

CareDx, Inc.
Form 10-Q
November 14, 2014
Table of Contents

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

or

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

For the transition period from _____ to _____

Commission file number: 001-36536

CareDx, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	94-3316839 (I.R.S. Employer Identification Number)
3260 Bayshore Boulevard Brisbane, California 94005 (Address of principal executive offices and zip code)	
(415) 287-2300 (Registrant's telephone number, including area code)	
N/A (Former name, former address and former fiscal year, if changed since last report)	

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

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

Edgar Filing: CareDx, Inc. - Form 10-Q

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

There were 11,803,484 shares of the registrant's Common Stock issued and outstanding as of November 11, 2014.

Table of Contents

CareDx, Inc.

TABLE OF CONTENTS

	Page No.
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Condensed Financial Statements (unaudited):</u>	3
<u>Consolidated Condensed Balance Sheets as of September 30, 2014 and December 31, 2013</u>	3
<u>Consolidated Condensed Statements of Operations for the three and nine months ended September 30, 2014 and 2013</u>	4
<u>Consolidated Condensed Statements of Cash Flows for the nine months ended September 30, 2014 and 2013</u>	5
<u>Notes to Consolidated Condensed Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	30
<u>Item 4. Controls and Procedures</u>	30
<u>PART II. OTHER INFORMATION</u>	32
<u>Item 1. Legal Proceedings</u>	32
<u>Item 1A. Risk Factors</u>	32
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
<u>Item 3. Defaults Upon Senior Securities</u>	33
<u>Item 4. Mine Safety Disclosures</u>	33
<u>Item 5. Other Information</u>	33
<u>Item 6. Exhibits</u>	33
<u>Signatures</u>	34
<u>Exhibit Index</u>	35

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

	September 30, 2014 (Unaudited)	December 31, 2013 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 39,048	\$ 5,128
Accounts receivable	1,749	2,270
Inventory	496	518
Prepaid and other assets	718	255
Total current assets	42,011	8,171
Property and equipment, net	2,049	1,553
Intangible assets, net	6,650	
Goodwill	12,005	
Restricted cash	147	147
Other noncurrent assets		2
Total assets	\$ 62,862	\$ 9,873
Liabilities, convertible preferred stock, and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,036	\$ 618
Accrued payroll liabilities	1,403	1,386
Accrued and other liabilities	1,911	1,048
Accrued royalties	297	
Deferred revenue	673	80
Current portion of long-term debt	5,798	4,461
Total current liabilities	11,118	7,593
Accrued royalties		2,804
Deferred rent, net of current portion	1,734	1,885
Deferred revenue, net of current portion	1,004	1,623
Long-term debt, net of current portion	6,930	10,914
Convertible preferred stock warrant liability		525
Contingent consideration	1,037	

Edgar Filing: CareDx, Inc. - Form 10-Q

Total liabilities	21,823	25,344
Commitments and contingencies (Note 7)		
Convertible preferred stock: \$0.001 par value; 0 and 6,417,954 shares authorized at September 30, 2014 and December 31, 2013, respectively; 0 and 5,155,673 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively; liquidation value of \$0 and \$137,221 at September 30, 2014 and December 31, 2013, respectively		135,202
Stockholders' equity (deficit):		
Preferred stock: \$0.001 par value; 10,000,000 and 0 shares authorized at September 30, 2014 and December 31, 2013, respectively; 0 and 0 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively		
Common stock: \$0.001 par value; 100,000,000 and 7,737,226 shares authorized at September 30, 2014 and December 31, 2013, respectively; 11,792,746 and 1,010,711 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	12	1
Additional paid-in capital	200,397	9,482
Accumulated deficit	(159,370)	(160,156)
Total stockholders' equity (deficit)	41,039	(150,673)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 62,862	\$ 9,873

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue:				
Testing revenue	\$ 6,601	\$ 5,714	\$ 19,145	\$ 15,856
Collaboration and license revenue	53	91	209	387
Total revenue	6,654	5,805	19,354	16,243
Operating expenses:				
Cost of testing	1,772	2,502	6,337	6,745
Research and development	1,036	668	2,548	2,516
Sales and marketing	1,753	1,452	4,837	4,569
General and administrative	1,976	1,515	6,087	3,779
Change in estimated fair value of contingent consideration	(1,276)		(1,276)	
Total operating expenses	5,261	6,137	18,533	17,609
Income (loss) from operations	1,393	(332)	821	(1,366)
Interest expense, net	(535)	(497)	(1,727)	(1,603)
Other income (expense), net	355	(1)	192	(11)
Income (loss) before income taxes	1,213	(830)	(714)	(2,980)
Income tax benefit			1,500	
Net income (loss)	\$ 1,213	\$ (830)	\$ 786	\$ (2,980)
Net income (loss) per share (Note 3):				
Basic	\$ 0.13	\$ (0.82)	\$ 0.21	\$ (2.95)
Diluted	\$ 0.12	\$ (0.82)	\$ 0.11	\$ (2.95)
Shares used to compute net income (loss) per share:				
Basic	9,279,649	1,011,136	3,798,559	1,011,001
Diluted	11,219,377	1,011,136	8,298,903	1,011,001

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

4 of 35

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

	Nine Months Ended September 30, 2014 2013	
Operating activities		
Net income (loss)	\$ 786	\$ (2,980)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	354	540
Stock-based compensation	350	57
Amortization of deferred revenue	(26)	(172)
Accretion of debt discount and noncash interest expense	792	407
Change in fair value of warrants	14	
Change in fair value of embedded derivative	(239)	
Change in estimated fair value of contingent consideration	(1,276)	
Non-cash income tax benefit	(1,500)	
Changes in operating assets and liabilities:		
Accounts receivable	521	(341)
Inventory	22	32
Prepaid expenses and other assets	(461)	42
Accounts payable	204	754
Accrued payroll liabilities	17	178
Accrued royalties	(2,507)	920
Deferred revenue		1,083
Accrued and other liabilities	321	(148)
Net cash (used in) provided by operating activities	(2,628)	372
Investing activities		
Payment for acquisitions, net of cash acquired	(406)	
Purchase of property and equipment	(333)	(60)
Net cash used in investing activities	(739)	(60)
Financing activities		
Proceeds from initial public offering, net of underwriters discount	39,246	
Payment of initial public offering costs	(3,716)	
Proceeds from subordinated convertible debt, net of issuance costs	4,982	
Repayment of capital lease obligations	(55)	(45)

Issuance costs in connection with loan modification		(6)
Principal payments on debt	(3,175)	
Proceeds from exercise of stock options	5	
Net cash provided by (used in) financing activities	37,287	(51)
Net increase in cash and cash equivalents	33,920	261
Cash and cash equivalents at beginning of period	5,128	5,830
Cash and cash equivalents at end of period	\$ 39,048	\$ 6,091

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

Table of Contents**CareDx, Inc.****Notes to Unaudited Interim Consolidated 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 for acute cellular rejection in heart transplant recipients. The Company was incorporated in Delaware in December 1998, as Hippocratic Engineering, Inc. In April 1999, the Company changed its name to BioCardia, Inc., in June 2002 to Expression Diagnostics, Inc., in July 2007 to XDx, Inc. and in March 2014 to CareDx, Inc. The Company's operations are based in Brisbane, California and it operates in one segment.

