

CareDx, Inc.
Form 10-Q
May 16, 2016

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 March 31, 2016

or

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

For the transition period from _____ to _____

Commission file number: 001-36536

CAREDX, INC.

(Exact name of registrant as specified in its charter)

Delaware 94-3316839
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification Number)

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

3260 Bayshore Boulevard

Brisbane, California 94005

(Address of principal executive offices and zip code)

(415) 287-2300

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer Accelerated filer

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

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

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

There were 13,960,762 shares of the registrant's Common Stock issued and outstanding as of April 29, 2016.

CareDx, Inc.

TABLE OF CONTENTS

	Page No.
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Unaudited Condensed Financial Statements</u>	3
<u>Condensed Balance Sheets as of March 31, 2016 and December 31, 2015</u>	3
<u>Condensed Statements of Operations for the Three Months Ended March 31, 2016 and 2015</u>	4
<u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2016 and 2015</u>	5
<u>Notes to Unaudited Condensed Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>Item 4. Controls and Procedures</u>	34
 <u>PART II. OTHER INFORMATION</u>	 34
<u>Item 1. Legal Proceedings</u>	34
<u>Item 1A. Risk Factors</u>	34
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
<u>Item 3. Defaults Upon Senior Securities</u>	38
<u>Item 4. Mine Safety Disclosures</u>	38
<u>Item 5. Other Information</u>	38
<u>Item 6. Exhibits</u>	38
<u>Signatures</u>	39
<u>Exhibit Index</u>	40

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED FINANCIAL STATEMENTS

CareDx, Inc.

Condensed Balance Sheets

(Unaudited)

(In thousands, except share and per share data)

	March 31, 2016	December 31, 2015 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	\$23,752	\$29,888
Accounts receivable	2,512	2,367
Inventory	595	766
Prepaid and other assets	807	1,341
Total current assets	27,666	34,362
Property and equipment, net	2,346	2,425
Intangible assets, net	6,650	6,650
Goodwill	12,005	12,005
Restricted cash	147	147
Other noncurrent assets	20	49
Total assets	\$48,834	\$55,638
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$2,536	\$1,644
Accrued payroll liabilities	1,609	2,366
Accrued and other liabilities	5,298	2,892
Accrued royalties	232	242
Deferred revenue	137	142
Current portion of long-term debt	4,419	2,866
Total current liabilities	14,231	10,152
Deferred rent, net of current portion	1,347	1,426
Deferred revenue, net of current portion	693	703
Long-term debt, net of current portion	11,368	12,887
Contingent consideration	735	948
Other liabilities	—	28
Total liabilities	28,374	26,144
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at March 31, 2016	—	—
and December 31, 2015; no shares issued and outstanding at March 31, 2016 and		

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

December 31, 2015

Common stock: \$0.001 par value; 100,000,000 shares authorized at March 31, 2016

and December 31, 2015; 11,977,491 shares and 11,902,363 shares issued and

outstanding at March 31, 2016 and December 31, 2015, respectively	12	12
Additional paid-in capital	203,284	202,564
Accumulated deficit	(182,836)	(173,082)
Total stockholders' equity	20,460	29,494
Total liabilities and stockholders' equity	\$48,834	\$55,638

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

CareDx, Inc.

Condensed Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2016	2015
Revenue:		
Testing revenue	\$6,452	\$7,096
Collaboration, license and other revenue	110	120
Total revenue	6,562	7,216
Operating expenses:		
Cost of testing	2,772	2,711
Research and development	3,159	1,421
Sales and marketing	1,737	2,023
General and administrative	5,676	2,705
Change in estimated fair value of contingent consideration	(213)	(253)
Total operating expenses	13,131	8,607
Loss from operations	(6,569)	(1,391)
Interest expense	(266)	(827)
Other (expense) income, net	(2,917)	(54)
Net loss	\$(9,752)	\$(2,272)
Net loss per share (Note 3):		
Basic and diluted	\$(0.81)	\$(0.19)
Weighted average shares used to compute net loss per share:		
Basic and diluted	11,969,714	11,814,467

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

CareDx, Inc.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Operating activities:		
Net loss	\$(9,752)	\$(2,272)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	261	165
Stock-based compensation	446	280
Amortization of deferred revenue	(16)	(29)
Amortization of debt discount and noncash interest expense	41	407
Revaluation of contingent consideration to estimated fair value	(213)	(253)
Changes in operating assets and liabilities:		
Accounts receivable	(145)	893
Inventory	171	(88)
Prepaid and other assets	563	(180)
Accounts payable	820	242
Accrued payroll liabilities	(758)	(389)
Accrued royalties	(10)	14
Accrued and other liabilities	2,400	196
Net cash used in operating activities	(6,192)	(1,014)
Investing activities:		
Purchase of property and equipment	(109)	(364)
Net cash used in investing activities	(109)	(364)
Financing activities:		
Proceeds from debt, net of issuance costs	—	15,625
Proceeds from issuances of common stock under employee stock purchase plan	175	—
Principal payments on debt and capital lease obligations	(16)	(11,704)
Proceeds from exercise of stock options	6	11
Net cash provided by financing activities	165	3,932
Net (decrease) increase in cash and cash equivalents	(6,136)	2,554
Cash and cash equivalents at beginning of period	29,888	36,431
Cash and cash equivalents at end of period	\$23,752	\$38,985

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

CareDx, Inc.

Notes to Unaudited Condensed Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc., (“CareDx” or the “Company”) is a molecular diagnostics company focused on discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant patients. The Company’s first commercialized testing solution, the AlloMap heart transplant molecular test (“AlloMap”), an FDA-cleared test, is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate/severe acute cellular rejection. The Company is pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, its next-generation sequencing-based test to detect donor-derived cell-free DNA, or dd-cfDNA, after transplantation.

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.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of \$182.8 million at March 31, 2016. As of March 31, 2016, the Company had cash and cash equivalents of \$23.8 million, and \$15.9 million of debt outstanding under its debt and capital lease obligations, net of debt discount and issuance costs.

On April 14, 2016, the Company acquired 98.3% of the outstanding common stock of Allenex AB (“Allenex”). Allenex is a transplant diagnostic company based in Stockholm, Sweden that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Allenex has 58 employees. Under the terms of the Conditional Share Purchase Agreements entered into on December 16, 2015, as amended and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the purchase consideration is expected to total approximately \$35.0 million, consisting of \$27.8 million of cash, of which approximately \$6.2 million is deferred purchase consideration and payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB (collectively, the “Majority Shareholders”) no later than March 31, 2017, and the issuance of 1,375,029 shares of the Company’s common stock valued at \$7.2 million. Additionally, \$8.0 million of cash purchase consideration payable to the Majority Shareholders of Allenex is being held in escrow by the Company and relates to a commitment by the Majority Shareholders of Allenex to purchase the Company’s equity securities in a future financing (“Subsequent Financing”). The equity securities are expected to be sold no later than 30 days following the receipt of certain Company stockholder approvals required pursuant to the rules of the NASDAQ Stock Market (the “Requisite Stockholder Approval”), which is expected to occur on June 16, 2016, on terms, including price, substantially equivalent to the terms of a Private Placement described below. The Company intends to initiate compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. See Note 11 for more detail about the Allenex acquisition.

On April 14, 2016, the Company completed the sale of 591,860 units (“Units”) to certain accredited investors (the “Private Placement”) at a purchase price of \$23.94 per Unit. On closing on April 14, 2016, the aggregate gross proceeds to the Company from the Private Placement were approximately \$14.1 million. Concurrently, the Company also entered into commitment letters (the “Commitment Letters”) pursuant to which the Majority Shareholders of Allenex agreed to purchase the Company’s equity securities in a Subsequent Financing, as described above. If the Subsequent Financing is not completed within 30 days of the Requisite Stockholder Approval, and provided that the Loan Agreement (as defined in Note 9) is still in place, the Lender (as defined in Note 9) has the right to require that the Company complete the Subsequent Financing and issue securities to the Majority Shareholders in exchange for the \$8.0 million of cash held in escrow. If neither the Company nor the Lender exercise their rights by September 30, 2016, the \$8.0 million held in escrow will be released to the Majority Shareholders without any further obligation on the part of the Majority Shareholders of Allenex. The Company made payments of approximately \$1.1 million and \$97,000 in placement fees and other offering expenses, respectively, to placement agents in connection with the sale of the 591,860 Units in the Private Placement. Following the closing of the Private Placement, the Company agreed to a number of requirements such as submitting the Private Placement to the Company’s stockholders for approval, which is expected to be approved after the receipt of the Requisite Stockholder Approval expected on June 16, 2016, granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3 within 45 days of closing. Additionally, if the Company fails to file an effective registration statement on Form S-3 within 45 days of closing the Private Placement, the Company shall be obligated to pay an aggregate penalty amount equal to approximately \$0.3 million for each month that the Company has not filed the required registration statement, up to a maximum of \$1.4 million. See Note 11 for more detail about the Private Placement.

The Company will require additional financing and/or refinancing to fund working capital, repay debt and to pay its obligations. A potential working capital benefit of refinancing the Company's existing debt obligations is deferral of debt payments otherwise due in 2016. The Company may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities.

Absent the receipt of additional funding or refinancing, the Company will exhaust its cash and cash equivalents in December 2016 unless the Company substantially reduces its costs and operations, including research and development activities, marketing activities and programs, and other general and administrative expenses. As a result of the Company's obligations and lack of immediately available financial resources, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt about the Company's ability to continue as a going concern. If the Company is unsuccessful in its efforts to raise outside financing, or refinance certain of its current obligations in the near term, the Company will be required to significantly reduce or cease operations.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern through December 31, 2016, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), and follow the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The condensed balance sheet as of December 31, 2015 has been derived from audited financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three months ended March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

The accompanying unaudited condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K filed on March 29, 2016 with the SEC.

