CareDx, Inc. Form 10-Q May 14, 2015 Table of Contents

### **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 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

94-3316839 (I.R.S. Employer

incorporation or organization)

**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 x 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 x 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 x (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 x

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

There were 11,837,866 shares of the registrant s Common Stock issued and outstanding as of April 30, 2015.

# CareDx, Inc.

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### PART I. FINANCIAL INFORMATION

# ITEM 1. UNAUDITED CONDENSED FINANCIAL STATEMENTS CareDx, Inc.

### **Condensed Balance Sheets**

(Unaudited)

(In thousands, except share and per share data)

	March 31, 2015		December 31 2014 (Note 2)	
Assets				
Current assets:				
Cash and cash equivalents	\$	38,985	\$	36,431
Accounts receivable		1,794		2,687
Inventory		775		686
Prepaid and other assets		747		542
Total current assets		42,301		40,346
Property and equipment, net		2,174		1,968
Intangible assets, net		6,650		6,650
Goodwill		12,005		12,005
Restricted cash		147		147
Other noncurrent assets				25
Total assets	\$	63,277	\$	61,141
Liabilities and stockholders equity				
Current liabilities:				
Accounts payable	\$	1,371	\$	1,128
Accrued payroll liabilities		1,295		1,684
Accrued and other liabilities		1,810		1,616
Accrued royalties		255		241
Deferred revenue		488		505
Current portion of long-term debt		1,056		5,961
		·		
Total current liabilities		6,275		11,135
Deferred rent, net of current portion		1,619		1,684
Deferred revenue, net of current portion		458		471
Long-term debt, net of current portion		14,609		5,451
Contingent consideration		821		1,074

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Other Liabilities	28	28
Total liabilities	23,810	19,843
Commitments and contingencies (Note 7)		
Stockholders equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at March 31, 2015 and December 31, 2014; 0 shares issued and outstanding at March 31, 2015 and December 31, 2014		
Common stock: \$0.001 par value; 100,133,900 and 100,000,000 shares authorized at March 31, 2015 and December 31, 2014, respectively; 11,816,796 and 11,803,970 shares issued and outstanding at March 31, 2015 and		
December 31, 2014, respectively	12	12
Additional paid-in capital	201,104	200,661
Accumulated deficit	(161,649)	(159,375)
Total stockholders equity	39,467	41,298
Total liabilities and stockholders equity	\$ 63,277	\$ 61,141

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

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### CareDx, Inc.

### **Condensed Statements of Operations**

# (unaudited)

# (In thousands, except share and per share data)

	Three Months Ended Marcl 2015 2014			March 31, 2014
Revenue:				
Testing revenue	\$	7,096	\$	5,834
Collaboration and license revenue		120		90
Total revenue		7,216		5,924
Operating expenses:				
Cost of testing		2,711		2,162
Research and development		1,421		720
Sales and marketing		2,023		1,474
General and administrative		2,705		1,795
Change in estimated fair value of contingent consideration		(253)		
Total operating expenses		8,607		6,151
Loss from operations		(1,391)		(227)
Interest expense, net		(827)		(548)
Other expense, net		(54)		(529)
Net loss	\$	(2,272)	\$	(1,304)
Net loss per share (Note 3):				
Basic and diluted	\$	(0.19)	\$	(1.29)
Shares used to compute net loss per share: Basic and diluted	_1	1 914 467		1 011 000
Dasic and unitied	1	1,814,467		1,011,980

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

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### CareDx, Inc.