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.

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 and increase the authorized common stock to 10,000,000 shares, after giving effect to the Reverse Stock Split. 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. Effective July 22, 2014, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of \$0.001 per share, and 10,000,000 authorized shares of preferred stock with a par value of \$0.001 per share. 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**Basis of Presentation**

The accompanying unaudited consolidated condensed financial statements include the accounts of CareDx, Inc. and its wholly-owned subsidiary, ImmuMetrix, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation. In September 2014, the Company's wholly-owned subsidiary, ImmuMetrix, Inc., was

merged into CareDx, Inc., and as a result, at September 30, 2014, the financial statements of the former ImmuMetrix, Inc. are included in the financial statements of CareDx, Inc.

The accompanying unaudited consolidated 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 consolidated condensed balance sheet as of December 31, 2013 has been derived from audited financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014.

Table of Contents

The accompanying consolidated 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, 2013 included in the Company's Prospectus filed pursuant to Rule 424(b)(4) on July 18, 2014 with the SEC (the Prospectus).

Use of Estimates

The preparation of 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 financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to (i) revenue recognition, (ii) the differences between amounts billed and estimated receipts from payers, (iii) the determination of the accruals for clinical studies, (iv) the determination of refunds to be requested by third-party payers, (v) the fair value of assets and liabilities, (vi) the valuation of warrants to purchase convertible preferred stock, (vii) the determination of fair value of the Company's common stock, (viii) the contingent consideration in a business acquisition, (ix) the fair value of the embedded derivative 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.

Concentration of Credit Risk

The Company is 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 September 30, 2014 and 2013, 52% and 59%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2014 and 2013, 50% and 55%, respectively, of total revenue was derived from Medicare. No other payer represented more than 10% of testing revenue for these periods. At September 30, 2014, 63% of accounts receivable were from Medicare. No other payer represented more than 10% of accounts receivable at September 30, 2014.

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 the subordinated convertible note equity call option liability (see Note 9) also represent their fair value.

Cash Equivalents

The Company considers all highly liquid investments that are readily convertible into cash having maturities at the time of purchase of three months or less to be cash equivalents. Cash equivalents include money market funds,

obligations of U.S. government agencies, and government-sponsored entities which are carried at fair value.

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

Table of Contents

the fees charged under the arrangement. Such judgments include review of past payment history. AlloMap testing may be considered investigational by some payers and not covered under their reimbursement policies. Others may cover the test, but not pay a set or determinable amount. As a result, in the absence of a reimbursement agreement or sufficient payment history, collectability cannot reasonably be assured so revenue is not recognized at the time the test is delivered.

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

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

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.

The Company recognizes contingent consideration received from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various license and collaboration agreements. The Company did not recognize any milestones during the three months or nine month periods ended September 30, 2014 or 2013.

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.

Table of Contents

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.

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 valuation 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, and 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 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.

Equity instruments granted to nonemployees are valued using the Black-Scholes valuation model and are subject to periodic revaluation over their vesting terms. Nonemployee stock compensation is recognized upon vesting of the stock options which is commensurate with the period over which services are provided.

Impairment

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.

Warrants

At September 30, 2014, the Company had freestanding warrants enabling counterparties to purchase shares of its common stock. Prior to the Company's initial public offering in July 2014, the Company also had freestanding warrants enabling counterparties to purchase shares of its convertible preferred stock. 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 sheets and are 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 income (expense), net on the statements of operations. Prior to the IPO, the Company adjusted the liability for changes in estimated fair value until the earlier of the exercise or expiration of the warrants. Upon the IPO, certain preferred stock warrants were converted into warrants to purchase common stock, and, accordingly, the liability was reclassified to equity, while other warrants expired pursuant to their terms.

Table of Contents

The Company accounts for its warrants to purchase shares of common stock as equity in accordance with the accounting guidance distinguishing liabilities from equity.

Comprehensive Income (Loss)

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

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 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.

3. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share has been computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for common share equivalents.

Diluted net income (loss) per share has been computed by dividing the net income (loss) by the sum of the weighted-average number of common shares and common share equivalents outstanding during the period, to the extent that such common share equivalents are dilutive.

For the three and nine months ended September 30, 2014, certain common share equivalents have been included in diluted net income per share, as their effect is dilutive. For the three and nine months ended September 30, 2014, common share equivalents include: (i) options and warrants to purchase common stock; (ii) options and warrants to purchase convertible preferred stock prior to their conversion into options and warrants to purchase common stock upon the IPO on July 22, 2014; and (iii) convertible preferred stock and the subordinated convertible note prior to their conversion into common stock upon the IPO. Common share equivalents for convertible preferred stock and the subordinated convertible note are determined using the if-converted method. Common share equivalents for options and warrants are determined using the treasury-stock method.

