands except for Allomap results)***

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Allomap results delivered	9,793	8,843
Revenue:		
Testing revenue	\$ 21,147	\$ 19,145
Collaboration and license revenue	349	209
<b>Total revenue</b>	<b>21,496</b>	<b>19,354</b>
Operating expenses:		
Cost of testing	7,786	6,337
Research and development	6,629	2,548
Sales and marketing	6,453	4,837
General and administrative	8,553	6,087
Change in estimated fair value of contingent consideration	(456)	(1,276)
<b>Total operating expenses</b>	<b>28,965</b>	<b>18,533</b>
<b>(Loss) income from operations</b>	<b>(7,469)</b>	<b>821</b>
Interest expense, net	(1,334)	(1,727)
Other (expense) income, net	(142)	192
<b>Loss before income taxes</b>	<b>(8,945)</b>	<b>(714)</b>
<b>Income tax benefit</b>		<b>1,500</b>
<b>Net (loss) income</b>	<b>\$ (8,945)</b>	<b>\$ 786</b>

***Testing Revenue***

Testing revenue increased by \$2.0 million, or 10%, for the nine months ended September 30, 2015 compared to the same period of 2014. AlloMap test results delivered increased by approximately 950 or 11% for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014. The revenue increase was primarily related to test volume.

***Collaboration and License Revenue***

Collaboration and license revenue increased by \$140,000 or 67%, for the nine months ended September 30, 2015 compared to the same period in 2014 primarily due to \$60,000 in increased revenue recognized from our collaboration with Diaxonhit, and an increase in royalties of \$110,000 from CardioDx, partially offset by decreases in collaboration revenue of \$30,000 from LabCorp and other collaborations, respectively.

*Cost of Testing*

Cost of testing increased by approximately \$1.4 million or 23%, for the nine months ended September 30, 2015 compared to the same period in 2014. The main driver in this increase was higher headcount expenses of \$0.8 million. In addition, there was an increase in royalty expense of \$0.4 million in 2015 compared to 2014 as a result of a settlement with Roche in 2014 which resulted in a one-time credit in 2014. Other drivers in the increase in cost of testing expense include increased material and other expenses of \$0.2 million. We expect to see our cost of testing increase in absolute dollars as we expect test volumes to increase in the future.

*Research and Development*

Research and development expenses increased by \$4.1 million, or 160%, for the nine months ended September 30, 2015 compared with the same period in 2014. The increase was primarily due to increased headcount and consulting related expenses of \$2.7 million, an increase of \$0.6 million in the area of cfDNA technology, increased clinical trial expenses of \$0.6 million, and an increase of \$0.2 million

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in various research and development activities. We expect our research and development expenses will increase in absolute dollars in future periods as we invest in research and discovery work to develop our cell-free DNA technology, as well as clinical outcomes studies for AlloMap and new tests, if and when developed.

*Sales and Marketing*

Sales and marketing expenses increased by approximately \$1.6 million or 33%, for the nine months ended September 30, 2015 compared with the same period in 2014. The increase was primarily related to increased headcount and consulting expenses of \$0.9 million, an increase of \$0.4 million in marketing programs such as physician forums, speaker programs and advertising, and an increase in \$0.3 million in other marketing expenses as we ramp up our commercialization efforts. We expect sales and marketing expenses to increase in the future as we continue to expand our presence in the diagnostic surveillance market.

*General and Administrative*

General and administrative expenses increased by approximately \$2.5 million, or 41%, for the nine months ended September 30, 2015 compared with the same period of 2014, primarily due to a \$1.4 million increase in headcount related expenses driven primarily by the hiring of key management personnel and the in-sourcing of our billing function, an increase in professional fees of \$0.8 million, and an increase in \$0.3 million in other expenses. The increased professional fees were primarily due to the expenses associated with the filing of a registration statement on Form S-3 with the Securities and Exchange Commission which will allow the Company to raise up to \$75 million from the capital markets, and business development activities. We anticipate our general and administrative expenses will increase as we continue to operate as a public company.

*Change in Fair Value of Contingent Consideration*

The consideration for our business combination with ImmuMetrix, Inc. includes a future payment that is contingent upon the achievement of a specified milestone. We recorded a contingent consideration liability at its fair value in September 2014, at the acquisition date. We revalue our contingent consideration obligation each reporting period. Changes in the fair value of our contingent consideration obligation are recognized as a component of operating expense within our condensed statements of operations.