### **Condensed Statements of Cash Flows**

# (Unaudited)

# (In thousands)

	Three Months Ended March 31 2015 2014			
Operating activities:				
Net loss	\$	(2,272)	\$	(1,304)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:				
Depreciation and amortization		165		106
Stock-based compensation		280		48
Amortization of deferred revenue		(29)		(17)
Amortization of debt discount and non-cash interest expense		407		153
Revaluation of contingent consideration to estimated fair value		(253)		
Revaluation of warrants to estimated fair value				528
Changes in operating assets and liabilities:				
Accounts receivable		893		177
Inventory		(88)		(207)
Prepaid and other assets		(180)		(1,570)
Accounts payable		242		163
Accrued payroll liabilities		(389)		(560)
Accrued royalties		14		
Accrued and other liabilities		196		2,663
Net cash (used in) provided by operating activities		(1,014)		180
Investing activities:				
Purchase of property and equipment		(364)		(19)
Net cash used in provided by investing activities		(364)		(19)
Financing activities:				
Proceeds from debt, net of issuance costs		15,625		
Proceeds from exercise of stock options		11		4
Principal payments on debt and capital leases		(11,704)		(456)
Net cash provided by (used in) financing activities		3,932		(452)
Net increase (decrease) in cash and cash equivalents		2,554		(291)
Cash and cash equivalents at beginning of period		36,431		5,128
Cash and cash equivalents at end of period	\$	38,985	\$	4,837

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 a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a transplant patient s lifetime. The Company s commercialized testing solution, the AlloMap heart transplant molecular test ( AlloMap ), an FDA-cleared test, is a blood-based test used to monitor 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 \$3.8 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 months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015.

The accompanying 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,

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(v) the fair value of assets and liabilities, (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 determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (xi) any impairment of long-lived assets including in-process technology and goodwill and (xii) legal contingencies. Actual results could differ from those estimates.

#### 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 three months ended March 31, 2015 and 2014, approximately 52%, and 50%, respectively, of testing revenue was derived from Medicare. No other payers represented more than 10% of testing revenue for these periods. At March 31, 2015 and December 31, 2014 approximately 57% and 78%, respectively, of accounts receivable was from Medicare. No other payer represented more than 10% of accounts receivable at March 31, 2015 and December 31, 2014.

#### **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 amount of the convertible preferred stock warrant liability and contingent consideration liability represent their fair values.

### **Testing Revenue**

The Company recognizes revenues 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 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.

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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 months ended March 31, 2015, the Company changed its revenue recognized from two of its payers from a cash basis to an accrual basis based on the Company s consistent history of obtaining reimbursement from these two payers. The impact of this change in accounting estimate is to increase revenues by \$100,000 and to change loss per share from \$0.20 to \$0.19 for the three months ended March 31, 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. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, royalty rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

Goodwill and indefinite-lived intangible assets including acquired in-process technology are reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that goodwill or indefinite-lived intangible assets may be impaired. The Company s goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit s fair value is more likely than not to exceed its carrying value, including goodwill. 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 values. 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. The Company performs its annual evaluation of goodwill during the fourth quarter of each fiscal year. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test.

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.

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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 calculated using the Black-Scholes Model and 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, 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, 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.

### **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. ASU 2014-09 will be effective for the Company beginning in its first quarter of 2017. Early adoption is not permitted. The new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. 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. 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 March 31, 2015 and December 31, 2014 were \$188,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of March 31, 2015 and December 31, 2014 were \$245,000 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.

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#### 3. NET LOSS PER SHARE

Basic and net loss per share has been computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common share equivalents as their effect would have been antidilutive.

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

	Three Months Ended March 31,			
	,	2015		2014
Net loss	\$	(2,272)	\$	(1,304)
Shares used to to compute net loss per common share, basic and diluted	11,814,467		1,	,011,980
Net loss per common share, basic and diluted	\$	(0.19)	\$	(1.29)

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

	Three Months Ended March 31		
	2015	2014	
Shares of common stock subject to outstanding			
options	1,436,429	547,731	
Shares of common stock subject to conversion from			
common stock warrants	576,096	82,190	
Shares of common stock subject to conversion from			
preferred stock		5,160,085	
Shares of common stock subject to conversion from			
preferred stock warrants		541,613	
Total shares of common stock equivalents	2,012,525	6,331,619	

#### 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 on a recurring basis, as of March 31, 2015 and December 31, 2014 (in thousands):