For the three and nine months ended September 30, 2013, all common share equivalents have been excluded from the calculation of diluted net loss per share, as the effect would be antidilutive.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Numerator:				
Net income (loss)	\$ 1,213	\$ (830)	\$ 786	\$ (2,980)
Add: interest expense related to subordinated convertible note	231		364	
Less: gain on change in fair value of derivative related to subordinated convertible note			(118)	
Less: gain on extinguishment of derivative related to subordinated convertible note	(120)		(120)	
Net income (loss) attributable to common stockholders	\$ 1,324	\$ (830)	\$ 912	\$ (2,980)
Denominator:				
Weighted-average shares used to compute basic net income (loss) per share attributable to common stockholders	9,279,649	1,011,136	3,798,559	1,011,001
Effect of potentially dilutive securities:				
Shares of common stock subject to conversion from preferred stock	1,446,313		3,973,622	
Shares of common stock subject to conversion from subordinated convertible note	122,142		179,614	
Shares of common stock subject to outstanding options	371,273		347,108	
Weighted-average shares used to compute diluted net income (loss) per share attributable to common stockholders	11,219,377	1,011,136	8,298,903	1,011,001
Net income (loss) per share attributable to common stockholders:				
Basic	\$ 0.13	(\$ 0.82)	\$ 0.21	(\$ 2.95)
Diluted	\$ 0.12	(\$ 0.82)	\$ 0.11	(\$ 2.95)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Shares of common stock subject to conversion from preferred stock		5,160,085		5,160,085
Shares of common stock subject to outstanding options	514,370	491,259	514,370	491,259
Shares of common stock subject to outstanding warrants	266,586	623,803	266,586	623,803
Total	780,956	6,275,147	780,956	6,275,147

Shares contingently issuable upon the achievement of a future milestone in conjunction with the Company's business combination with ImmuMetrix, Inc. (see Note 11) are not included in the above table due to the uncertainty of the Company achieving this performance metric.

4. FAIR VALUE MEASUREMENTS

The Company's financial instruments are measured and recorded at fair value except for debt, which is recorded at amortized cost. 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.

Table of Contents

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis, as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	\$ 38,964	\$	\$	\$ 38,964
Liabilities				
Contingent consideration	\$	\$	\$ 1,037	\$ 1,037
Total liabilities	\$	\$	\$ 1,037	\$ 1,037

	December 31, 2013			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	\$ 5,204	\$	\$	\$ 5,204
Liabilities				
Warrants to purchase convertible preferred stock	\$	\$	\$ 525	\$ 525
Total liabilities	\$	\$	\$ 525	\$ 525

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

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

Money market funds - Investments in money market funds are classified within Level 1. At September 30, 2014 and December 31, 2013, money market funds were included on the balance sheets in cash and cash equivalents and in restricted cash.

Contingent consideration - As of September 30, 2014, 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 contractual conditions that would result in the payment of the contingent consideration. The fair value of the contingent consideration was estimated using the fair value of the shares to be paid if the contingency is met multiplied by

management's 65% estimate at September 30, 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.

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 statements of operations for the three months ended June 30, 2014. Upon the Company's IPO in July 2014, the fair value of the derivative became \$0, and a gain of \$120,000 was recorded in other

Table of Contents

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.

Warrants to purchase convertible preferred stock At December 31, 2013, the Company's warrants to purchase convertible preferred stock were classified as Level 3 because they were valued based on unobservable inputs and management's judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of such financial instruments. These assumptions are inherently subjective and involve significant management judgment. The significant unobservable input used in the fair value measurement of the warrant liability was the fair value of the underlying convertible preferred stock at the valuation remeasurement date. Generally, increases (decreases) in the fair value of the underlying stock would result in a directionally similar impact to the fair value measurement of the preferred stock warrants. Any change in estimated fair value is recognized in other income or expense on the statements of operations. Upon the Company's IPO in July 2014, certain warrants to purchase convertible preferred stock were converted into warrants to purchase common stock and were reclassified to equity, while other warrants to purchase preferred stock expired pursuant to their terms.

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.

The estimated fair value of the convertible preferred stock warrant liability as of December 31, 2013 was determined using the Black-Scholes option pricing model using the following assumptions:

Estimated fair value of common stock	\$	12.40
Risk-free interest rate		0.8% - 2.1%
Volatility		40% - 45%
Estimated term equal to the remaining contractual term		3.3 - 5.6 years
Expected dividend yield		

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	Warrants	Derivative	
	Consideration	to	Liability	
	Liability	Purchase	Related to	
		Convertible	Subordinated	
		Preferred	Convertible	
		Stock	Note	Total
Balance as of December 31, 2013	\$	\$ 525	\$	\$ 525
Issuance of financial instruments	2,313		239	2,552

Edgar Filing: CareDx, Inc. - Form 10-Q

Change in estimated fair value	(1,276)	14	(239)	(1,501)
Reclassification to stockholders' equity		(539)		(539)
Balance as of September 30, 2014	\$ 1,037	\$	\$	\$ 1,037

13 of 35

Table of Contents**5. INVENTORY**

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

	September 30, 2014	December 31, 2013
Finished goods	\$ 234	\$ 230
Raw materials	262	288
Total inventory	\$ 496	\$ 518

6. ACCRUED AND OTHER LIABILITIES

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

	September 30, 2014	December 31, 2013
Accrued professional fees	\$ 391	\$ 175
Accrued test sample processing fees	260	195
Consideration payable in connection with business combination	194	
Deferred rent – current portion	187	145
Accrued clinical studies	135	84
Accrued overpayments and refunds	98	215
Accrued interest	98	
Capital leases – current portion	79	43
Other accrued expenses	469	191
	\$ 1,911	\$ 1,048

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 income statements in the periods to which the royalties relate.

On September 11, 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. As a result of the Company's

Table of Contents

September 2014 settlement and payment to Roche of \$2.8 million as payment in full of all royalties under the license agreement from July 1, 2011 through June 30, 2014, the Company recorded a reduction of \$566,000 to cost of testing and \$132,000 to interest expense in the statements of operations for the three and nine months ended September 30, 2014. Of the \$2.8 million paid by the Company under the terms of the settlement agreement, \$0.4 million represented royalties on AlloMap revenue for the six months ended December 31, 2011, \$0.9 million represented royalties on AlloMap revenue for the year ended December 31, 2012, \$1.0 million represented royalties on AlloMap revenue for the year ended December 31, 2013, and \$0.5 million represented royalties on AlloMap revenue for the nine months ended September 30, 2014.

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 were terminated by mutual agreement. The agreement provided that CareDx and LabCorp would share equally the costs of developing the lupus flare predictor test; however LabCorp's share of the development cost was subject to certain limits at each stage of the arrangement.

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

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

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

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

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

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

As of September 30, 2014, \$611,000 of the upfront license fee was included in current deferred revenue. That amount, plus the \$500,000 termination fee, will be recognized as collaboration and license revenue upon CareDx's delivery to LabCorp of the clinical samples and clinical data and documentation during the three months ending December 31,

2014.