*Interest Expense, Net*

Interest expense, net decreased by \$0.4 million for the nine months ended September 30, 2015 compared with the same period of 2014. Interest expense, net in the quarter ended September 30, 2015 includes a loss on extinguishment of \$0.6 million as the company paid off a previous term loan in January 2015, and interest expense of \$0.7 million on the new term loan. Interest expense, net was \$1.7 million for the nine months ended September 30, 2014 and reflects interest associated with the \$5.0 million Illumina subordinated convertible note issued in April 2014 as well as interest expense associated with a previous term loan that was subsequently paid off in January 2015.

*Other (Expense) Income, Net*

Other (expense) income, net for the nine months ended September 30, 2015 was \$(142,000) consisting primarily of state franchise taxes. We recorded other (expense) income, net of \$0.2 million for the nine months ended September 30, 2014 which was primarily for the remeasurement of the convertible preferred warrants and the derivative associated with the Illumina subordinated convertible note.

*Income Tax Benefit*

In conjunction with the acquisition of IMX a tax benefit of \$1.5 million was recognized during the nine months ended September 30, 2014. This benefit resulted from the expectation that amortization of the in-process technology acquired, when completed and placed in service, is not expected to be deductible for tax purposes, as the transaction was structured as a tax-free reorganization. Accordingly, a deferred tax liability was recorded at the acquisition date for the difference between the financial reporting and tax basis of the acquired in-process technology. While the in-process technology is considered an indefinite lived intangible asset, this asset is expected to be amortized or impaired prior to the expiration of net operating loss carryforwards available to us.

**Table of Contents*****Cash Flows for the Nine Months Ended September 30, 2015 and 2014***

The following table summarizes the primary sources and uses of cash for the periods presented:

<b>(in thousands)</b>	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Net cash (used in) provided by:		
Operating activities	\$ (5,776)	\$ (2,628)
Investing activities	(1,123)	(739)
Financing activities	4,422	37,287
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>\$ (2,477)</b>	<b>\$ 33,920</b>

***Operating Activities***

Net cash used in operating activities consists of net loss or income, adjusted for certain non-cash items in the statements of operations and changes in operating assets and liabilities.

Cash used in operating activities for the nine months ended September 30, 2015 was \$5.8 million. The net loss of \$8.9 million included \$1.2 million of net non-cash expenses. These net noncash expenses include non-cash interest expenses of \$0.2 million for the amortization of debt issuance costs associated with new debt, and a loss on extinguishment from a previous debt. Other non-cash expenses include stock-based compensation expense of \$1.0 million and depreciation and amortization of \$0.6 million.

These non-cash expenses were partially offset by a non-cash revaluation gain of \$0.5 million on a contingent consideration liability related to our acquisition of ImmuMetrix, Inc. in June 2014. This revaluation gain was driven by a decrease in our stock price.

In addition to net non-cash expenses, our net operating assets decreased which generated \$1.9 million in operating cash flow. The decrease in net operating assets was primarily driven by a decrease in accounts receivable of \$0.4 million as our reimbursement efforts improved over the nine month period ended September 30, 2015, increases in accounts payable and accrued and other liabilities of \$1.5 million as we strengthened our cash management processes, an increase in payroll liabilities of \$0.5 million as a result of accrued employee bonuses, partially offset by increases in inventory, prepaid expenses and other assets of \$0.5 million.

Cash used in operating activities for the nine months ended September 30, 2014 was \$2.6 million. The net income of \$0.8 million reflects a non-cash income tax benefit of \$1.5 million, a decrease in the estimated fair value of a contingent consideration liability of \$1.3 million and a decrease in the estimated fair value of an embedded derivative of \$0.2 million, offset in part by an increase in debt discount accretion and other non-cash interest expense of \$0.8 million, depreciation and amortization of \$0.4 million and stock-based compensation expense of \$0.4 million.

For the nine months ended September 30, 2014, an increase in net operating assets of \$1.9 million was primarily comprised of a decrease in accrued royalties of \$2.5 million and an increase in prepaid expenses and other assets of \$0.5 million, offset in part by a decrease in accounts receivable of \$0.5 million and an increase in accrued and other liabilities of \$0.3 million.