	Fair Va			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	\$ 35,641	\$	\$	\$ 35,641
Liabilities				
Contingent consideration	\$	\$	\$ 821	\$ 821
		Decembe	r 31, 2014	
	Fair Va	lue Measure	d Using	
			, and the second	Total
	Fair Va (Level 1)	lue Measure (Level 2)	d Using (Level 3)	Total Balance
Assets	(Level 1)	(Level 2)	(Level 3)	Balance
Assets Money market funds			, and the second	
	(Level 1)	(Level 2)	(Level 3)	Balance

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):

		Level 3				
	Contingent Consideration Liability	Warrants to Purchase Convertible Preferred Stock	Derivative Liability Related to Subordinated Convertible Note	Total		
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	(253)			(253)		
Balance as of March 31, 2015	\$ 821	\$	\$	\$ 821		

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 March 31, 2015 and December 31, 2014, money market funds were included on the balance sheets in cash and cash equivalents.

Contingent consideration - As of March 31, 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. in conjunction with the Company s acquisition of ImmuMetrix, Inc. (see Note 11). 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 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 March 31, 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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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. The valuation of the warrants used assumptions that 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. A change in estimated fair value of \$528,000 was recognized in other expense, net in the statement of operations for the three months ended March 31, 2014. Upon the Company s IPO in July 2014 certain warrants to purchase convertible preferred stock were converted into warrants to purchase common stock which were reclassified to equity and are no longer subject to remeasurement, while other warrants to purchase convertible 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 in control is an equity call option with a potentially variable value to be received and meets the definition of a derivative which would be 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. As of June 30, 2014 management estimated repayment upon a change in control within the loan term at a 5% probability. The \$239,000 original estimated fair value of the embedded derivative liability was included in accrued and other liabilities. At June 30, 2014, the fair value of the derivative was remeasured to \$120,000, resulting in a gain of \$119,000, which was recorded in other income in the statement of operations for the three months ended June 30, 2014. 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 \$120,000 was recorded in other income. 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 income (expense) 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. INVENTORIES**

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

	rch 31, 015	nber 31, 014
Finished Goods	\$ 323	\$ 277
Raw Materials	452	409
Total Inventory	\$ 775	\$ 686

### 6. ACCRUED AND OTHER LIABILITIES

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

	March 31, 2015		mber 31, 2014
Professional fees	\$	378	\$ 273
Test sample processing fees		348	318
Accrued overpayments and refunds		147	146
Clinical Studies		218	144
Deferred rent current portion		216	202
Capital leases current portion		64	70
Other accrued expenses		439	463
Total accrued and other liabilities	\$	1,810	\$ 1,616

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#### 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 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 March 31, 2015 and 2014, royalty expenses in connection with the Roche agreement were \$255,000 and \$315,000, respectively.

#### **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.

#### 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

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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 months ended March 31, 2015 and 2014, the Company recognized \$0 and \$29,000, 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 \$14,000, respectively. Such revenues are included in collaboration and license revenue on the unaudited condensed statements of operations.

Included in research and development expenses were \$0 and \$29,000 for the three months ended March 31, 2015 and 2014, respectively, for development costs associated with the 2012 Agreement.

#### 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 is expected to occur in late 2014 or early 2015.

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 months ended March 31, 2015 was \$27,000.

#### CardioDx, Inc. (CDX)

In 2005, the Company entered into a services agreement with what at the time was a related party, 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. Two board members of CDX serve on the Company s board of directors and are affiliated with stockholders of the Company. Royalty revenues, recorded when earned, were \$90,000 and \$58,000 for the three months ended March 31, 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 \$90,000 and \$54,000 at March 31, 2015 and December 31, 2014, respectively.

#### **9. DEBT**

On January 30, 2015, the Company entered into a Loan and Security Agreement (the Loan Agreement) with East West Bank (the Lender) 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 pay-off the Company s existing term debt of \$11.3 million. A loss on extinguishment of debt of \$0.6 million costs from the previous loan due to a termination fee and unamortized debt issuance was recognized as interest expense during the three months ended March 31, 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.