During the three months ended September 30, 2014 and 2013, the Company recognized \$0 and \$64,000, respectively, in revenue under this arrangement, which consisted of amortization of upfront license fee of \$0 and \$47,000, respectively, and reimbursement of research and development expenses of \$0 and \$17,000, respectively. During the nine months ended September 30, 2014 and 2013, the Company recognized \$31,000 and \$331,000, respectively, in revenue under this arrangement, which consisted of amortization of upfront license fee of \$15,000 and \$172,000, respectively, and reimbursement of research and development expenses of \$16,000 and \$159,000, respectively. Such revenues are included in collaboration and license revenue on the statements of operations.

Included in research and development expenses were \$0 and \$34,000 for the three months ended September 30, 2014 and 2013, respectively, for development costs associated with the 2012 Agreement. Such amounts were \$32,000 and \$318,000 for the nine months ended September 30, 2014 and 2013, respectively.

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.

Table of Contents

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). 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 have not yet begun in the EEA. However, the Company has delivered a small number of AlloMap-related services to DHT. Total revenue recognized from this arrangement through September 30, 2014 is immaterial.

CardioDx, Inc. (CDX)

In 2005, the Company entered into a services agreement with 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. One board member of CDX serves on the Company's board of directors and is affiliated with stockholders of the Company. Royalty revenues, recorded when earned, were \$49,000 and \$27,000 for the three months ended September 30, 2014 and 2013, respectively. Such amounts were \$167,000 and \$57,000 for the nine months ended September 30, 2014 and 2013, respectively. The Company had receivable balances from CDX of \$49,000 and \$37,000 at September 30, 2014 and December 31, 2013, respectively.

9. SUBORDINATED CONVERTIBLE NOTE

On April 17, 2014, the Company issued a \$5.0 million Subordinated Convertible Promissory Note to Illumina, Inc. (the Note) which provides for interest at an annual rate of 8.0%. The Note matures one year following its issuance with principal and unpaid interest due at that time unless the Note is converted into equity prior to the maturity date. As described below, conversion is mandatory in the event of a Qualified Initial Public Offering (as defined in the Note). Upon the closing of the IPO on July 22, 2014, the Note converted into 510,777 shares of common stock in accordance with its terms.

The original estimated fair value of the embedded derivative was accounted for as a debt discount to the subordinated convertible note payable on the consolidated condensed balance sheet. The estimated fair value of the embedded derivative liability was included in accrued and other liabilities on the condensed balance sheets. Amortization of the debt discount was \$51,000 for the period from April 17, 2014 to June 30, 2014, and \$205,000 for the period from July 1, 2014 until July 22, 2014, when the Note was converted into common stock. Extinguishment of the embedded derivative liability at July 22, 2014 resulted in other income of \$120,000 for the three months ended September 30, 2014.

10. STOCK OPTION PLANS

Prior to its IPO, the Company had one active stock option plan, the 2008 Equity Incentive Plan, one assumed stock option plan, the ImmuMetrix 2013 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 will also include an annual increase on the first day of each year beginning in 2014, equal to the least of:

357,075 shares

16 of 35

Table of Contents

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 during the nine months ended September 30, 2014 under the 2014 Equity Incentive Plan, the ImmuMetrix 2013 Equity Incentive Plan and the 2008 Plan and for options that remain outstanding under such plans:

	Nine Months Ended September 30, 2014		
	Shares Available for Grant	Options Outstanding Number of Shares	Weighted- average Exercise Price
Beginning balance	332,995	466,965	\$ 1.99
Increase in shares reserved for issuance	940,884		\$
Granted	(530,570)	530,570	\$ 12.10
Assumed in business combination		23,229	\$ 2.06
Exercised		(3,038)	\$ 2.04
Forfeited	18,983	(18,983)	\$ 10.31
Expired	12,638	(12,638)	\$ 2.85
Ending balance	774,930	986,105	\$ 7.41

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2014 using the Black-Scholes valuation model was \$5.07 per share.

Options outstanding and exercisable that have vested or are expected to vest as of September 30, 2014 are as follows:

	Number of Shares	Weighted- average Exercise Price	Weighted- average Remaining Contractual Life(Years)	Aggregate Intrinsic Value(in thousands)
Vested	389,976	\$ 2.69	6.17	\$ 1,775
Expected to vest	596,129	\$ 10.51	9.31	\$ 593
Total	986,105	\$ 7.41	8.07	\$ 2,368

In the table above, aggregate intrinsic value represents the difference between the exercise price and the \$7.00 price per share of the Company's common stock as of September 30, 2014.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Cost of testing	\$ 6	\$ 1	\$ 15	\$ 3
Research and development	35	2	57	6
Sales and marketing	13		22	2
General and administrative	111	16	256	46
	\$ 165	\$ 19	\$ 350	\$ 57

Table of Contents**Valuation Assumptions**

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

	Three Months Ended		Nine Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Risk-free interest rate	2.05%	1.72%	1.76%	1.09%
Volatility	43.81%	45.03%	42.30%	45.37%
Expected term, in years	6.0	6.0	5.3	6.0
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

At September 30, 2014, there was approximately \$2.3 million of total unrecognized stock-based compensation, net of estimated forfeitures, related to nonvested employee stock option awards granted that will be recognized on a straight-line basis over the remaining vesting period of 3.1 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 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 and at June 30, 2014, and \$1.0 million at September 30, 2014.

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 period from June 11, 2014 through September 30, 2014 are included in the Company's consolidated 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).

	Nine Months Ended September 30,	
	2014	2013
Net revenue	\$ 19,354	\$ 16,243
Net income (loss)	\$ (1,075)	\$ (2,904)
Net income (loss) per common share - basic	\$ (0.28)	\$ (2.87)
Net income (loss) per common share - diluted	\$ (0.28)	\$ (2.87)

The unaudited pro forma consolidated financial information was prepared using the acquisition method of accounting and is based on the historical financial information of the Company and IMX, reflecting the Company's and IMX's results of operations for the nine month periods ended September 30, 2014 and 2013. The historical financial information has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable and (iii) expected to have a continuing impact on the combined results. The unaudited pro forma consolidated financial information reflects: (a) the removal of acquisition-related costs of \$1.7 million incurred by both CareDx and IMX for the nine months ended September 30, 2014 including the removal of \$0.2 million of IMX stock-based compensation expense that resulted from modifications to options in anticipation of the acquisition; (b) the removal of a \$1.5 million tax benefit for the nine months ended September 30, 2014 that resulted from the acquisition; (c) the addition of salaries, benefits and fees for IMX employees and consultants retained after the acquisition; and (d) the addition of the \$1.5 million acquisition-related tax benefit for the nine months ended September 30, 2013, as if the acquisition had occurred on January 1, 2013 and the benefit had been recognized during the nine months ended September 30, 2013. Acquisition related expenses are primarily included in general and administrative expenses.