The decrease in accrued royalties was the result of a \$2.8 million payment of past due royalties to Roche in September 2014 upon settlement of a dispute (for more information, see Note 7 to unaudited interim condensed financial statements elsewhere in this Quarterly Report). The increase in prepaid expenses and other assets was primarily due to our purchase of a directors and officers insurance policy when we became a public company in July 2014.

*Investing Activities*

During the nine months ended September 30, 2015, net cash used in investing activities was \$1.1 million for purchases of property and equipment. During the nine months ended September 30, 2014 we used \$0.7 million for investing activities, primarily comprised of \$0.4 million for our acquisition of ImmuMetrix and \$0.3 million to purchase property and equipment.



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We expect capital expenditures to increase as we expand our research and discovery work to develop new transplant surveillance solutions. We believe that we are not currently capacity constrained and that our current facility can support a substantial increase in testing volume and support new surveillance solutions currently being developed.

*Financing Activities*

For the nine months ended September 30, 2015, net cash provided by financing activities was \$4.4 million and consisted primarily of \$15.6 million in net proceeds received from a new term loan in January 2015, and proceeds of \$0.2 million from the issuance of common stock as part of our employee stock purchase plan and the exercise of stock options, partially offset by the pay-off of a previous term loan and capital leases of \$11.4 million.

For the nine months ended September 30, 2014, net cash provided by financing activities was \$37.3 million and consisted primarily of \$35.5 million of proceeds from our July 2014 initial public offering, net of underwriters discounts and issuance costs, and \$5.0 million of net proceeds from our April 2014 issuance of a subordinated convertible note, partially offset by principal payments on debt and capital leases of \$3.2 million.

*Liquidity and Capital Resources*

Since our inception, substantially all of our operations have been financed through the issuance of our convertible preferred stock, the issuance of common stock in our July 2014 initial public offering, the incurrence of debt, and cash received from AlloMap testing revenues. Through September 30, 2015, we have received net proceeds of approximately \$146 million from AlloMap testing revenues, \$151 million from the issuances of preferred stock, including preferred stock issued on conversion of promissory notes, \$35.5 million from our initial public offering, and \$35.3 million in net proceeds from debt issuances, including \$5.0 million from a subordinated convertible note. As of September 30, 2015, we had cash and cash equivalents of \$34.0 million and \$15.7 million of debt outstanding under our long-term debt and capital lease obligations.

On August 10, 2015, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission which will allow the Company to raise up to \$75 million from the capital markets.

We plan to use the \$35.5 million of net proceeds from our initial public offering and the \$15.6 million in net proceeds from debt issuances in the nine months ended September 30, 2015 for research and development, including research aimed at expanding the clinical utility of AlloMap and the development of new solutions for the surveillance of heart and kidney transplants, sales and marketing activities, general and administrative expenses and for working capital and other general corporate purposes. A portion of the net proceeds may also be used to acquire or invest in complementary businesses, technologies, services or products. We have no current agreements or commitments with respect to any such potential future acquisition or investment.

CMS recently announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the current proposed fee schedule, AlloMap reimbursement from the Medicare program would be reduced by 77% effective, January 1, 2016. The draft fee schedule is subject to an open comment period and has not yet been adopted as final, but if the current proposal is adopted, that could require us to discontinue testing for Medicare patients which would increase our need to raise additional capital.

We currently anticipate that our cash and cash equivalents and projected cash receipts from AlloMap sales to customers will be sufficient to fund our operations for at least the next 18 months. We cannot be certain that any of our development of new transplant surveillance solutions will be successful or that we will be able to raise sufficient additional funds, if necessary, to see these programs through to a successful result.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risk and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these unaudited condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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There have been no material changes in our critical accounting policies and estimates during the three and nine months ended September 30, 2015, as compared to those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K filed with the SEC on March 31, 2015.

The Company has issued warrants to purchase shares of its common stock in connection with the issuance of debt on January 30, 2015. The Company accounted for these warrants as equity at fair value on the date the warrants were issued. The fair value of the outstanding warrants was estimated using the Black-Scholes Option Pricing Model (the Black-Scholes Model). The Black-Scholes Model requires inputs such as the expected term of the warrants, expected volatility and risk-free interest rate. These inputs are subjective and require significant analysis and judgment to develop. For the estimate of the expected term, the Company used the full remaining contractual term of the warrant.