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The maturity date of the loan is December 1, 2018. Principal amortization of the loan begins on January 1, 2016 with the loan being payable in 36 equal monthly installments. The principal amortization may be deferred until July 1, 2016 and payable in 30 equal monthly installments, if on December 31, 2015, the Company has achieved certain 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 when 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 March 31, 2015 and December 31, 2014 were \$188,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of March 31, 2015 and December 31, 2014 were \$245,000 and \$11,000, respectively.

In connection with the Loan Agreement, the Company agreed to issue to the Lender 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 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 March 31, 2015, the Company was in compliance with all loan covenants.

#### 10. STOCK INCENTIVE PLANS

#### **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:

	Shares Available for Grant	Stock Options Outstanding	av Ex	ighted- erage ercise Price
Balance December 31, 2014	722,906	1,031,804	\$	7.36
Additional options authorized	357,075			
Granted	(423,548)	423,548		6.58
Exercised		(4,549)		2.42
Forfeited	14,374	(14,374)		9.53
Balance March 31, 2015	670,807	1,436,429	\$	7.12

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Options outstanding and exercisable that have vested or are expected to vest as of March 31, 2015 are as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	471,025	\$ 3.53	6.47	\$ 1,367
Expected to Vest	965,404	8.88	9.37	272
Total	1,436,429			\$ 1,639

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 March 31, 2015 for stock options that were in-the-money. The fair market value of the Company s common stock as of March 31, 2015 was \$5.55 per share.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2015 using the Black-Scholes Model was \$2.76 per share.

#### **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 En	Three Months Ended March 31,		
	2015	2014		
Expected term (in years)	6.0	4.6		
Expected volatility	41.04%	40.68%		
Risk-free interest rate	1.91%	1.55%		
Expected dividend yield				

### **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 three months ended March 31, 2015 is summarized below:

	Weig	Weighted Average Grant-	
	Date Fair		
	<b>Number of Shares</b>	Value	
Unvested balance at December 31, 2014			

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Granted	114,400	\$ 6.49
Vested		
Forfeited	(300)	6.49
Unvested balance at March 31, 2015	114,100	\$ 6.49

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The Company s results of operations include expense relating to employee and nonemployee stock-based payment awards from stock options and RSUs are as follows (in thousands):

	Three Mon	Three Months Ended March 31,	
	2015	2	2014
Cost of testing	\$ 1	4 \$	1
Research and development	4	.9	1
Sales and marketing	1	8	
General and administrative	19	9	46
	\$ 28	0 \$	48

At March 31, 2015, there was approximately \$3.9 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 vesting period of 3.3 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 \$821,000 at March 31, 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.

IMX s post-acquisition results of operations for the three months ending March 31, 2015 are included in the Company s condensed statements 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).

	Ma	Three Months Ended March 31, 2014	
Net revenue	\$	5,924	
Net loss	\$	(1,770)	
Net loss per common share - basic and diluted	\$	(1.75)	

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 three month periods ended March 31, 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 financial

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information reflects: (a) the removal of acquisition-related costs of \$54,000 incurred by both CareDx and IMX for the three months ended March 31, 2014 which were included in general and administrative expenses and b) The addition of \$82,000 in research and development expenses for the three months ended March 31, 2014 which are primarily salaries, benefits and fees for IMX employees and consultants retained after the acquisition.

# 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, expect and the negative and plural forms of the continue, anticipate, intend, could, would, project, plan, 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;

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. 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.

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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 a diagnostic surveillance solution for heart transplant recipients to help clinicians make personalized treatment decisions throughout a patient s lifetime. Our 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 67,000 commercial AlloMap tests, including more than 11,000 tests in 2014, in our Brisbane, California laboratory. In 2014, the test was used in 110 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.

### **Financial Operations Overview**

#### Testing Revenue

Our testing revenue is derived from AlloMap tests, which represented 98% of our total revenues for the three months ended March 31, 2015 and 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 revenues 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 March 31, 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 March 31, 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 3,400 and 3,200, 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, utilities and royalties. Due to the significant fixed costs of testing, cost per test and gross margin are sensitive to changes in test volume. 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

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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. (Roche). In September 2014, we agreed with Roche to a downward adjustment of the royalty rate. As part of this agreement, no further royalties will be payable by us for periods after September 30, 2017. For more information about the Roche royalty payments, see Note 7 to the unaudited condensed financial statements included in this Quarterly Report.