Table of Contents

12. DEBT

In August 2012, the Company entered into a \$15,000,000 loan and security agreement. In August 2013, the Company amended the loan to defer the beginning of principal repayment for six months, to March 1, 2014. To obtain this deferral, there was an additional fee of \$150,000 due at the end of the loan term. The loan, as amended, provides for interest-only payments for 18 months through February 28, 2014 followed by 30 equal monthly principal and interest payments of \$566,822 at an annual interest rate of 9.95%. In addition, a final payment of \$1,275,000 will be due at the end of the loan term. The loan also included a facility fee of \$75,000.

In connection with the loan, the Company issued to the lenders warrants to purchase 167,181 shares of Series G convertible preferred stock at \$21.78 per share. The warrants are exercisable until 2019. Upon the Company's IPO on July 22, 2014, the warrants became warrants to purchase common stock.

The loan is collateralized by a security interest in all of the Company's assets except intellectual property on which there is a negative pledge, and the loan agreement contains covenants, including a revenue covenant, and restrictions on the Company's ability to pay cash dividends. At September 30, 2014 and December 31, 2013, the Company was in compliance with all loan covenants.

13. INCOME TAXES

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

Table of Contents

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 consolidated 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 final prospectus filed with the Securities and Exchange Commission on July 18, 2014, which we refer to as the Prospectus.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words believe, may, will, potentially, estimate, continue, anticipate, intend, could, would, project, plan, expect and the negative and plural forms of the similar expressions are intended to identify forward-looking statements.

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

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

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

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

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

our compliance with federal, state and foreign regulatory requirements;

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

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

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 the Prospectus and elsewhere in this Quarterly Report. 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.

Table of Contents

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 product, the AlloMap heart transplant molecular test, is a blood-based test used to monitor heart transplant recipients for 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 immunosuppressant drug therapy. We believe that there is a significant unmet need for post-transplant surveillance solutions and are applying our expertise in molecular diagnostics and transplantation towards the development of additional solutions for other organ transplant recipients, including recipients of heart and kidney transplant patients.

Since the launch of AlloMap in January 2005, we have performed approximately 61,000 commercial AlloMap tests, including approximately 9,000 tests during the nine months ended September 30, 2014 in our Brisbane, California laboratory.

On June 10, 2014, we acquired ImmuMetrix, Inc. for 888,135 shares of our Series G preferred stock, assumed stock options that will be exercisable for 23,229 shares of Series G preferred stock and \$600,000 in cash. All such shares of Series G preferred stock and options to acquire Series G preferred stock converted into common stock and options to acquire common stock immediately prior to the closing of our initial public offering. ImmuMetrix was a privately held development-stage company working on cfDNA-based solutions in transplantation and other fields. Through this acquisition, we added to our existing know-how, expertise and intellectual property in applying cfDNA technology to the surveillance of transplant recipients. The intellectual property rights of ImmuMetrix include an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using cfDNA. In connection with this acquisition, we entered into a consulting agreement with ImmuMetrix founder and Stanford University professor Dr. Stephen Quake.

The agreement pursuant to which we acquired ImmuMetrix provides that if we complete 2,500 commercial tests involving the measurement of cfDNA in organ transplant recipients within six years of the acquisition closing date, we will issue an additional 227,845 shares of our common stock to the former stockholders of ImmuMetrix. Such shares will be issuable whether or not ImmuMetrix technology is included in such commercial tests. cfDNA tests performed without charge in parallel with a commercialized test will be considered commercial tests for this purpose.

On July 22, 2014, we completed our initial public offering (IPO) of 4,000,000 shares of our common stock. In August 2014, the underwriters partially exercised their overallotment option, at which time we sold an additional 220,000 shares. We received net cash proceeds of \$35.5 million from the IPO, net of underwriting discounts and commissions and expenses paid by us.

Financial Operations Overview

Testing Revenue

Our revenue is primarily derived from AlloMap tests, which represented 99% and 98% of our total revenue for the three months ended September 30, 2014 and 2013, respectively, and 99% and 98% of our total revenue for the nine months ended September 30, 2014 and 2013, respectively. This 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 AlloMap are generally not responsible for the payment of these services. We generally bill third-party payers upon delivery of an AlloMap score report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients. As of September 30, 2014, 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.

Table of Contents***Collaboration and License Revenue***

Revenue from our collaboration and license agreements was less than 3% of total revenue for each period presented. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Our performance obligations under the collaboration and license agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated periods of performance on a prospective basis.

Cost of Testing

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

Royalties included in cost of testing are associated with a license from Roche Molecular Systems, Inc., or Roche. In February 2014, we received a demand for arbitration from Roche regarding our claim that the royalty rate being assessed under the Roche license should be reduced. In September 2014, we entered into an agreement with Roche to settle the dispute. See Legal Proceedings included elsewhere in this Quarterly Report for more information about the settlement.

We expect cost of testing to increase, in absolute dollars, as the number of tests we perform increases. However, due to the fixed nature of expenses associated with direct labor, equipment and infrastructure, we expect the cost per test will decrease over time as volume increases.

Research and Development Expenses

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

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. We have infrastructure in place to cover most of the key transplant centers in the United States both for offerings of our existing AlloMap product as well as future products. We may increase our product range and our geographic reach in the future which would lead to an expansion of our sales and marketing efforts.

Table of Contents

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 Estimated 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 income.

Interest Expense, Net

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

Other Income (Expense), Net

Other income (expense), net is primarily associated with the remeasurement of the estimated fair value of warrants to purchase shares of our convertible preferred stock and changes in the estimated fair value of a derivative associated with our subordinated convertible debt. Convertible preferred warrants and the subordinated convertible debt were converted to common stock warrants and common stock, respectively, upon the closing of our initial public offering on July 22, 2014.