## **Factors Affecting Our Performance**

### ***The Number of AlloMap Tests We Receive and Report***

The growth of our business is tied to the number of AlloMap tests we receive and report. Historically, less than two percent of tests received are not reported due to improper sampling or damage in transit or other causes. We incur costs of collecting and shipping all samples and a portion of the costs where we cannot ultimately issue a score report. As a result, the number of samples received largely directly correlates to the number of score reports.

### ***How We Recognize Revenue***

Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allows us to recognize the related revenue on an accrual basis. For the nine months ended September 30, 2015 and 2014, 33% and 37%, respectively, of our revenue was recognized when cash was received. Until we achieve our revenue recognition criteria for a larger number of payers, we will continue to recognize a large portion of our revenue when cash is received. Because we often need to appeal prior to being paid for certain tests, it can take over a year for a test to result in revenue being recorded, and for a portion of our tests, we may never realize revenue.

Additionally, as we commercialize new products, we will need to achieve our revenue recognition criteria for each payer for each new product prior to being able to recognize the related revenue on an accrual basis. Because the timing and amount of cash payments received from payers is difficult to predict, we expect our revenue may fluctuate significantly in any given quarter. In addition, even if we begin to accrue larger amounts of revenue related to AlloMap, when we introduce new products, we do not expect we will be able to recognize revenue from new products on an accrual basis for some period of time.

### ***Continued Adoption of and Reimbursement for AlloMap***

Our reimbursement rate has steadily increased over time since the launch of AlloMap, as payers adopt coverage policies and fewer payers consider AlloMap as experimental and investigational. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. As of September 30, 2015, we had been reimbursed for approximately 80% of AlloMap results delivered in the twelve months ended March 31, 2015. Reimbursement performance is reviewed using a lagging metric of six months as any period less than this is considered not to be reflective of future performance, as the reimbursement process can typically take six months or more to complete depending on the payer. Revenue growth depends on our ability to achieve broader reimbursement from third party payers, to expand the number of tests per patient and the base of ordering physicians.

CMS recently announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the current proposed fee schedule, AlloMap reimbursement from the Medicare program would be reduced by 77%. If this proposal is adopted, some hospitals may reduce the use of AlloMap if it is made available only to non-Medicare recipients.

### ***Development of Additional Products***

We rely on sales of AlloMap to generate the majority of our revenue. Our product development pipeline includes other surveillance solutions for organ transplant recipients to help clinicians make personalized treatment decisions throughout a transplant patient's lifetime. Accordingly, we expect to invest in research and development in order to develop additional products. Our success in developing new products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.

### ***Timing of Research and Development Expenses***

Our spending on experiments may vary substantially from quarter to quarter. We also spend to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products as well as on-going clinical and outcome studies to further the published evidence to support our commercialized AlloMap test. Spending on research and development for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

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During the nine months ended September 30, 2015, there was a material increase in our contractual obligations and commitments. On January 30, 2015, we entered into a Loan and Security Agreement (the "Loan Agreement") which provides a secured term loan facility in an aggregate principal amount of up to \$20.0 million. We borrowed the first advance of \$16.0 million ("Draw A") on January 30, 2015. Under the terms of the Loan Agreement, following a six month period from the closing date and until any time before December 31, 2015, the Company may, at its option, borrow from the lender a second advance of \$4.0 million ("Draw B"), subject to the Company's satisfaction of certain conditions described in the Loan Agreement. Draw A was used to pay-off the Company's existing term debt of \$11.3 million. Draw A and Draw B each bear interest at a daily floating rate equal to 2.00%, over the greater of (i) 3.25% or (ii) the prime rate published by the lender.