## 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.

## 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.

## 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 is associated with borrowings under our loan agreements.

# Other Expense, Net

For the three months ended March 31, 2014, other expense, 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. For the three months ended March 31, 2015, other expense, net is primarily state franchise taxes.

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## **Results of Operations**

	e Months E 2015	nded	March 31, 2014
Allomap results delivered	3,111		2,793
Revenue:			
Testing revenue	\$ 7,096	\$	5,834
Collaboration and license revenue	120		90
Total revenue	7,216		5,924
Operating expenses:			
Cost of testing	2,711		2,162
Research and development	1,421		720
Sales and marketing	2,023		1,474
General and administrative	2,705		1,795
Change in estimated fair value of contingent			
consideration	(253)		
Total operating expenses	8,607		6,151
Loss from operations	(1,391)		(227)
Interest expense, net	(827)		(548)
Other expense, net	(54)		(529)
-			
Net loss	\$ (2,272)	\$	(1,304)

## Testing Revenue

Testing revenue increased by \$1.2 million, or 22%, for the three months ended March 31, 2015 compared to the same period of 2014. AlloMap test results delivered increased by approximately 320, or 11%, for the three months ended March 31, 2015 as compared to the three months ended March 31, 2014. The increase primarily reflects higher test volume among payers for whom we recognize revenue on an accrual basis of approximately \$1.0 million, including additional Medicare volume of approximately \$0.8 million. The increase in testing revenue also reflects incremental cash collected primarily from Medicaid and other cash payers of approximately \$0.2 million.

## Collaboration and License Revenue

Collaboration and license revenue increased by approximately \$30,000, or 33%, for the three months ended March 31, 2015 compared to the same period in 2014 primarily due to an increase in royalties of \$30,000 from the CardioDx license arrangement.

## Cost of Testing

Cost of testing increased by approximately \$0.5 million, or 24%, for the three months ended March 31, 2015 compared to the same period in 2014. The increase was primarily a result of increased expenditures on laboratory materials of \$320,000 and increased headcount related costs of \$180,000.

## Research and Development

Research and development expenses increased by \$0.7 million, or 98%, for the three months ended March 31, 2015 compared with the same period in 2014. The increase was primarily due to an increase in headcount related expenses of \$0.4 million, increased expenditure of \$0.2 million in the area of cell-free DNA technology and an increase in expenditure of \$0.1 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, particularly with respect to the Circulating Donor-Derived Cell-Free DNA in blood for diagnosing Acute Rejection in Kidney Transplant Recipients (DART) study, as well as clinical outcomes studies for AlloMap and new tests, if and when developed.

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## Sales and Marketing

Sales and marketing expenses increased by approximately \$0.5 million, or 37%, for the three months ended March 31, 2015 compared with the same period in 2014. The increase was primarily related to increased headcount and consulting expenses of \$0.3 million, and an increase of \$0.2 million in marketing programs such as physician forums and speaker programs. 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 \$0.9 million, or 51%, for the three months ended March 31, 2015 compared with the same period of 2014 primarily due to a \$0.4 million increase in employee costs, increased audit fees of \$0.2 million, increased professional and consulting expenses of \$0.2 million, and increased expenses of \$0.2 million associated with being a public company, which were offset in part by decreased recruiting costs of \$0.1 million. 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 which is on the Company s balance sheets as a contingent consideration liability. We revalued the contingent consideration liability at March 31, 2015 and recognized a non-cash gain of \$0.3 million in our condensed statements of operations for the three months ended March 31, 2015 as a result of the decline of our stock price during that period.

## Interest Expense, Net

Interest expense, net increased by \$0.3 million, or 51%, for the three months ended March 31, 2015 compared with the same period of 2014. Interest expense, net in the quarter ended March 31, 2015 includes a loss on extinguishment of debt of \$0.6 million as the Company paid off a term loan in January 2015, interest expense of \$0.3 million incurred before the loans were paid off, partially offset by higher interest expense of \$0.5 million in the quarter ended March 31, 2014 due to the higher effective interest rate on the previous loan.