Use of Estimates

The preparation of unaudited condensed financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the unaudited condensed financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to (i) revenue recognition, (ii) the differences between amounts billed and estimated receipts from payers, (iii) the determination of the accruals for clinical studies, (iv) the determination of refunds to be requested by third-party

payers, (v) the fair value of assets and liabilities, (vi) the valuation of warrants to purchase common stock, (vii) the fair value of contingent consideration in a business acquisition, (viii) the fair value of embedded derivatives, (ix) measurement of stock-based compensation expense, (x) the determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (xi) any impairment of long-lived assets including in-process technology and goodwill and (xii) legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

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

The Company is also subject to credit risk from its accounts receivable which are derived from revenue earned from AlloMap tests provided for patients located in the U.S. and billed to various third-party payers. The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the three months ended March 31, 2016 and 2015, approximately 47%, and 52%, respectively, of testing revenue was derived from Medicare. No other payers represented more than 10% of testing revenue for these periods. At March 31, 2016, Medicare, Aetna and Humana accounted for approximately 30%, 21% and 11% of accounts receivable, respectively. At December 31, 2015, Medicare and Aetna accounted for approximately 35% and 21% of accounts receivable, respectively. No other payers represented more than 10% of accounts receivable at March 31, 2016 and December 31, 2015.

Cash Equivalents

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

Purchased Intangible Assets

Acquired intangible assets with indefinite useful lives are related to in-process research and development or IPR&D, projects and are measured at their respective fair values as of the acquisition date. The Company does not amortize intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

The Company tests IPR&D for impairment on an annual basis and in between annual tests if it becomes aware of events or changes that would indicate that it is more likely than not that the fair value of the assets is below their carrying amounts. The IPR&D annual impairment test is performed as of December 1 of each fiscal year. If the fair value exceeds the carrying value, then there is no impairment. 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. The Company has not identified any such impairment losses to date.

Impairment of Long-lived Assets

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

Goodwill

Goodwill represents the excess of the cost of an acquisition over the sum of the amounts assigned to tangible and identifiable intangible assets acquired, less liabilities assumed. Goodwill is not subject to amortization, but is tested for impairment on an annual basis and whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable.

The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of diagnostic products. In the event that the Company determines that it is more likely than not that the carrying value of the reporting unit is higher than its fair value, quantitative testing is performed comparing recorded values to estimated fair values. If impairment is present, it is measured as the excess of recorded goodwill over its implied fair value. The Company performs its annual evaluation of goodwill on December 1 of each fiscal year. There have been no impairments recorded to date.

Fair Value of Financial Instruments

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

The carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value due to their short maturities.

Testing Revenue

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

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

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

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

During the three months ended March 31, 2016, the Company changed its revenue recognized from one of its payers from the cash basis to the accrual basis based on its consistent history of obtaining timely reimbursement from this payer. The impact of this change in accounting estimate was insignificant to revenues and loss per share for the three months ended March 31, 2016. During the three months ended March 31, 2015, the Company changed its revenue recognized from two of its payers from the cash basis to the accrual basis based on the Company's consistent history of obtaining timely reimbursement from these two payers. The impact of this change in accounting estimate was to increase revenues by \$0.1 million and to change loss per share from \$0.20 to \$0.19 for the three months ended March 31, 2015.

Collaboration, License and Other 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 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 ended March 31, 2016 and 2015.

9

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

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.

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 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 its own historical stock prices and stock prices of peer companies in the diagnostics industry, risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected option lives, and dividend yield based on the Company's expectations and historical data.

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

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

Warrants

The Company had freestanding warrants enabling counterparties to purchase shares of its convertible preferred stock as of December 31, 2013, which were converted to purchase common stock on the Company's IPO date.

Freestanding warrants for convertible preferred stock that were contingently redeemable were classified as liabilities on the balance sheet and recorded at their estimated fair value. These warrants were remeasured at each balance sheet date and any change in estimated fair value was recognized in other expense on the condensed statements of operations.

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

Comprehensive Loss

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

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). This guidance requires the Company to evaluate whether there are conditions and events that raise substantial doubt about its ability to continue as a going concern within one year after the financial statements are issued, and if there is substantial doubt about the Company's ability to continue as a going concern, the disclosure of such is required. The Company is required to make this evaluation for both annual and interim reporting periods, if applicable. The Company also is required to evaluate and disclose whether its plans alleviate that doubt. This guidance is effective for the annual periods ending after December 15, 2016, and annual and interim periods thereafter. Early adoption is permitted. The Company is currently assessing the impact of this guidance on its condensed financial statements.

In April 2015, the FASB issued ASU 2015-05, Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350-40). This updated standard provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. The Company adopted this guidance as of January 1, 2016 as required using the prospective method. There have been no new or existing arrangements that were materially modified following the adoption date.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred income taxes by requiring deferred tax assets and liabilities be classified as noncurrent on the balance sheet. The guidance is effective for the Company beginning January 1, 2017 with early adoption permitted as of the beginning of any interim or annual reporting period, and it may be applied either (1) prospectively to all deferred tax assets and liabilities or (2) retrospectively to all periods presented. If an entity applies the guidance prospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and a statement that prior periods were not retrospectively adjusted. If an entity applies the guidance retrospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and quantitative information about the effects of the accounting change on prior periods. The Company adopted this guidance early as of January 1, 2016 prospectively, which required its deferred tax assets and liabilities to be reclassified from other current assets and liabilities to their respective noncurrent categories on its condensed balance sheets. However, as of March 31, 2016, all of the Company's net deferred tax assets and liabilities were subject to a full valuation allowance, and therefore, no reclassifications were required. The adoption of this guidance did not result

in any impact on the Company's condensed financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases, which, for operating leases, requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. This guidance will be effective for the Company in fiscal year 2019 and must be adopted using a modified retrospective transition approach. Early adoption is permitted. The Company is currently assessing the impact of this guidance.

In March 2016, the FASB issued ASU 2016-06, Derivatives and Hedging: Contingent Put and Call Options in Debt Instruments, to clarify when a contingent put or call option to accelerate the repayment of debt is an embedded derivative. The guidance is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this guidance is on a modified retrospective basis. The Company is currently assessing the impact of this guidance on its condensed financial statements.

In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606):

Principal versus Agent Considerations (Reporting Revenue Gross versus Net). These amendments provide additional clarification and implementation guidance on the previously issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which 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. The amendments in ASU 2016-10 provide clarifying guidance on materiality of performance obligations; evaluating distinct performance obligations; treatment of shipping and handling costs; and determining whether an entity's promise to grant a license provides a customer with either a right to use an entity's intellectual property or a right to access an entity's intellectual property. The amendments in ASU 2016-08 clarify how an entity should identify the specified good or service for the principal versus agent evaluation and how it should apply the control principle to certain types of arrangements. The adoption of ASU 2016-10 and ASU 2016-08 is to coincide with an entity's adoption of ASU 2014-09, which the Company intends to adopt for interim and annual reporting periods beginning after December 15, 2017, as required. The guidance may be applied (1) retrospectively to each prior period presented or (2) retrospectively with the cumulative effect recognized as of the date of adoption. The Company is currently evaluating the impact that this guidance will have on its condensed financial statements.

3. NET LOSS PER SHARE

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

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

	Three Months Ended March 31,	
	2016	2015
Numerator:		
Net loss	\$(9,752)	\$(2,272)
Denominator:		
Weighted-average shares used to compute basic and diluted		
net loss per share	11,969,714	11,814,467
Net loss per share:		
Basic and diluted	\$(0.81)	\$(0.19)

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

	Three Months Ended March 31,	
	2016	2015
Shares of common stock subject to outstanding options	1,860,420	1,436,429
Shares of common stock subject to outstanding common		
stock warrants	301,069	576,096
Restricted stock units	178,975	—
Total common stock equivalents	2,340,464	2,012,525

4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value except for its debt, which is recorded at amortized cost. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The accounting guidance for fair value provides a framework for measuring fair value,

clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.
- Level 2: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	March 31, 2016			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Money market funds	\$21,564	\$ —	\$ —	\$21,564
Liabilities				
Contingent consideration	\$—	\$ —	\$ 735	\$735

	December 31, 2015			
	Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Money market funds	\$28,774	\$ —	\$ —	\$28,774
Liabilities				
Contingent consideration	\$—	\$ —	\$ 948	\$948

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

	(Level 3) Contingent Consideration Liability
Balance as of December 31, 2014	\$ 1,074
Change in estimated fair value	(126)
Balance as of December 31, 2015	948
Change in estimated fair value	(213)
Balance as of March 31, 2016	\$ 735

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

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

- Money market funds - Investments in money market funds are classified within Level 1. At March 31, 2016 and December 31, 2015, money market funds were included on the balance sheets in cash and cash equivalents.
- Contingent consideration - As of March 31, 2016 and December 31, 2015, the Company had a contingent obligation to issue 227,845 shares of its common stock to the former owners of ImmuMetrix, Inc. ("IMX") in conjunction with its acquisition of IMX in June 2014. The issuance will occur if the Company completes 2,500 commercial tests involving the measurement of dd-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 March 31, 2016 and December 31, 2015 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 item captioned "change in estimated fair value of contingent consideration" 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. The carrying amount of the contingent consideration liability represents its fair value.

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 carrying values of the Company's debt approximate their fair values at March 31, 2016 and December 31, 2015 as the market rates currently available to the Company and other assumptions have not changed significantly since the debt was issued.

5. INVENTORIES

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

	March 31,	December 31,
	2016	2015
Finished goods	\$ 247	\$ 237
Raw materials	348	529
Total inventory	\$ 595	\$ 766

6. ACCRUED AND OTHER LIABILITIES

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

	March 31,	December 31,
	2016	2015
Debt financing fees	\$1,687	\$ —
Transaction related fees	674	589
Tax, audit and compliance related fees	286	89
Test sample processing fees	451	426
Accrued overpayments and refunds	212	163
Clinical studies	999	756
Deferred rent – current portion	272	258
Capital leases – current portion	63	71
Other accrued expenses	654	540
Total accrued and other liabilities	\$5,298	\$ 2,892

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 had been reflected as an expense in the Company's statements of operations in the periods revenue was recorded to which the royalties relate.