Table of Contents**Results of Operations**

	Three Months Ended September 30,	
	2014	2013
Allomap results delivered	3,000	2,600
Revenue:		
Testing revenue	\$ 6,601	\$ 5,714
Collaboration and license revenue	53	91
Total revenue	6,654	5,805
Operating expenses:		
Cost of testing	1,772	2,502
Research and development	1,036	668
Sales and marketing	1,753	1,452
General and administrative	1,976	1,515
Change in estimated fair value of contingent consideration	(1,276)	
Total operating expenses	5,261	6,137
Income (loss) from operations	1,393	(332)
Interest expense, net	(535)	(497)
Other income (expense), net	355	(1)
Net income (loss)	\$ 1,213	\$ (830)

Testing Revenue

AlloMap test results delivered increased by approximately 400 or 15% for the three months ended September 30, 2014 as compared to the three months ended September 30, 2013. Testing revenue increased by \$0.9 million, or 16%, for the three months ended September 30, 2014 compared to the same period of 2013. The increase primarily reflects higher test volume among payers for whom we recognize revenue on an accrual basis of approximately \$0.8 million, including additional Medicare volume of approximately \$0.3 million. The increase in testing revenue also reflects incremental cash collected primarily from Medicaid and other cash payers of approximately \$0.1 million

Collaboration and License Revenue

Collaboration and license revenue decreased by approximately \$38,000, or 42%, for the three months ended September 30, 2014 compared to the same period in 2013 primarily due to decreased activity associated with our LabCorp collaboration, partially offset by an increase in royalties from CardioDx.

Cost of Testing

Cost of testing decreased by approximately \$0.7 million, or 29%, for the three months ended September 30, 2014 compared to the same period in 2013. The decrease was primarily a result of a royalty settlement with Roche. As a result, upon our September 2014 settlement with Roche, we recorded a one-time reduction of \$0.6 million to cost of testing for the three and nine month periods ended September 30, 2014. We expect to see our cost of testing increase in absolute dollars as we expect test volumes to increase in the future.

Research and Development

Research and development expenses increased by \$0.4 million, or 55%, for the three months ended September 30, 2014 compared with the same period in 2013. The increase was primarily related to costs associated with our cell-free DNA research and development, such as employee costs, consulting and other outside costs, materials and supplies and related overhead. 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 and new tests, if and when developed.

Sales and Marketing

Sales and marketing expenses increased by approximately \$0.3 million, or 21%, for the three months ended September 30, 2014 compared with the same period in 2013. The increase was primarily related to increased travel costs, advertising, market research, headcount and consulting expenses incurred in the three months ended September 30, 2014. We expect sales and marketing expenses to increase modestly in the future, until such time as we have an additional marketed product.

Table of Contents*General and Administrative*

General and administrative expenses increased by approximately \$0.5 million, or 30%, for the three months ended September 30, 2014 compared with the same period of 2013 primarily due to a \$0.3 million increase in employee costs, including an increase in stock-based compensation expense of \$0.1 million, increased recruiting and corporate events expenses of \$0.2 million, and increased consulting expenses of \$0.1 million, offset in part by decreased legal expenses of \$0.1 million. We anticipate our general and administrative expenses will increase as we operate as a public company.

Interest Expense, Net

Interest expense, net was largely flat for the three months ended September 30, 2014 compared with the same period of 2013. Interest expense, net was impacted in the quarter ended September 30, 2014 by our settlement with Roche, which resulted in a one-time reduction in interest expense of \$0.1 million, and by the conversion of our Illumina subordinated convertible note upon our IPO in July 2014, resulting in the amortization of the remaining debt discount to interest expense of approximately \$0.2 million.

Other Income (Expense), Net

We recorded other income, net of \$0.4 million for the three months ended September 30, 2014, compared to a negligible amount of other expense, net for the same period of 2013. This increase was due to our remeasurement of the estimated fair value of warrants to purchase shares of our convertible preferred stock of \$0.3 million, and \$0.1 million associated with the derivative bifurcated from our Illumina debt. Upon our July 2014 IPO, certain warrants became warrants for common stock and the then fair value of such warrants was reclassified to additional paid-in capital.

Comparison of the Nine Months Ended September 30, 2014 and 2013

	Nine Months Ended September 30,	
	2014	2013
Allomap results delivered	8,800	7,300
Revenue:		
Testing revenue	\$ 19,145	\$ 15,856
Collaboration and license revenue	209	387
Total revenue	19,354	16,243
Operating expenses:		
Cost of testing	6,337	6,745
Research and development	2,548	2,516
Sales and marketing	4,837	4,569
General and administrative	6,087	3,779
Change in estimated fair value of contingent consideration	(1,276)	
Total operating expenses	18,533	17,609

Edgar Filing: CareDx, Inc. - Form 10-Q

Income (loss) from operations	821	(1,366)
Interest expense, net	(1,727)	(1,603)
Other income (expense), net	192	(11)
Income (loss) before income taxes	(714)	(2,980)
Income tax benefit	1,500	
Net income (loss)	\$ 786	\$ (2,980)

25 of 35

Table of Contents

Testing Revenue

AlloMap test results delivered increased by approximately 1,500 or 21% for the nine months ended September 30, 2014 as compared to the nine months ended September 30, 2013. Testing revenue increased by \$3.3 million or 21% for the nine months ended September 30, 2014 compared to the same period in 2013 primarily due to increased volume of tests delivered to payers for whom we recognize revenue on an accrual basis of approximately \$1.9, including additional Medicare volume of \$1.1 million and additional cash collections of approximately \$1.4 million.

Collaboration and License Revenue

Collaboration and license revenue decreased by approximately \$0.2 million, or 46%, for the nine months ended September 30, 2014 compared to the same period in 2013 primarily due to decreased activities with LabCorp of approximately \$0.3 million, partially offset by increased royalties from CardioDx.

Cost of Testing

Cost of testing decreased by approximately \$0.4 million, or 6% for the nine months ended September 30, 2014 compared to the same period in 2013 primarily due to a royalty settlement with Roche, which resulted in a one-time reduction to royalty expense for the nine months ended September 30, 2014 of approximately \$0.6 million. The decrease was partially offset by increased volume and related variable and overhead costs.

Research and Development

Research and development expenses were largely flat for the nine months ended September 30, 2014 compared to the same period in 2013.

Sales and Marketing

Sales and marketing expenses increased by approximately \$0.3 million, or 6%, for the nine months ended September 30, 2014 compared to the same period in 2013. The increase primarily reflects increased travel and conference expenses.