## Other Expense, Net

Other expense, net for the three months ended March 31, 2015 was \$54,000 as a result of state franchise taxes. For the three months ended March 31, 2014, we recorded other expense, net of \$0.5 million due primarily to a remeasurement loss in the estimated fair value of warrants to purchase shares of our convertible preferred stock of \$0.5 million. 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.

#### Cash Flows for the Three months Ended March 31, 2015 and 2014

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

**Three Months Ended March 31,** 

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(in thousands)	2015	2	2014
Net cash (used in) provided by:			
Operating activities	\$ (1,014)	\$	180
Investing activities	(364)		(19)
Financing activities	3,932		(452)
Net increase (decrease) in cash and cash equivalents	\$ 2,554	\$	(291)

## **Operating Activities**

Net cash provided by or used in operating activities consists of net loss, 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 three months ended March 31, 2015 was \$1.0 million. The net loss of \$2.3 million includes \$0.6 million of net non-cash expenses, which primarily comprised of non-cash interest expenses of \$0.4 million as a result of the non-cash portion of a loss on extinguishment from a previous debt and the issuance costs associated with new debt, stock-based compensation expense of \$0.3 million, and depreciation and amortization of \$0.2 million, which was partially offset by a revaluation gain of \$0.3 million on a contingent

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consideration liability driven by a decrease in our stock price. A decrease in net operating assets of \$0.7 million primarily comprised of a decrease in accounts receivable of \$0.9 million as our reimbursement efforts improved over the fourth quarter of 2014, increases in accounts payable and accrued and other liabilities of \$0.4 million, which was partially offset by a decrease in payroll liabilities of \$0.4 million due to the pay out of employee bonuses, an increase in prepaid expenses and other assets of \$0.2 million primarily due to the prepayment of facilities rent and an increase in inventory of \$0.1 million due to an increase in the price of a key raw material.

Cash provided by operating activities for the three months ended March 31, 2014 was \$0.2 million. The net loss of \$1.3 million includes \$0.8 million of net non-cash expenses, which primarily comprised of a revaluation loss of \$0.5 million on preferred stock warrants driven by an increase in our stock price, accretion of debt discount and other non-cash interest expenses of \$0.2 million, and depreciation and amortization of \$0.1 million. A decrease in net operating assets of \$0.7 million was primarily comprised of a reduction in accounts receivable of \$0.2 million due to the timing of reimbursements, and increases in accounts payable and accrued and other liabilities of \$2.9 million partially offset by an increase in prepaid and other assets of \$1.6 million due to increased costs incurred in anticipation of an IPO, a decrease in accrued payroll liabilities of \$0.6 million due to the pay-out of employee bonuses and an increase in inventory of \$0.2 million due to an increase in testing revenue.

## **Investing Activities**

During the three months ended March 31, 2015, net cash used in investing activities was \$0.4 million for purchases of property and equipment. During the three months ended March 31, 2014, net cash used in investing activities was negligible.

We expect capital expenditures to increase modestly 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 three months ended March 31, 2015, net cash provided by financing activities was \$3.9 million and consisted primarily of \$15.6 million in net proceeds received from a new term loan in January 2015, partially offset by the pay-off of a previous term loan of \$11.3 million and \$0.4 million of payments made on capital leases.

For the three months ended March 31, 2014, net cash used in financing activities was \$0.5 million and consisted primarily of principal payments of \$0.4 million on debt and payments of \$0.1 million on capital lease obligations.

## 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 March 31, 2015, we have received net proceeds of \$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, \$35.3 million in proceeds from debt issuances including, \$5.0 million from a subordinated convertible note and approximately \$139 million from AlloMap testing revenues. As of March 31, 2015, we had cash and cash equivalents of \$39.0 million and \$15.7 million of debt outstanding under our debt and capital lease obligations.

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 three months ended March 31, 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, including the use of cell-free DNA, 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.