In September 2014, the Company entered into a settlement and mutual release agreement with Roche whereby: (i) for the period beginning July 1, 2011 through June 30, 2014, the Company agreed to pay the amount of \$2,827,220 in settlement of past royalties due; (ii) for the period beginning July 1, 2014 through September 30, 2014, the Company agreed to pay royalties based on the same combination services percentage used to determine the past royalties due; (iii) for the period beginning October 1, 2014 through September 30, 2017, Roche and the Company agreed to a downward adjustment of the combination services percentage used to determine the portion of the AlloMap testing revenue that is royalty bearing under the terms of the license; (iv) the Company agreed to report and pay quarterly royalties within 45 days of the end of each calendar quarter; (v) Roche agreed that, subject to the Company's timely payment of all applicable royalties through such date, no further royalties will be payable by the Company for periods after September 30, 2017; (vi) the Company and Roche agreed to mutually release all claims under the license agreement through the settlement date; and (vii) Roche agreed to dismiss the arbitration claims. For all time periods, the contractual royalty rate in the license agreement was or will be applied to the applicable combination services percentage to determine the royalties payable for the AlloMap service.

Under the license agreement, the Company incurs royalty expenses as a percentage of combination services revenue and classifies those expenses as a component of cost of testing in the statements of operations. For the three months ended March 31, 2016 and 2015, royalty expenses in connection with the Roche agreement were \$0.2 million and \$0.3 million, respectively.

Contingencies

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

8. COLLABORATION AND LICENSING AGREEMENTS

Diaxonhit ("DHT")

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

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

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

Commercial sales began in the EEA in June 2014. Total revenues recognized from this arrangement for the three months ended March 31, 2016 and 2015 were \$15,000 and \$27,000, respectively.

CardioDx, Inc. ("CDX")

In 2005, the Company entered into a services agreement with what at the time was a related party, CDX, whereby the Company provided CDX with biological samples and related data and performed laboratory services on behalf of CDX. Each company granted the other a worldwide license under certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company of a low single-digit percentage of the cash collected from sales of CDX licensed products. In 2009, CDX terminated the services portion of this agreement, however, the royalty obligation from CDX continues until the tenth anniversary of the first commercial sale of a CDX licensed product. The first commercial sale of such product by CDX occurred in 2009, therefore the royalty obligation to the Company

continues until 2019. Royalty revenues were recognized when earned. Starting the fourth quarter of 2015, royalty revenues are recognized when payments are received as it was assessed that collection was not reasonably assured prior to receipt of payment. Royalty revenues were \$96,000 and \$90,000 for the three months ended March 31, 2016 and 2015, respectively, and are included in collaboration and license revenue on the condensed statements of operations. The Company had no receivable balance from CDX at March 31, 2016, and a receivable balance of \$90,000 at March 31, 2015.

9. DEBT

On January 30, 2015, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with East West Bank ("the Lender") that provides a secured term loan facility in an aggregate principal amount of up to \$20.0 million. The Company borrowed the first and only advance of \$16.0 million ("Draw A") on January 30, 2015. Draw A was used to pay-off the Company's existing term debt of \$11.3 million. A loss on extinguishment of debt of \$0.6 million related to costs from the pay-off of the previously existing term loan was recognized as interest expense during the three months ended March 31, 2015. Draw A bears interest at a daily floating rate equal to 2.00%, plus the greater of (i) 3.25% or (ii) the prime rate published by the lender. The maturity date of the loan is December 1, 2018. The principal pay-down of the loan begins on July 1, 2016 with the loan being payable in 30 equal monthly installments.

A fully non-refundable commitment fee of \$160,000 was paid on January 30, 2015 when Draw A for \$16.0 million was received. The loan has no prepayment penalty. Commitment fees are included in debt issuance costs which are netted against the debt outstanding and are amortized to interest expense using the effective interest method over the term of the loan. Debt discount and issuance costs, current, as of March 31, 2016 and December 31, 2015 were \$0.1 million and \$0.2 million, respectively. Debt discount and issuance costs, non-current, as of both March 31, 2016 and December 31, 2015 were \$0.1 million.

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

The Loan Agreement requires collateral by a security interest in all of the Company's assets except intellectual property and contains customary affirmative and negative covenants including financial maintenance covenants, and also includes standard events of default, including payment defaults. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. As of February 29, 2016, the Company was in violation of one of its financial covenants under the Loan Agreement. This violation was waived in principal by virtue of a contemporaneous verbal amendment to the Loan Agreement received from the Lender, which was subsequently memorialized in a written amendment to the Loan Agreement dated May 12, 2016. As of March 31, 2016, the Company was in compliance with its debt covenants.

In April 2016, the Lender consented to the acquisition of Allenex by the Company, which occurred on April 14, 2016. The consent was contingent upon the closing of a Private Placement for aggregate cash proceeds of at least \$12.0 million and separately depositing into escrow cash of \$8.0 million that relates to a commitment by the Majority Shareholders of Allenex to purchase the Company's equity securities in a Subsequent Financing, all of which occurred on April 14, 2016. The Lender also requires the Company to subsequently raise another \$20.0 million through equity financing by March 31, 2017, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders of Allenex.

10. STOCK INCENTIVE PLANS

Stock Option Plans

Prior to its IPO, the Company had one active stock option plan, the 2008 Equity Incentive Plan ("2008 Plan"), one assumed stock option plan ("the ImmuMetrix 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 also includes an annual increase on the first day of each year equal to the lesser of:

- 357,075 shares
- 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding year; or
- such other number of shares as the Company’s board of directors may determine.

17

The following table summarizes option activity and related information:

	Shares Available for Grant	Shares Underlying Stock Outstanding	Weighted-Average Exercise Price
Balance—December 31, 2015	510,892	1,577,317	\$ 6.87
Additional options authorized	357,075	—	—
Granted	(371,970)	371,970	5.14
Exercised	—	(1,823)	3.11
Forfeited	86,888	(86,888)	6.08
Expired	156	(156)	5.00
Balance—March 31, 2016	583,041	1,860,420	6.56

Options outstanding that have vested or are expected to vest as of March 31, 2016 are as follows:

	Number of Shares Issued	Weighted Average Exercise Price	Weighted Average Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	844,288	\$ 6.03	6.79	\$ 1,219
Expected to vest	1,016,132	7.00	9.06	141
Total	1,860,420	6.56	8.03	\$ 1,360

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at March 31, 2016 for stock options that were in-the-money. The fair market value of the Company's common stock as of March 31, 2016 was \$4.96 per share.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2016 and 2015 using the Black-Scholes Model was \$2.07 per share and \$2.76 per share, respectively.

As of March 31, 2016, there was approximately \$2.6 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to non-vested stock options that will be recognized on a straight-line basis over the remaining average vesting period of 2.72 years.

2014 Employee Stock Purchase Plan

The Company's board of directors adopted its 2014 Employee Stock Purchase Plan ("the ESPP") in March 2014 and its stockholders approved the ESPP in July 2014. However, the Company's ESPP was not made available to its employees until January 1, 2015. The first offering period in 2016 began on January 1, 2016 and will end on June 30, 2016. There have not been any ESPP shares purchased under this offering period at March 31, 2016. Under the second offering period in 2015 that ended on December 31, 2015, 32,232 shares were purchased for aggregate proceeds of \$0.2 million from the issuance of shares, which occurred on January 4, 2016.

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

Valuation Assumptions

The estimated fair values of employee stock options and ESPP shares were estimated using the Black-Scholes option-pricing model based on the following weighted-average assumptions:

	Three Months Ended March 31, 2016		2015	
Employee stock options				
Expected term (in years)	6.0		6.0	
Expected volatility	39.60 – 39.69%		41.04 %	
Risk-free interest rate	1.54 – 1.65%		1.91 %	
Expected dividend yield	— %		— %	
Employee stock purchase plan				
Expected term (in years)	0.5		0.5	
Expected volatility	64.21 %		34.08 %	
Risk-free interest rate	0.49 %		0.11 %	
Expected dividend yield	— %		— %	

Restricted Stock Units

The Company's 2014 Plan allows restricted stock units ("RSUs") to be granted in addition to stock options. The RSUs vest annually over four years in equal increments. The Company began granting RSUs starting March 2015.

Unvested RSU activity for the three months ended March 31, 2016 is summarized below:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested balance—December 31, 2015	106,200	\$ 6.49
Granted	111,900	5.12
Vested	(26,550)	6.49
Forfeited	(12,575)	5.42
Unvested balance—March 31, 2016	178,975	5.71

As of March 31, 2016, there was approximately \$0.9 million of unrecognized stock-based compensation expense, net of estimated forfeitures, related to non-vested RSUs that will be recognized on a straight-line basis over the remaining average vesting period of 3.33 years.

Stock-based Compensation Expense

The following table summarizes stock-based compensation expense relating to employee and nonemployee stock options, RSUs, and ESPP shares for the three months ended March 31, 2016 and 2015, included in the statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Cost of testing	\$28	\$14
Research and development	113	49
Sales and marketing	28	18
General and administrative	277	199
Total	\$446	\$280

No tax benefit was recognized related to share-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of stock-based compensation were capitalized for the periods presented.

11. SUBSEQUENT EVENTS

Completion of Allenex Acquisition

On April 14, 2016, the Company acquired 98.3% of the outstanding common stock of Allenex. Allenex is a transplant diagnostic company based in Stockholm, Sweden that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Allenex has 58 employees. Under the terms of the Conditional Share Purchase Agreements entered into on December 16, 2015, as amended and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the purchase consideration is expected to total approximately \$35.0 million, consisting of \$27.8 million of cash, of which approximately \$6.2 million is deferred purchase consideration payable to the Majority Shareholders no later than March 31, 2017, and the issuance of 1,375,029 shares of the Company's common stock valued at \$7.2 million. Additionally, \$8.0 million of cash purchase consideration payable to the Majority Shareholders of Allenex is being held in escrow by the Company and relates to a commitment by the Majority Shareholders of Allenex to purchase the Company's equity securities in a Subsequent Financing. The equity securities are expected to be sold no later than 30 days following the receipt of the Requisite Stockholder Approval, which is expected to occur on June 16, 2016, on terms, including price, substantially equivalent to the terms of a Private Placement described below. The Company intends to initiate compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. In connection therewith, the Company subsequently intends to initiate a delisting of Allenex from Nasdaq Stockholm.