The maturity date of the loan is December 1, 2018. Principal pay-down of the loan begins on January 1, 2016 with the loan being payable in 36 equal monthly installments. The principal pay-down of the loan may be delayed to July 1, 2016 with the loan being payable in 30 equal monthly installments, if on December 31, 2015, the Company has achieved certain net product revenue milestones as described in the Loan Agreement. There have otherwise been no material changes to our contractual obligations since our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on March 31, 2015.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

**JOBS Act Accounting Election**

We are an emerging growth company, as defined in the Jumpstart Our Business startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

**Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) ("ASU 2014-09"), which amends the existing accounting standards for revenue recognition. ASU 2014-09 is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled to when products are transferred to customers. On July 9, 2015, the FASB decided to delay the effective date of the new standard by one year. The standard would become effective for us beginning in the first quarter of 2018. Early application would be permitted in 2017. Entities would have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The Company is currently evaluating the impact of adopting the new revenue standard on its financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). This ASU requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is applicable to the Company beginning January 1, 2016. However, early adoption of ASU 2015-03 is permitted and the Company adopted ASU 2015-03 as of January 1, 2015.

using the retrospective method as required. Debt discount and issuance costs, current, as of September 30, 2015 and December 31, 2014 were \$170,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of September 30, 2015 and December 31, 2014 were \$177,000 and \$11,000, respectively. There is no impact from the adoption of ASU 2015-03 on the unaudited condensed statements of operations or in the loss per share calculations.

In April 2015, the FASB issued ASU 2015-05 Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) (ASU 2015-05). This ASU provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. This ASU will be effective for annual periods, including interim periods beginning after December 15, 2015. Early adoption is permitted. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. The Company is currently evaluating the impact of adopting ASU 2015-05 on its financial statements.

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### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of \$34.0 million at September 30, 2015, which consist of bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our unaudited condensed financial statements.

All of our revenues are recognized in U.S. dollars. Upfront payments received from the collaboration agreement in the European Union (see Note 8 to our unaudited condensed financial statements included in this Quarterly Report) were paid in foreign currency and converted to U.S. dollars. As a result, factors such as changes in foreign currency exchange rates or weak economic conditions in foreign markets will affect our financial results. Although the impact of currency fluctuations on our financial results has been immaterial to date, there can be no guarantee the impact of currency fluctuations related to our international activities will not be material in the future.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

Management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure. We believe the condensed financial statements included in this Form 10-Q for the quarter ended September 30, 2015 present, in all material respects, our financial position, statements of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the three month period covered by this Quarterly Report on Form 10-Q that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not currently a party to any material legal proceedings that we believe are material to our business, financial condition or results of operations. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

**ITEM 1A. RISK FACTORS**

We operate in a rapidly changing environment that involves a number of risks that could materially and adversely affect our business, financial condition, operating results or cash flows. For a detailed discussion of the risk factors that should be understood by any investor contemplating an investment in our stock, you should carefully consider the factors discussed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 as filed with the Securities and Exchange Commission on March 31, 2015, which is incorporated herein by reference. With the exception of the risk factor below, there have been no other material changes from the risk factors previously disclosed in the Form 10-K.



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**Risks Related to Our Business**

*We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance.*

On September 25, 2015, the Centers for Medicare and Medicaid Services (CMS) announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the draft fee schedule, which would become effective January 1, 2016, AlloMap reimbursement from CMS for patients covered by Medicare would be reduced by 77%. The draft fee schedule is subject to an open comment period through October 26, 2015 and has not yet been adopted as final. If the current proposal is adopted, it could require us to discontinue testing for Medicare patients. Given the significant portion of payments represented by Medicare, the remaining test revenue may be insufficient to sustain our operations. Additionally, some hospitals may reduce the use of AlloMap if it is not available to all patients, and only to non-Medicare recipients.

We are working with industry peers, the medical community, patients, the Coalition for 21st Century Medicine, elected representatives in state and federal government, and other stakeholders during the comment period to ensure that value-based reimbursement at the current price is maintained for AlloMap and other molecular diagnostics tests. However, there is no guarantee that these efforts will be successful. Even if the reimbursement levels are increased from the proposed fee schedule, if they are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. We may also not be able to maintain or increase the portion of our tests reimbursed by Medicare for a variety of other reasons, including changes in reimbursement practices and general policy shifts.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

*Sales of Unregistered Securities*

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The exhibits listed in the Exhibit Index to this Quarterly Report on Form 10-Q are incorporated herein by reference.

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**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.

CAREDX, INC.  
(Registrant)

Date: November 12, 2015

By: /s/ Peter Maag  
Peter Maag  
President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Kenneth E. Ludlum  
Kenneth E. Ludlum  
Chief Financial Officer  
(Principal Accounting and Financial Officer)

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**EXHIBIT INDEX**

Exhibit	
Number	
31.1	Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Periodic Report by Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and 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