General and Administrative

General and administrative expenses increased approximately \$2.3 million, or 61%, for the nine months ended September 30, 2014 compared with the same period in 2013, primarily due to increased employee costs of \$0.6 million, including stock based compensation expenses of \$0.2 million, increased tax, audit and professional fees of \$0.5 million as a result of our acquisition of ImmuMetrix and growth of the business, \$0.4 million of increased consulting fees, increased legal costs of \$0.3 million largely as a result of our acquisition of ImmuMetrix and arbitration with Roche, and \$0.3 million associated with recruiting and corporate events.

Interest Expense, Net

Interest expense, net increased by approximately \$0.1 million, or 8%, for the nine months ended September 30, 2014 compared with the same period of 2013 primarily due to interest of approximately \$0.4 million associated with the \$5.0 million Illumina subordinated convertible note issued in April 2014 with an interest rate of 8%. Additionally, interest expense, net for the nine months ended September 30, 2014 reflects a one-time reduction in interest expense of approximately \$0.1 million due to the Roche settlement, and a \$0.1 million decrease in interest under our debt

obligations due to principal payments.

Other Income (Expense), Net

Other income, net was \$0.2 million for the nine months ended September 30, 2014, compared to negligible other expense, net for the same period of 2013. The other income, net for the nine months ended September 30, 2014 was primarily due to \$0.2 million of other income as a result of remeasurement of the derivative associated with the Illumina subordinated convertible note. The subordinated convertible note was converted to common stock in July 2014, in connection with our IPO.

Income Tax Benefit

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

Table of Contents***Cash Flows for the Nine Months Ended September 30, 2014 and 2013***

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

(in thousands)	September 30, 2014 2013 (unaudited)	
Net cash provided by (used in):		
Operating activities	\$ (2,628)	\$ 372
Investing activities	(739)	(60)
Financing activities	37,287	(51)
Net increase (decrease) in cash and cash equivalents	\$ 33,920	\$ 261

Operating Activities

Net cash provided by or used in operating activities consists of net income or 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 nine months ended September 30, 2014 was \$2.6 million. The net income of \$0.8 million reflects a non-cash income tax benefit of \$1.5 million, a decrease in the estimated fair value of a contingent consideration liability of \$1.3 million and a decrease in the estimated fair value of an embedded derivative of \$0.2 million, offset in part by an increase in debt discount accretion and other non-cash interest expense of \$0.8 million, depreciation and amortization of \$0.4 million and stock-based compensation expense of \$0.4 million. An increase in net operating assets of \$1.9 million was primarily comprised of a decrease in accrued royalties of \$2.5 million and an increase in prepaid expenses and other assets of \$0.5 million, offset in part by a decrease in accounts receivable of \$0.5 million and an increase in accrued and other liabilities of \$0.3 million. The decrease in accrued royalties was the result of a \$2.8 million payment of past due royalties to Roche in September 2014 upon settlement of a dispute (for more information, see Note 7 to unaudited interim consolidated condensed financial statements elsewhere in this Quarterly Report). The increase in prepaid expenses and other assets was primarily due to our purchase of a directors and officers insurance policy when we became a public company in July 2014.

Cash provided by operating activities for the nine months ended September 30, 2013 was \$0.4 million. The net loss of \$3.0 million reflects \$0.8 million of net non-cash expenses, which were primarily comprised of depreciation and amortization of \$0.5 million and accretion of debt discount and other non-cash interest expense of \$0.4 million, offset in part by the amortization of deferred revenue of \$0.2 million. A decrease in net operating assets of \$2.5 million was primarily comprised of increases in deferred revenue of \$1.1 million, accrued royalties of \$0.9 million and accounts payable of \$0.8 million, offset in part by an increase in accounts receivable of \$0.3 million. The increase in deferred revenue was primarily due to prepayments received from DHT in connection with a distribution and licensing agreement (for more information, see Note 8 to unaudited interim consolidated condensed financial statements elsewhere in this Quarterly Report). The increase in accrued royalties was due to non-payment of royalties to Roche, pending settlement of a dispute (for more information, see Note 7 to unaudited interim consolidated condensed financial statements elsewhere in this Quarterly Report).

Investing Activities

During the nine months ended September 30, 2014 we used \$0.7 million in investing activities, which was primarily comprised of \$0.4 million paid for our acquisition of ImmuMetrix and \$0.3 million paid to purchase property and equipment. During the nine months ended September 30, 2013, 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 nine months ended September 30, 2014, net cash provided by financing activities was \$37.3 million and consisted primarily of \$35.5 million of proceeds from our July 2014 initial public offering, net of underwriters discounts and issuance costs, and \$5.0 million of net proceeds from our April 2014 issuance of a subordinated convertible note, partially offset by principal payments on debt and capital leases of \$3.2 million.

For the nine months ended September 30, 2013, net cash used in financing activities was negligible and primarily consisted of principal payments on capital lease obligations.

Table of Contents

Liquidity and Funding Requirements

Since our inception, substantially all of our operations have been financed through the issuance of our convertible preferred stock, the issuance of stock in our July 2014 initial public offering, the incurrence of debt, and cash received from AlloMap testing revenues. Through September 30, 2014, 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, \$15.0 million in proceeds from a venture debt loan and approximately \$125 million from AlloMap testing revenues. As of September 30, 2014, we had cash and cash equivalents of \$39.0 million and \$12.9 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 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 transplant, 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 acquisition or investment.

In April 2014, we issued a \$5.0 million subordinated convertible note to Illumina, Inc., which provided for interest at an annual rate of 8.0%. Conversion was mandatory in the event of a qualified initial public offering, and the note converted into shares of our common stock upon our IPO in July 2014 at a conversion price of \$10.00 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 18 months. We cannot be certain that any of our development of new transplant surveillance solutions will be successful or that we will be able to raise sufficient additional funds, if necessary, to see these programs through to a successful result.

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these 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 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 significant and material changes in our critical accounting policies during the three months ended September 30, 2014, 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 Prospectus filed with the SEC on July 18, 2014.

Factors Affecting Our Performance

The Number of AlloMap Tests We Receive and Report

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

How We Recognize Revenue

Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allows us to recognize the related revenue on an accrual basis. For the three months ended September 30, 2014 and 2013, 35% and 38%,

Table of Contents

respectively, of our revenue was recognized when cash was received. For the nine months ended September 30, 2014 and 2013, 37% and 36%, respectively, of our revenue was recognized when cash was received. Until we achieve our revenue recognition criteria for a larger number of payers, we will continue to recognize a large portion of our revenue when cash is received. Because we often need to appeal prior to being paid for certain tests, it can take over a year for a test to result in revenue being recorded, and for a portion of our tests, we may never realize revenue.