As of April 11, 2016, the Company reassessed the probability of the completion of a six-month bridge loan of \$18.0 million with Oberland Capital SA Davos LLC and determined that it was not probable that the bridge loan would be consummated. The Company is currently disputing the fees associated with the bridge loan with Oberland Capital SA Davos LLC, but in the interim the Company has recorded a charge of \$2.9 million in the three months ended March 31, 2016 to expense financing costs associated with this bridge loan. These costs have been included as a component of other (expense) income, net on the Company's condensed statements of operations.

The cash portion of the acquisition purchase price was paid from the Company's general working capital. The acquisition required and the Company obtained a consent from the Lender. The consent was contingent upon the Company closing a Private Placement for aggregate proceeds of at least \$12.0 million and separately depositing into escrow cash of \$8.0 million that relates to a commitment by the Majority Shareholders of Allenex to purchase the Company's equity securities in a Subsequent Financing as described above, all of which occurred on April 14, 2016. The Lender also requires the Company to subsequently raise another \$20.0 million through equity financing by March 31, 2017, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders of Allenex. As of February 29, 2016, the Company was in violation of one of its financial covenants under the Loan Agreement. This violation was waived in principal by virtue of a contemporaneous verbal amendment to the Loan Agreement received from the Lender, which was subsequently memorialized in a written amendment to the Loan Agreement dated May 12, 2016. As of March 31, 2016, the Company was in compliance with its debt covenants.

The acquisition of Allenex will be accounted for and reported as a business combination during the second quarter of 2016. The Company is in the process of determining the total purchase price and allocation thereof, however, it is impracticable to make any other disclosures related to this acquisition at this time.

Private Placement

On April 14, 2016, the Company completed a Private Placement transaction for the offering of 591,860 Units. Each Unit is comprised of: (i) one share of Common Stock, (ii) five shares of Series A Mandatorily Convertible Preferred Stock ("Series A Preferred"), and (iii) three warrants, each to purchase one share of Common Stock. The purchase price was \$23.94 per Unit (the equivalent of \$3.99 per share of Common Stock, assuming conversion of the Series A

Preferred). The closing of the Private Placement was conditioned upon the closing of the Allenex acquisition, the consent of East West Bank to the Allenex acquisition, and certain other customary closing conditions, all of which occurred on April 14, 2016. The aggregate proceeds to the Company from the Private Placement were approximately \$14.1 million, of which \$1.4 million was paid for payment of placement agents, escrow agents and legal fees.

On April 13, 2016, the Company filed a Certificate of Designation that established the rights and preferences of the Series A Preferred. Each share of Series A Preferred is mandatorily convertible into Common Stock upon the Company's receipt of the Requisite Stockholder Approval. Subject to obtaining the Requisite Stockholder Approval, each share of Series A Preferred is initially convertible into one share of Common Stock, subject to certain adjustments. The Series A Preferred are not entitled to receive dividends and are not redeemable at the election of the Company. Series A Preferred could be required to be redeemed upon a deemed liquidation event, as defined, at \$3.99 per share, or if the Company is unable to issue share certificates without sale restriction legend in certain circumstances, at amounts at which the holder purchases the Company's shares required to satisfy its sale obligations. Except as required by the Delaware General Corporation Law, the Series A Preferred do not have voting rights and will not be included in determining the number of shares voting or entitled to vote on any matter of the Company.

Each warrant is exercisable for a period of seven years to purchase one share of Common Stock at an initial exercise price of \$4.98 per share, subject to certain adjustments. The Company also issued warrants to purchase an aggregate of 200,000 shares of Common Stock to certain of its placement agents (“Placement Agent Warrants”). Each Placement Agent Warrant is exercisable for a period of five years to purchase one share of Common Stock at an initial exercise price of \$3.99 per share, subject to certain adjustments. Pursuant to the terms of the warrants, the holder of the warrant cannot exercise the warrant until the Company has obtained the Requisite Stockholder Approval. The warrants are expected to be recorded as a liability and be subject to ongoing remeasurement.

Concurrently, the Company also entered into Commitment Letters pursuant to which the Majority Shareholders of Allenex agreed to purchase the Company’s equity securities in a Subsequent Financing as described above. If the Subsequent Financing is not completed within 30 days of the Requisite Stockholder Approval, and provided that the Loan Agreement is still in place, the Lender has the right to require that the Company complete the Subsequent Financing and issue securities to the Majority Shareholders in exchange for the \$8.0 million of cash held in escrow. If neither the Company nor the Lender exercise their rights by September 30, 2016, the \$8.0 million held in escrow will be released to the Majority Shareholders without any further obligation on the part of the Majority Shareholders of Allenex. The Company expects to issue an additional 334,169 Units, which consist of (i) a total of 334,169 shares of Common Stock, (ii) a total of 1,670,845 shares of Series A Preferred that are all convertible to Common Stock, and (iii) 1,002,507 warrants in the Subsequent Financing. If the Subsequent Financing occurs following receipt of the Requisite Stockholder Approval on June 16, 2016, the Company will issue 2,005,014 shares of Common Stock and warrants to the Majority Shareholders of Allenex to purchase 1,002,507 shares of Common Stock instead of issuing the Units.

Following the closing of the Private Placement, the Company agreed to a number of requirements such as submitting the Private Placement to the Company’s stockholders for approval, which is expected to be approved after the receipt of the Requisite Stockholder Approval expected on June 16, 2016, granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3 within 45 days of closing. Additionally, if the Company fails to file an effective registration statement on Form S-3 within 45 days of closing the Private Placement, the Company shall be obligated to pay an aggregate penalty amount equal to approximately \$0.3 million for each month that the Company has not filed the required registration statement, up to a maximum of \$1.4 million.

The Company engaged M.M. Dillon & Co. Group (“M.M. Dillon”), an investment banking firm, to act as one of its financial advisors and placement agents in connection with a private equity placement of Common Stock and the execution of any such Private Placement that the Company may choose to pursue. A member of the Company’s board of directors is a managing director of M.M. Dillon, and as such, M.M. Dillon is considered a related party to the Company. As a result of the Private Placement and Subsequent Financing, the Company paid approximately \$1.1 million in placement fees to its placement agents, of which \$0.2 million pertained to fees paid to M.M. Dillon. Additionally, M.M. Dillon also received Placement Agent Warrants to purchase 100,000 shares of the Company’s Common Stock.

The Company expects to use the proceeds from the Private Placement and the Subsequent Financing for additional working capital, acquisitions and general corporate purposes.

The Company is soliciting the Requisite Stockholder Approval, which requires the support a majority of the Company’s stockholders, at its annual general meeting on June 16, 2016, and filed a definitive proxy statement on May 5, 2016. The Company and certain stockholders representing a majority of the Company’s outstanding Common Stock entered into voting agreements on April 14, 2016, pursuant to which each stockholder agreed to vote certain of its shares of Common Stock in favor of granting the Company the Requisite Stockholder Approval.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed financial statements and related notes included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 as filed with the Securities and Exchange Commission on March 31, 2016.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements contained in this Quarterly Report on Form 10-Q other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and the negative and plural forms of these words and 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 dd-cfDNA, solutions for the surveillance of heart and kidney transplant recipients;
- our ability to obtain, 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 dependence on certain of our suppliers and service providers;
- 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;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our ability to comply with the requirements of being a public company; and,
- our ability to integrate the businesses of Allenex with ours, and obtain additional financing.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may

make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

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

Overview and Recent Developments

We are a molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant patients. Our first commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate/severe acute cellular rejection. Since 2008, we have sought to expand the adoption and utilization of our AlloMap solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap, secure positive reimbursement decisions for AlloMap from large private and public payers, develop and enhance our relationships with key members of the transplant community, including opinion leaders at major transplant centers, and explore opportunities and technologies for the development of additional solutions for post-transplant surveillance. We believe the use of AlloMap, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant. In particular, we believe AlloMap can improve patient care by helping healthcare providers to avoid the use of unnecessary, invasive surveillance biopsies and to determine the appropriate dosage levels of immunosuppressants. We are also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, our proprietary next-generation sequencing test to detect donor-derived cell-free DNA, or dd-cfDNA, after transplantation.

Since the launch of AlloMap in January 2005, we have performed more than 81,000 commercial AlloMap tests, including 3,358 tests during the first three months in 2016, in our Brisbane, California laboratory. During the first quarter of 2016, AlloMap was used in 120 of the approximately 130 heart transplant centers in the United States. As of March 31, 2016, significantly all of our testing revenue has come from the United States and all of our assets and operations are located in the United States. In 2014, we began to expand our AlloMap offering through a partnership in Europe for which we have secured a dedicated laboratory.

We are also engaged in efforts to develop additional testing solutions in the heart transplant market and new testing solutions in other organ transplant markets. For instance, AlloSure, our development stage transplant surveillance solution, applies proprietary next generation sequencing to detect and quantitate genetic differences between donor derived cell-free DNA, or dd-cfDNA, in the blood stream emanating from the donor heart. We believe this solution may help determine rejection-specific activity manifested as cell damage in the transplanted heart and other organs. As part of our efforts to demonstrate the clinical utility of AlloSure, our proprietary next-generation sequencing test that measures the percent of dd-cfDNA in solid organ transplant recipients, irrespective of the type of organ transplanted, in May 2015 we initiated the DART trial. DART is designed to establish clinical validation, or the clinical performance characteristics of dd-cfDNA in detecting clinical and sub-clinical rejection in kidney allograft recipients. DART is a multicenter observational study of kidney transplant recipients where blood specimens are

drawn periodically after transplant during follow up visits and also after treatment for acute rejection. DART is also designed to demonstrate the correlation of dd-cfDNA to renal function through comparison to both serum creatinine and estimated glomerular filtration rate. We expect DART to run for a minimum of 18 months and we expect to complete the first analysis of the data in 2016. Once we receive relevant information from the first analysis, we expect to initiate a second clinical trial to establish the clinical utility of our dd-cfDNA kidney solution. At the end of March 2016, DART had enrolled over 300 patients in 14 centers. Additionally, in late 2015, we announced the completion of analytical validation for AlloSure. Samples used in the analytical validation included donor recipient pairs with unrelated as well as closely related family members.