In January 2015, we entered into a loan and security agreement with East West Bank 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 in January 2015 and may, at our option borrow the remaining \$4.0 million during the period from July 2015 through December 2015, subject to certain conditions. We used the first advance to pay-off our existing debt of \$11.3 million. The loan will bear interest at a daily floating rate equal to 2.0% 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. In connection with the loan, we issued the lender a warrant to purchase shares of our common stock equal to 1.5% of the amount drawn, divided by the exercise price per share for that tranche. In connection with the initial advance, we issued a warrant to purchase an aggregate of 34,483 shares of our common stock at an exercise price equal to \$6.96 per share.

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 12 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.

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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.

There have been no material changes in our critical accounting policies and estimates during the three months ended March 31, 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 in the three months ended March 31, 2015. The Company accounted for these warrants as equity at fair value on the date the warrants are 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 under US GAAP rules. For the three months ended March 31, 2015 and 2014, 34% and 38%, 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. 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.

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## **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.

## **Contractual Obligations**

During the three months ended March 31, 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%, 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.

## **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 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 when products are transferred to customers. ASU 2014-09 will be effective for us beginning in the first quarter of 2017. Early adoption is not permitted. The new revenue standard may be applied retrospectively to each prior period presented or retrospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating the impact of adopting the new revenue standard on our 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. 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 March 31, 2015 and December 31, 2014 were \$188,000 and \$76,000, respectively. Debt discount and issuance costs, non-current, as of March 31, 2015 and December 31, 2014 were \$245,000 and \$11,000, respectively. There is no impact of ASU 2015-03 on the unaudited condensed statements of operations or in the loss per share calculations.

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# ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK Interest Rate 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 \$39.0 million at March 31, 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 50 basis point change in interest rates, which is approximately a 10% increase in the cost of borrowing, during any of the periods presented would not have had a material impact on our unaudited condensed financial statements.

## Foreign Currency Exchange Risk

All of our revenues are recognized in U.S. dollars. Upfront payments received from the collaboration agreement in the European Union 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 Quarterly Report on Form 10-Q. 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 on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level and are effective to provide reasonable assurance 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.

## **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**

In addition to the information set forth in this Quarterly Report on Form 10-Q and before deciding to invest in, or retain, shares of our common stock, you also should carefully review and consider the information contained in our other reports and periodic filings that we make with the SEC, including, without limitation, the information contained under the caption Part I, Item 1A Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2014. Those risk factors could materially affect our business, financial condition and results of operations. The risks that we describe in our public filings are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we presently deem to be immaterial, also may materially adversely affect our business, financial condition and results of operations.

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There have been no material additions or changes in our risk factors from those previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on March 31, 2015.

# ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS Sales of Unregistered Securities

In connection with entry into a loan agreement, we issued a warrant to purchase an aggregate of 34,483 shares of common stock with an exercise price equal to \$6.96 per share. The foregoing transaction did not involve any underwriters, underwriting discounts or commissions, or any public offering. We believe the offer, sale, and issuance of the above securities were exempt from registration under the Securities Act of 1933, as amended, by virtue of Section 4(a)(2) of the Securities Act of 1933, as amended, as transactions not involving a public offering. The recipient of the securities in each of these transactions represented its intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof. The recipient had adequate access, through its relationship with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

## **Use of Proceeds from Public Offering of Common Stock**

On July 16, 2014, the Registration Statement on Form S-1 (File No. 333-196494) for our initial public offering of our common stock was declared effective by the SEC, pursuant to which we sold 4,000,000 shares of our common stock at a public offering price of \$10.00 per share for an aggregate offering price of approximately \$40.0 million. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 18, 2014 pursuant to Rule 424(b)(4).

## **Issuer Purchases of Equity 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: May 13, 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** 

## **EXHIBIT INDEX**

Number	
10.1(1)	Loan and Security Agreement dated January 30, 2015 between CareDx, Inc. and East West Bank
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

- (1) Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed with the Securities and Exchange Commission on February 4, 2015.
- \* Filed herewith.
- \*\* Furnished herewith.

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