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

Continued Adoption of and Reimbursement for AlloMap

Our reimbursement rate has steadily increased over time since the launch of AlloMap, as payers adopt coverage policies and fewer payers consider AlloMap as experimental and investigational. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. As of September 30, 2014, we had been reimbursed for approximately 79% of AlloMap results delivered in the twelve months ended March 31, 2014. Reimbursement performance is reviewed using a lagging metric of six months as any period less than this is considered not to be reflective of future performance, as the reimbursement process can take six months or more to complete depending on the payer. Revenue growth depends on our ability to achieve broader reimbursement from third party payers, to expand the number of tests per patient and the base of ordering physicians.

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 September 30, 2014, there was a material decrease in our contractual obligations and commitments due to our settlement with Roche. For more information, see Part II, Item I, Legal Proceedings in this Quarterly Report.

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.

Table of Contents**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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of \$39.0 million at September 30, 2014, which consist of bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

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

ITEM 4. CONTROLS AND PROCEDURES**Evaluation of Disclosure Controls and Procedures**

Management, including our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), as of the end of the period covered by this report. Based upon the evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Prior to our initial public offering in July 2014, we were a private company with limited accounting personnel and other resources with which to address our internal controls and procedures. In reviewing our preliminary purchase accounting and supporting analyses related to our pending acquisition of ImmuMetrix, Inc., we identified a material weakness in our internal control over financial reporting. The material weakness related to our internal controls over financial reporting pertaining to complex accounting in connection with a business combination. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. The material weakness involved aspects of our proposed purchase accounting for our ImmuMetrix acquisition that required adjustment, including adjustments to valuation primarily relating to in-process technology, deferred income tax liability related to acquired in-process technology and goodwill.

We are in the process of implementing measures designed to remediate our system of internal control over financial reporting. We hired a new Chief Financial Officer, added an experienced finance executive to our audit committee and subsequent to September 30, 2014 have hired a corporate controller who possesses experience preparing periodic reports under the Securities Exchange Act. While we believe that our efforts will be sufficient to remediate the material weakness and prevent further internal control deficiencies, we cannot assure you that our remediation efforts will be successful.

Table of Contents

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 is reasonably likely to materially affect, our internal control over financial reporting.

31 of 35

Table of Contents**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

In November 2004, we entered into a license agreement with Roche Molecular Systems, Inc., or Roche, that grants us 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 the claims in multiple Roche patents. We 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, we 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 we had materially breached the Roche license agreement by failing to report and pay royalties owing to Roche in respect of the licensed services performed by us after July 1, 2014. Since July 1, 2011, we fully reserved the amount of these unpaid royalties on our balance sheets, and the amount of these unpaid royalties has been reflected as an expense in our income statements in the periods to which the royalties relate.

In September 2014, we entered into a settlement and mutual release agreement with Roche whereby (i) for the period beginning July 1, 2011 through June 30, 2014, we 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, we 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, we agreed to a downward adjustment of the combination services percentage used to determine the portion of the AlloMap service that is royalty bearing under the terms of the license; (iv) we agreed to report and pay quarterly royalties within 45 days of the end of each calendar quarter; (v) Roche agreed that, subject to our timely payment of all applicable royalties through such date, no further royalties will be payable by us for periods after September 30, 2017; (v) mutual releases by the Company and Roche of all claims under the license agreement through the settlement date; and (vi) dismissal of 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.

We incur royalty expense under the license agreement with Roche that are based on a percentage of test revenues and are recorded as a component of cost of testing in the statements of operations. Since July 1, 2011, we have fully accrued the amount of unpaid royalties and related interest claimed by Roche on our balance sheets, and the amount of these unpaid royalties and related interest has been reflected as an expense in our income statements in the periods to which the royalties relate. As a result of our September 2014 settlement and payment to Roche of \$2.8 million as payment in full of all royalties under the license agreement from July 1, 2011 through June 30, 2014, we recorded a reduction of \$566,000 to cost of testing and \$132,000 to interest expense in the statements of operations for the three and nine months ended September 30, 2014. Of the \$2.8 million paid by us under the terms of the settlement agreement, \$0.4 million represented royalties on AlloMap revenue for the six months ended December 31, 2011, \$0.9 million represented royalties on AlloMap revenue for the year ended December 31, 2012, \$1.0 million represented royalties on AlloMap revenue for the year ended December 31, 2013, and \$0.5 million represented royalties on AlloMap revenue for the nine months ended September 30, 2014.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves a number of risks that could materially and adversely affect our business, financial condition, prospectus, operating results or cash flows. For a detailed discussion of the risk factors that should be understood by any investor contemplating an investment in our stock, you should carefully

consider the factors discussed in the section entitled **Risk Factors** in the Prospectus, which are incorporated herein by reference. There have been no material changes from the risk factors previously disclosed in the Prospectus.

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

Sales of Unregistered Securities

None.

Use of Proceeds from the Sale of Registered Securities

On July 16, 2014, our registration statement on Form S-1 (File No. 333-196494) relating to the initial public offering of our common stock was declared effective by the SEC. The IPO closed on July 22, 2014, at which time we sold 4,000,000 shares,

Table of Contents

and on August 13, 2014 the underwriters partially exercised their overallotment option, at which time we sold an additional 220,000 shares. We received net cash proceeds of \$35.5 million from the IPO, including the subsequent partial overallotment exercise, net of underwriting discounts and commissions and expenses paid by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of our equity securities, or to their associates, or to our affiliates. Piper Jaffray and Leerink Partners acted as joint book-running managers and Raymond James and Mizuho Securities acted as co-managers for the offering.

We hold the proceeds received from our initial public offering as cash, cash equivalents and marketable securities and intend to continue to invest the funds in short-term marketable securities, including U.S. government, government agency and corporate debt securities. There has been no material change in the planned use of proceeds from our initial public offering as described in our Prospectus filed with the U.S. Securities and Exchange Commission on July 18, 2014 pursuant to Rule 424(b).

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.

Table of Contents

SIGNATURES

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

CAREDX, INC.
(Registrant)

Date: November 14, 2014

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

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

34 of 35

Table of Contents**EXHIBIT INDEX**

Exhibit	
Number	Exhibit Description
10.14.1*	Settlement Agreement and Mutual Release dated September 11, 2014 between CareDx, Inc. and Roche Molecular Systems, Inc.
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

* Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and filed separately with the Securities and Exchange Commission.