Completion of Allenex Acquisition

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex. Allenex is a transplant diagnostic company based in Stockholm, Sweden that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Allenex has 58 employees. Under the terms of the Conditional Share Purchase Agreements entered into on December 16, 2015, as amended and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the purchase consideration is expected to total approximately \$35.0 million, consisting of \$27.8 million of cash, of which \$6.2 million is deferred purchase consideration payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB (collectively, “the Majority

Shareholders”) no later than March 31, 2017, and the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Additionally, \$8.0 million of cash purchase consideration payable to the Majority Shareholders of Allenex is being held in escrow by us and relates to a commitment by the Majority Shareholders of Allenex to purchase our equity securities in a future financing (“Subsequent Financing”). The equity securities will be sold no later than 30 days following the receipt of certain Company stockholder approvals required pursuant to the rules of the NASDAQ Stock Market (the “Requisite Stockholder Approval”), which is expected to occur on June 16, 2016, on terms, including price, substantially equivalent to the terms of the Private Placement described below. We intend to initiate compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. In connection therewith, we subsequently intend to initiate a delisting of Allenex from Nasdaq Stockholm.

Our combination with Allenex creates an international transplant diagnostics company with product offerings along the pre- and post-transplant continuum. The Olerup SSP line, which addresses Human Leukocyte Antigen (“HLA”) testing, and AlloMap, are foundational diagnostics which are well recognized by the transplant community. The combined company will have a presence and direct distribution channels in the US and Europe, with additional third party distributors in other markets around the world.

As of April 11, 2016, we reassessed the probability of the completion of a six-month bridge loan of \$18.0 million with Oberland Capital SA Davos LLC and determined that it was not probable that the bridge loan would be consummated. We are currently disputing the fees associated with the bridge loan with Oberland Capital SA Davos LLC, but in the interim we have recorded a charge of \$2.9 million in the three months ended March 31, 2016 to expense financing costs associated with this bridge loan. These costs have been included as a component of other (expense) income, net on our condensed statements of operations. As a result, the cash portion of the acquisition purchase price was paid from our general working capital. The acquisition required and we obtained a consent of East West Bank (“the Lender”). The consent was contingent upon the closing of a Private Placement for aggregate proceeds of at least \$12.0 million and separately depositing into escrow cash of \$8.0 million that relates to a commitment by the Majority Shareholders of Allenex to purchase the Company’s equity securities in a Subsequent Financing as described above, all of which occurred on April 14, 2016. The Lender also requires us to subsequently raise another \$20.0 million through equity financing by March 31, 2017, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders of Allenex.

The acquisition of Allenex will be accounted for and reported as a business combination during the second quarter of 2016. We are in the process of determining the total purchase price and allocation thereof, however, it is impracticable to make any other disclosures related to this acquisition at this time.

Private Placement

On April 14, 2016, we completed the sale and offering of 591,860 Units to certain accredited investors (the “Private Placement”). Each Unit is comprised of: (i) one share of Common Stock, (ii) five shares of Series A Mandatorily Convertible Preferred Stock, and (iii) three warrants, each to purchase one share of Common Stock. The purchase price was \$23.94 per Unit (the equivalent of \$3.99 per share of Common Stock, assuming conversion of the Series A Preferred). The closing of the Private Placement was conditioned upon the closing of the Allenex acquisition, the consent of East West Bank to the Allenex acquisition, and certain other customary closing conditions, all of which occurred on April 14, 2016. The aggregate proceeds to us from the Private Placement were approximately \$14.1 million, of which \$1.4 million was reserved for payment of placement agents, escrow agents, and legal fees.

On April 13, 2016, we filed a Certificate of Designation that established the rights and preferences of the Series A Preferred. Each share of Series A Preferred is mandatorily convertible into Common Stock upon our receipt of the Requisite Stockholder Approval required pursuant to the rules of the NASDAQ Stock Market. Subject to obtaining the Requisite Stockholder Approval, each share of Series A Preferred is initially convertible into one share of Common

Stock, subject to certain adjustments. The Series A Preferred are not entitled to receive dividends and are not redeemable at our election. Series A Preferred could be required to be redeemed upon a deemed liquidation event, as defined, at \$3.99 per share, or if we are unable to issue share certificates without sale restriction legend in certain circumstances, at amounts at which the holder purchases our shares required to satisfy our sale obligations. Except as required by the Delaware General Corporation Law, the Series A Preferred do not have voting rights and will not be included in determining the number of shares voting or entitled to vote on any matter of ours.

Each warrant is exercisable for a period of seven years to purchase one share of Common Stock at an initial exercise price of \$4.98 per share, subject to certain adjustments. We also issued Placement Agent Warrants to purchase an aggregate of 200,000 shares of Common Stock to certain of our placement agents. Each Placement Agent Warrant is exercisable for a period of five years to purchase one share of Common Stock at an initial exercise price of \$3.99 per share, subject to certain adjustments. Pursuant to the terms of the warrants, the holder of the warrant cannot exercise the warrant until we have obtained the Requisite Stockholder Approval. The warrants are expected to be recorded as a liability and be subject to ongoing remeasurement.

Concurrently, we also entered into commitment letters (the “Commitment Letters”) pursuant to which the Majority Shareholders of Allenex agreed to purchase our equity securities in a Subsequent Financing as described above. If the Subsequent Financing is not

completed within 30 days of the Requisite Stockholder Approval, and provided that the Loan Agreement (as described in Note 9) is still in place, the Lender has the right to require that we complete the Subsequent Financing and issue securities to the Majority Shareholders in exchange for the \$8.0 million of cash held in escrow. If neither we nor the Lender (as described in Note 9) exercise their rights by September 30, 2016, the funds will be released to the Majority Shareholders without any further obligation on the part of the Majority Shareholders of Allenex. We expect to issue an additional 334,169 Units, which consists of (i) a total of 334,169 shares of Common Stock, (ii) a total of 1,670,845 shares of Series A Preferred that are all convertible to Common Stock, and (iii) 1,002,507 warrants in the Subsequent Financing. If the Subsequent Financing occurs following receipt of the Requisite Stockholder Approval on June 16, 2016, we will issue 2,005,014 shares of Common Stock and warrants to the Majority Shareholders of Allenex to purchase 1,002,507 shares of Common Stock instead of Units.

Following the closing of the Private Placement, we agreed to a number of requirements such as submitting the Private Placement to our stockholders for approval, which is expected to be approved after the receipt of the Requisite Stockholder Approval expected on June 16, 2016, granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3 within 45 days of the closing. Additionally, if we fail to file an effective registration statement on Form S-3 within 45 days of the closing of the Private Placement, we shall be obligated to pay an aggregate penalty amount equal to approximately \$0.3 million for each month that we have not filed the required registration statement, up to a maximum of \$1.4 million.

We engaged M.M. Dillon & Co. Group (“M.M. Dillon”), an investment banking firm, to act as one of our financial advisors and placement agents in connection with a private equity placement of Common Stock and the execution of any such Private Placement that we may choose to pursue. A member of our board of directors is a managing director of M.M. Dillon, and as such, M.M. Dillon is considered a related party to us. As a result of the Private Placement and Subsequent Financing, we paid approximately \$1.1 million in placement fees to our placement agents, of which 0.2 million pertained to fees paid to M.M. Dillon. Additionally, M.M. Dillon also received Placement Agent Warrants to purchase 100,000 shares of our Common Stock.

We expect to use the proceeds from the Private Placement and the Subsequent Financing for additional working capital, acquisitions and general corporate purposes.

We are soliciting the Requisite Stockholder Approval, which requires the support of a majority of our stockholders, at our annual general meeting on June 16, 2016, and filed a definitive proxy statement on May 5, 2016. We and certain stockholders representing a majority of our outstanding Common Stock entered into voting agreements on April 14, 2016, pursuant to which each stockholder agreed to vote certain of our shares of Common Stock in favor of granting us the Requisite Stockholder Approval.

Financial Operations Overview

Testing Revenue

Our testing revenue is derived from AlloMap tests, which represented 98% of our total revenues for the three months ended March 31, 2016 and 2015. Our testing revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; (v) our ability to expand into markets outside of the United States; and (vi) how quickly we can successfully commercialize new product offerings.

We currently market AlloMap to healthcare providers through our direct sales force that targets transplant centers and their physicians, coordinators and nurse practitioners. The healthcare providers that order the tests and on whose behalf we provide our testing services are generally not responsible for the payment of these services. As of March 31, 2016, the list price of AlloMap was \$3,600 per test. However, amounts actually received by us vary from payer to payer based on each payer's internal coverage practices and policies. We generally bill third-party payers upon delivery of an AlloMap score report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

Collaboration, License and Other Revenue

Revenue from our collaboration and license agreements was approximately 2% of total revenues for each period presented. Collaboration and license agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Our performance obligations under the collaboration and license agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue. We periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated periods of performance on a prospective basis.

Cost of Testing

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

Royalties incurred for licensed technology, calculated as a percentage of test revenues, are recorded as license fees in cost of testing at the time the test revenues are recognized. Royalties included in cost of testing are associated with a license from Roche Molecular Systems, Inc. ("Roche"). In September 2014, we agreed with Roche to a downward adjustment of the royalty rate. As part of this agreement, no further royalties will be payable by us for periods after September 30, 2017.

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 expect sales and marketing expenses to increase in the future as we continue to expand our presence in the diagnostic surveillance market.

General and Administrative 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 to increase in absolute dollars related to anticipated testing volume and collections growth. For the three months ended March 31, 2016, general and administrative expenses also included transaction related fees and expenses associated with the acquisition of Allenex. Following the acquisition, we also expect our general and administrative expenses to increase as we incur additional costs to integrate Allenex's business with ours, implement and comply with internal control requirements and other costs to operate globally.

Change in Estimated Fair Value of Contingent Consideration

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

Interest Expense

Interest expense is associated with borrowings under our loan agreements.

Other (Expense) Income, Net

For the three months ended March 31, 2016, other (expense) income, net primarily consists of a charge recorded to expense financing costs associated with a six-month bridge loan with Oberland Capital SA Davos LLC as we determined that it was not probable that the bridge loan would be consummated. For the three months ended March 31, 2015, other (expense) income, net is primarily state franchise taxes.

Results of Operations

	Three Months Ended March 31,	
	2016	2015
AlloMap results delivered	3,364	3,111
Revenue:		
Testing revenue	\$6,452	\$7,096
Collaboration, license and other revenue	110	120
Total revenue	6,562	7,216

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

Operating expenses:		
Cost of testing	2,772	2,711
Research and development	3,159	1,421
Sales and marketing	1,737	2,023
General and administrative	5,676	2,705
Change in estimated fair value of contingent		
consideration	(213)	(253)
Total operating expenses	13,131	8,607
Loss from operations	(6,569)	(1,391)
Interest expense	(266)	(827)
Other (expense) income, net	(2,917)	(54)
Net loss	\$(9,752)	\$(2,272)

Testing Revenue

Testing revenue decreased by \$0.6 million, or 9%, for the three months ended March 31, 2016 compared to the same period of 2015. AlloMap test results delivered increased by 253, or 8%, for the three months ended March 31, 2016 as compared to the same period of 2015. The decrease in testing revenue of \$0.6 million was due to slower collections from our cash basis payers, partially offset by a \$0.2 million increase in test volume from our accrual basis payers. We plan to add additional regular and temporary employees as part of a plan to increase the rate of collections.

Collaboration, License and Other Revenue

Collaboration, license and other revenue decreased by approximately \$10,000, or 8%, for the three months ended March 31, 2016 compared to the same period in 2015 due to a decrease in royalties from the Diaxonhit license arrangement.

Cost of Testing

Cost of testing increased by approximately \$61,000, or 2%, for the three months ended March 31, 2016 compared to the same period in 2015. The increase was primarily a result of increased expenditures on laboratory materials to support testing volume growth.

Research and Development

Research and development expenses increased by \$1.7 million, or 122%, for the three months ended March 31, 2016 compared with the same period in 2015. The increase was primarily due to higher headcount related expenses of \$0.9 million and additional expenditures of \$0.6 million to support the launch of the dd-cfDNA clinical trials, and the expansion of our existing laboratory facilities to accommodate CLIA-compliant space specifically designed for clinical-grade next generation sequencing testing.

Sales and Marketing

Sales and marketing expenses decreased by approximately \$0.3 million, or 14%, for the three months ended March 31, 2016 compared with the same period in 2015. The decrease was primarily related to reduced spending on discretionary marketing campaigns.

General and Administrative

General and administrative expenses increased by approximately \$3.0 million, or 110%, for the three months ended March 31, 2016 compared with the same period of 2015. This increase was primarily due to \$2.2 million of professional, legal and consulting fees incurred in connection with the acquisition of Allenex. Additionally, there was an increase of \$0.4 million in expenses related to infrastructure and systems implementation for our in-house billing and collections function, an increase in recruiting fees of \$0.2 million, and an increase of \$0.2 million related to higher headcount related expenses.

Change in Estimated Fair Value of Contingent Consideration

The consideration for our business combination with IMX includes a future payment that is contingent upon the achievement of a specified milestone which is included on our balance sheets as a contingent consideration liability. We revalued the contingent consideration liability for the three months ended March 31, 2016 and 2015 and recognized a non-cash gain of \$0.2 million and \$0.3 million, respectively, in our condensed statements of operations

as a result of the decline of our stock price during those periods.

Interest Expense

Interest expense decreased by \$0.6 million, or 68%, for the three months ended March 31, 2016 compared with the same period of 2015 due to lower interest rates on the new term loan that we entered into at the end of January 2015. Additionally, interest expense for the three months ended March 31, 2015 included a loss on extinguishment of debt of \$0.6 million as we paid off a term loan in January 2015.

Other (Expense) Income, Net

Other (expense) income, net for the three months ended March 31, 2016 increased by \$2.9 million compared to the same period in 2015 primarily due to a charge recorded in the interim to expense financing costs associated with a six-month bridge loan with Oberland Capital SA Davos LLC as we are currently disputing the fees associated with this bridge loan, and our assessment indicated

that it was not probable that the bridge loan would be consummated. Other (expense) income, net for three months ended March 31, 2015 was \$54,000, which was primarily state franchise taxes.

Cash Flows for the Three Months Ended March 31, 2016 and 2015

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

	Three Months Ended March 31, 2016 2015 (in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(6,192)	\$(1,014)
Investing activities	(109)	(364)
Financing activities	165	3,932
Net (decrease) increase in cash and cash equivalents	\$(6,136)	\$2,554

Operating Activities

Net cash used in operating activities consists of net loss, adjusted for certain noncash items in the statements of operations and changes in operating assets and liabilities. Cash used in operating activities for the three months ended March 31, 2016 was \$6.2 million. Net loss for the period was \$9.8 million, which included \$2.2 million of transaction related fees and expenses incurred in connection with the acquisition of Allenex and a charge of \$2.9 million recorded in the interim to expense financing costs associated with a six-month bridge loan with Oberland Capital SA Davos LLC as we are currently disputing the fees associated with this bridge loan, and our assessment indicated that it was not probable that the bridge loan would be consummated. The net loss included a number of noncash items including stock-based compensation expense of \$0.4 million, depreciation and amortization of \$0.3 million, and a revaluation gain of \$0.2 million on a contingent consideration liability that was a function of a decline in our stock price. Net operating assets decreased by \$3.0 million, which was primarily caused by an increase in accrued and other liabilities of \$2.4 million for expenses incurred for the launch of dd-cfDNA clinical trials, the acquisition of Allenex and financing charges; an increase in accounts payable of \$0.8 million for professional fees billed to us primarily related to the acquisition of Allenex; a decrease in prepaid and other assets of \$0.6 million. These were partially offset by a decrease of accrued payroll liabilities of \$0.8 million resulted from the net pay-out of accrued bonuses, and an increase of accounts receivable of \$0.1 million related to collections from an additional payer on the accrual basis and slower collection turnovers.

Cash used in operating activities for the three months ended March 31, 2015 was \$1.0 million. Net loss of \$2.3 million included \$0.6 million of net noncash expenses, which primarily comprised of noncash interest expenses of \$0.4 million as a result of the non-cash portion of a loss on extinguishment from a previous debt and the issuance costs associated with new debt, stock-based compensation expense of \$0.3 million, and depreciation and amortization of \$0.2 million, which was partially offset by a revaluation gain of \$0.3 million on a contingent consideration liability driven by a decrease in our stock price. A decrease in net operating assets of \$0.7 million primarily comprised of a decrease in accounts receivable of \$0.9 million as our reimbursement efforts improved over the fourth quarter of 2014, increases in accounts payable and accrued and other liabilities of \$0.4 million, which was partially offset by a decrease in payroll liabilities of \$0.4 million due to the pay out of employee bonuses, an increase in prepaid expenses and other assets of \$0.2 million primarily due to the prepayment of facilities rent and an increase in inventory of \$0.1 million

due to an increase in the price of a key raw material.

Investing Activities

During the three months ended March 31, 2016, net cash used in investing activities was \$0.1 million for purchases of property and equipment. During the three months ended March 31, 2015, net cash used in investing activities was \$0.4 million for purchases of property and equipment.

We expect capital expenditures to increase in 2016 and beyond due to the acquisition of Allenex and our expansion as a global company. We also plan to continue to expand our research and discovery work to develop new transplant surveillance solutions.

Financing Activities

For the three months ended March 31, 2016, net cash provided by financing activities was \$0.2 million primarily due to proceeds received from the exercise of employee stock options.

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

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$182.8 million at March 31, 2016. As of March 31, 2016, we had cash and cash equivalents of \$23.8 million, and \$15.9 million of debt outstanding under our debt and capital lease obligations, net of debt discount and issuance costs.

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex. Allenex is a transplant diagnostic company based in Stockholm, Sweden that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Allenex has 58 employees. Under the terms of the Conditional Share Purchase Agreements entered into December 16, 2015, as amended and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the purchase consideration is expected to total approximately \$35.0 million, which consisted of \$27.8 million of cash, of which \$6.2 million was deferred purchase consideration payable to the Majority Shareholders no later than March 31, 2017, and the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Additionally, \$8.0 million of cash purchase consideration payable to the Majority Shareholders of Allenex is being held in escrow by us and relates to a commitment by the Majority Shareholders of Allenex to purchase our equity securities in a Subsequent Financing. The equity securities will be sold no later than 30 days following the receipt of the Requisite Stockholder Approval, which is expected to occur on June 16, 2016 on terms, including price, substantially equivalent to the terms of the Private Placement described below. We intend to initiate compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex.

The acquisition of Allenex required and we obtained a consent of the Lender. The consent was contingent upon the closing of a Private Placement for aggregate cash proceeds of at least \$12.0 million and separately depositing into escrow cash of \$8.0 million that relates to a commitment by the Majority Shareholders of Allenex to purchase the Company's equity securities in a Subsequent Financing as described above, all of which occurred on April 14, 2016. The Lender also requires us to subsequently raise another \$20.0 million through equity financing by March 31, 2017, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders of Allenex.

On April 14, 2016, we completed a Private Placement transaction for the sale of 591,860 Units at a purchase price of \$23.94 per Unit. The aggregate proceeds to us from the Private Placement were approximately \$14.1 million. Concurrently, we also entered into Commitment Letters pursuant to which the Majority Shareholders of Allenex agreed to purchase our equity securities in a Subsequent Financing as described above. If the Subsequent Financing is not completed within 30 days of the Requisite Stockholder Approval, and provided that the Loan Agreement is still in place, the Lender has the right to require that we complete the Subsequent Financing and issue securities to the Majority Shareholders in exchange for the \$8.0 million of cash held in escrow. If neither we nor the Lender exercise their rights by September 30, 2016, the funds will be released to the Majority Shareholders without any further obligation on the part of the Majority Shareholders of Allenex. We made payments of approximately \$1.1 million and \$97,000 in placement fees and other offering expenses, respectively, to placement agents as part of closing the sale of the 591,680 Units in the Private Placement. Following the closing of the Private Placement, we agreed to a number of requirements such as submitting the Private Placement to our stockholders for approval, which is expected to be approved after the receipt of the Requisite Stockholder Approval expected on June 16, 2016, granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3 within 45 days of the closing. Additionally, if we fail to file an effective registration statement on Form S-3 within 45 days of closing the Private Placement, we shall be obligated to pay an aggregate penalty amount equal to approximately \$0.3 million for each month that we have not filed the required registration statement, up to a

maximum of \$1.4 million.

We will require additional financing and/or refinancing to fund working capital, repay debt and to pay our obligations. A potential working capital benefit of refinancing our existing debt obligations is deferral of debt repayments otherwise due in 2016. We may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities.

Absent additional funding or refinancing, we will exhaust our cash and cash equivalents in December 2016 unless we substantially reduce our costs and operations, including research and development activities, marketing activities and programs, and other general and administrative expenses. As a result of our obligations and lack of immediately available financial resources, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing or refinancing in the near term, we will be required to significantly reduce or cease operations.

30

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes in our critical accounting policies and estimates during the three months ended March 31, 2016, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations-Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K filed with the SEC on March 29, 2016.

Factors Affecting Our Performance

The Number of AlloMap Tests We Receive and Report

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

How We Recognize Revenue

Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allows us to recognize the related revenue on an accrual basis under US GAAP. For the three months ended March 31, 2016 and 2015, 32% and 34%, respectively of our revenue was recognized when cash was received. Until we achieve our revenue recognition criteria for a larger number of payers, we will continue to recognize a large portion of our revenue when cash is received. Because we often need to appeal prior to being paid for certain tests, it can take over a year for a test to result in revenue being recorded, and for a portion of our tests, we may never realize revenue.

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

Continued Adoption of and Reimbursement for AlloMap

Our reimbursement rate has steadily increased over time since the launch of AlloMap, as payers adopt coverage policies and fewer payers consider AlloMap as experimental and investigational. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. Revenue growth depends on our ability to achieve broader reimbursement from third party payers, to expand the number of tests per patient and the base of ordering physicians.

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

In 2015, there was a material increase in our contractual obligations and commitments. On January 30, 2015, we entered into a Loan Agreement, which provides a secured term loan facility in an aggregate principal amount of up to \$20.0 million. We borrowed the first and only advance of \$16.0 million (“Draw A”) on January 30, 2015. Draw A was used to pay-off our previously existing term debt of \$11.3 million. Draw A bears interest at a daily floating rate equal to 2.00%, over the greater of (i) 3.25% or (ii) the prime rate published by the lender.

The acquisition of Allenex required and we obtained a consent of the Lender. The consent was contingent upon the closing of a Private Placement for aggregate cash proceeds of at least \$12.0 million and separately depositing into escrow cash of \$8.0 million that relates to a commitment by the Majority Shareholders of Allenex to purchase our equity securities in a Subsequent Financing, all of which occurred on April 14, 2016. The Lender also requires us to subsequently raise another \$20.0 million through equity financing by March 31, 2017, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders of Allenex. The maturity date of the loan is December 1, 2018. The principal pay-down of the loan begins on July 1, 2016 with the loan being payable in 30 equal monthly installments. As of February 29, 2016, we were in violation of one of its financial covenants under the Loan Agreement. This violation was waived in principal by virtue of a contemporaneous verbal amendment to the Loan Agreement received from the Lender, which was subsequently memorialized in a written amendment to the Loan Agreement dated May 12, 2016. As of March 31, 2016, we were in compliance with our debt covenants.

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

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

Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40), Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”). This guidance requires us to evaluate whether there are conditions and events that raise substantial doubt about our ability to continue as a going concern within one year after the financial statements are issued, and if there is substantial doubt about our ability to continue as a going concern, the disclosure of such is required. We are required to make this evaluation for both annual and interim reporting periods, if applicable. We also are required to evaluate and disclose whether our plans alleviate that doubt. This guidance is effective for the annual periods ending after December 15, 2016, and annual and interim periods thereafter. Early adoption is permitted. We are currently assessing the impact of this guidance on our condensed financial statements.

In April 2015, the FASB issued ASU 2015-05, Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350-40). This updated standard provides guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. An entity can elect to adopt the amendments either (1) prospectively to all arrangements entered into or materially modified after the effective date or (2) retrospectively. For prospective transition, the only disclosure requirements at transition are the nature of and reason for the change in accounting principle, the transition method, and a qualitative description of the financial statement line items affected by the change. For retrospective transition, the disclosure requirements at transition include the requirements for prospective transition and quantitative information about the effects of the accounting change. We adopted this guidance as of January 1, 2016 as required using the prospective method. There have been no new or existing arrangements that were materially modified following the adoption date.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred income taxes by requiring deferred tax assets and liabilities be classified as noncurrent on the balance sheet. The guidance is effective for us beginning January 1, 2017 with early adoption permitted as of the beginning of any interim or annual reporting period, and it may be applied either (1) prospectively to all deferred tax assets and liabilities or (2) retrospectively to all periods presented. If an entity applies the guidance prospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and a statement that prior periods were not retrospectively adjusted. If an entity applies the guidance retrospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and quantitative information about the effects of the accounting change on prior periods. We adopted this guidance early as of January 1, 2016 prospectively, which required our deferred tax assets and liabilities to be reclassified from other current assets and liabilities to their respective noncurrent categories on our condensed balance sheets. However, as of March 31, 2016, all of our net deferred tax assets and liabilities were subject to a full valuation allowance, and therefore, no reclassifications were required. The adoption of this guidance did not result in any impact on our condensed financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases, which, for operating leases, requires the lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. This guidance will be effective for us in fiscal year 2019 and must be adopted using a modified retrospective transition approach. Early adoption is permitted. We are currently assessing the impact of this guidance.

In March 2016, the FASB issued ASU 2016-06, Derivatives and Hedging: Contingent Put and Call Options in Debt Instruments, to clarify when a contingent put or call option to accelerate the repayment of debt is an embedded derivative. The guidance is effective for interim and annual periods beginning after December 15, 2016, with early adoption permitted. The adoption of this guidance is on a modified retrospective basis. We are currently assessing the impact of this guidance on our condensed financial statements.

In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing. In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net). These amendments provide additional clarification and implementation guidance on the previously issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which 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. The amendments in ASU 2016-10 provide clarifying guidance on materiality of performance obligations; evaluating distinct performance obligations; treatment of shipping and handling costs; and determining whether an entity's promise to grant a license provides a customer with either a right to use an entity's intellectual property or a right to access an entity's intellectual property. The amendments in ASU 2016-08 clarify how an entity should identify the specified good or service for the principal versus agent evaluation and how it should apply the control principle to certain types of arrangements. The adoption of ASU 2016-10 and ASU 2016-08 is to coincide with an entity's adoption of ASU 2014-09, which we intend to adopt for interim and annual reporting periods beginning after December 15, 2017, as required. The guidance may be applied (1) retrospectively to each prior period presented or (2) retrospectively with the cumulative effect recognized as of the date of adoption. We are currently evaluating the impact that this guidance will have on our condensed financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of \$23.8 million and \$39.0 million at March 31, 2016 and 2015, respectively, which consisted of bank deposits and money market funds. Additionally, we had debt of \$15.8 million and \$15.7 million as of March 31, 2016 and 2015, respectively. Our current debt arrangement bears a daily floating rate. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 50 basis point change in interest rates, which is approximately a 10% increase in the cost of borrowing, during any of the periods presented would have had a material impact on our unaudited condensed financial statements.

Foreign Currency Exchange Risk

Since 2014, our AlloMap test has been offered in Europe through our agreement with Diaxonhit. From 2014 to August 2015, our AlloMap test was offered in Canada through our agreement with LifeLabs Medical Laboratory Services. Payments to us under these agreements are denominated in U.S. dollars. Expenses we incur in currencies other than U.S. dollars were not material through March 31, 2016. Following the acquisition of Allenex on April 14, 2016, with operations in Sweden and other countries in Europe, we will be subject to significant foreign currency exposures, including transacting in foreign currencies, investment in a foreign entity, and debts denominated in foreign currencies.

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(b) and 15d-15(e)), as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Securities Exchange Act of 1934, as amended, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Although we are not currently a party to any material litigation, we may become subject to legal proceedings and claims that arise in the ordinary course of business. We do not believe that any matters presently pending will have a material adverse effect, individually or in the aggregate, on our financial position, results of operations or liquidity. However, legal matters and proceedings are inherently unpredictable and subject to significant uncertainties, some of which are beyond our control. As such, there can be no assurance that the final outcome of these matters will not materially and adversely affect our financial position, results of operations or liquidity.

ITEM 1A. RISK FACTORS

In addition to the information set forth in this Quarterly Report on Form 10-Q and before deciding to invest in, or retain, shares of our common stock, you also should carefully review and consider the information contained in our other reports and periodic filings that we make with the SEC, including, without limitation, the information contained

under the caption Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, which is incorporated herein by reference. Those risk factors could materially affect our business, financial condition and results of operations. With the exception of the risk factors below, there have been no material changes from the risk factors previously disclosed in the Form 10-K. The risks that we describe in our public filings are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we presently deem to be immaterial, also may materially adversely affect our business, financial condition and results of operations.

Risks Related to the Acquisition

The acquisition of Allenex will require us to obtain additional financing.

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex. Allenex is a transplant diagnostic company based in Stockholm, Sweden that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Allenex has 58 employees. Under the terms of the Conditional Share Purchase Agreements entered into on December 16, 2015, as amended and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the purchase consideration is expected to total approximately \$35.0 million, consisting of \$27.8 million of cash, of which \$6.2 million is deferred purchase consideration payable to the Majority Shareholders of Allenex no later than March 31, 2017, and the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Additionally, \$8.0 million of cash purchase consideration payable to the Majority Shareholders of Allenex is being held in escrow by us and relates to a commitment by the Majority Shareholders of Allenex to purchase our equity securities in a Subsequent Financing. The equity securities will be sold no later than 30 days following the receipt of the Requisite Stockholder Approval, which is expected to occur on June 16, 2016, on terms, including price, substantially equivalent to the terms of a Private Placement. We intend to initiate compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex.

On April 14, 2016, we completed a Private Placement transaction for the sale of 591,860 Units at a purchase price of \$23.94 per Unit. The aggregate proceeds to us from the Private Placement were approximately \$14.1 million. Concurrently, we also entered into Commitment Letters pursuant to which the Majority Shareholders of Allenex agreed to purchase our equity securities in a Subsequent Financing as described above. If the Subsequent Financing is not completed within 30 days of the Requisite Stockholder Approval, and provided that the Loan Agreement is still in place, the Lender has the right to require that we complete the Subsequent Financing and issue securities to the Majority Shareholders in exchange for the \$8.0 million of cash held in escrow. If neither we nor the Lender exercise their rights by September 30, 2016, the funds will be released to the Majority Shareholders without any further obligation on the part of the Majority Shareholders of Allenex. We made payments of approximately \$1.1 million and \$97,000 in placement fees and other offering expenses, respectively, to placement agents as part of closing the sale of the 591,860 Units in the Private Placement. Following the closing of the Private Placement, we agreed to a number of requirements such as submitting the Private Placement to our stockholders for approval, which is expected to be approved after the receipt of the Requisite Stockholder Approval expected on June 16, 2016, granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3 within 45 days of closing. Additionally, if we fail to file an effective registration statement on Form S-3 within 45 days of closing the Private Placement, we shall be obligated to pay an aggregate penalty amount equal to approximately \$0.3 million for each month that we have not filed the required registration statement, up to a maximum of \$1.4 million.

We will require additional financing and/or refinancing to fund working capital, repay debt and to pay our obligations. A potential working capital benefit of refinancing our existing debt obligations is deferral of debt repayments in 2016. We may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities.

Absent the receipt of additional funding or refinancing, we will exhaust our cash and cash equivalents in December 2016 unless we substantially reduce our costs and operations, including research and development activities, marketing activities and programs, and other general and administrative expenses. As a result of our obligations and lack of immediately available financial resources, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, or refinance certain of our current obligations in the near term, we will be required to significantly reduce or cease operations

Our ability to raise additional financing for working capital and to refinance our indebtedness will depend, in part, on the conditions of the capital markets. Additional capital may not be available on attractive terms, or at all. Raising additional funds by issuing equity securities would result in dilution to our existing shareholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. Any refinancing of our indebtedness could be at significantly higher interest rates, require additional restrictive financial and operational covenants, require us to incur significant transaction fees and also require that we issue warrants or other equity securities, or issue convertible securities. Any debt arrangement we enter into may contain restrictive covenants, including restrictions on the ability of us and our subsidiaries to incur additional debt, grant liens, make investments, including acquisitions and pay dividends and distributions. These restrictions and covenants may restrict our ability to finance our operations and engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default and an acceleration of our obligations under a debt agreement. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we would have to curtail our research and

development and other activities and this would adversely affect our business and future prospects.

We may not be able to successfully integrate our business with the business of Allenex, and we may not be able to achieve the anticipated strategic benefits from our acquisition of Allenex.

The integration of Allenex will be a time-consuming process. The integration process will require substantial management time and attention, which may divert attention and resources from other important areas, including our existing business. In addition, we may not be able to fully realize the anticipated strategic benefits of the combination, which includes a complementary product portfolio and significant cross-selling opportunities. The failure to successfully integrate the combined operations, including retention of key employees, could impact our ability to realize the full benefits of our acquisition of Allenex. If we are not able to achieve the anticipated strategic benefits of the combination, it could adversely affect our business, financial condition and results of operations, and could adversely affect the market price of our common stock if the integration or the anticipated financial and strategic benefits of the acquisition are not realized as rapidly as, or to the extent anticipated by investors and analysts. Failure to achieve these anticipated benefits could result in increased costs and decreases in future revenue and/or net income following the acquisition.

Undetected errors or defects in our products could result in voluntary corrective actions or agency enforcement actions, including recall of our products, as well as harm our reputation, decrease market acceptance of our products and expose us to product liability claims.

Our products may contain undetected errors or defects that are not identified until after the products are first introduced. Disruptions or other performance problems with our products, or the perception of disruption or performance problems with our products, may require us to initiate a product recall, and may damage our customers' businesses and harm our reputation. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim, product recall or similar occurrence may cause us to incur significant expense, decrease market acceptance of our products and adversely impact our business and operating results.

In addition, the sale and use of products or services based on our technologies, or activities related to our research and clinical studies, could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot provide assurance that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. In addition, any product liability claim brought against us, with or without merit, could increase our product liability insurance rates and prevent us from securing insurance coverage in the future at reasonable coverage levels, or at all.

The market price of our shares may decline due to increased selling pressure as a result of the acquisition or subsequent equity financings.

In connection with the acquisition, we issued an aggregate of 1,375,026 shares of common stock to the holders of Allenex shares, and in connection with equity financings we expect to issue an aggregate of 8,534,261 shares of common stock. The common stock issued as consideration in the acquisition is freely tradable upon consummation of the acquisition, and upon filing of a Registration Statement covering the resale of such securities, the common stock issued in the equity financings will be freely tradeable. Sales of a substantial number of our shares of common stock in the public market in connection with the acquisition or the equity financings, or the perception that these sales could occur, could adversely affect the market price of our common stock and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Allenex shareholders who may not have the ability or desire to hold shares in a U.S. company may lead to sales of our shares of common stock or the perception that such sales may occur, either of which may adversely affect the market for, and the market price of, our shares.

The uncertainties associated with our combination with Allenex may cause key personnel to leave.

Our employees may perceive uncertainty about their future role with the combined business until strategies with regard to the combined business are announced or executed. Any uncertainty may affect our ability to attract and retain our key personnel, or the key employees of Allenex.

Charges to earnings resulting from acquisition and integration costs may materially adversely affect the market value of our shares following the completion of the acquisition.

As part of the acquisition, we expect to pay a substantial amount of cash and incur debt to pay for the acquisition. The incurrence of indebtedness is anticipated to also result in increased fixed obligations, increase interest expense, and

include covenants or other restrictions that could impede our ability to manage our operations. We may also discover liabilities or deficiencies associated with the acquisition of Allenex that were not identified in advance, which may result in significant unanticipated costs.

Intangibles acquired in connection with the acquisition may subsequently be impaired and, if so, could increase our net accumulated deficit.

We are accounting for the business combination with Allenex under the acquisition method of accounting in accordance with U.S. GAAP. The purchase price of Allenex is allocated to the fair value of the identifiable tangible and intangible assets and liabilities that are acquired from Allenex. The excess of the purchase price over Allenex's net assets and intangibles is allocated to goodwill. We are required to perform periodic impairment tests on goodwill and intangibles to evaluate whether the intangible assets and goodwill as a result of the acquisition of Allenex continue to have fair values that meet or exceed the amounts recorded on our balance sheet. If the fair values of such assets decline below their carrying value on the balance sheet, we may be required to recognize an impairment

charge related to such decline. We cannot predict whether or when there will be an impairment charge, or the amount of such charge, if any. However, if the charge is significant, it could cause the market price of our shares to decline.

Full integration of our business with Allenex may not be achieved until we acquire the remaining shares of Allenex shareholders.

Under Swedish law, we may only effect a compulsory acquisition if the holders of more than 90% of the outstanding shares in Allenex accept our tender offer. Though we acquired 98.37% of the outstanding shares in Allenex, full integration of the Allenex business may not be achieved until we have compulsorily acquired the remaining shares of Allenex.

Our acquisition of Allenex may not result in material benefits to our business and our development efforts.

Through the acquisition of Allenex, we expect to create an international transplantation diagnostics company with a strong presence and direct distribution in both the US and Europe. Allenex's products are used to evaluate organ transplant patients prior to their transplant procedure with Human Leukocyte Antigen, or HLA, matching diagnostic tests to ensure that a donor's organ is compatible with the transplant recipient's immune system to prevent rejection.

While Allenex has well-known products in the field of genomic HLA, Allenex faces market risk in the form of competition from other producers, transition to more automated typing processes as well as new technologies, which may make it difficult for the business to maintain current market share and margins. The markets for clinical diagnostic products are competitive, and there are a number of companies which currently compete with Allenex for product sales. Allenex's competitors or new market entrants may be in a better position than we are to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners. These competitors may also have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do, any of which may adversely affect the use of our genomic HLA products.

Additionally, the results from the acquisition of Allenex will be dependent on the performance of Allenex's new product, QTYPE. The development and commercialization of QTYPE may fail for many reasons, including:

- lack of clinical validation data to support the effectiveness of the test;

- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;

- failure to obtain or maintain necessary clearances or approvals to market the test; or

- lack of commercial acceptance by patients, clinicians, laboratories or third-party payers.

We have limited experience with respect to acquiring other companies and limited experience with respect to the acquisition of strategic assets or the formation of collaborations, strategic alliances and joint ventures. The acquisition of Allenex could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. We also may not realize the anticipated benefits of this acquisition.

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

Sales of Unregistered Securities

None

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

SIGNATURES

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

CAREDX, INC.
(Registrant)

Date: May 16, 2016 By: /s/ Peter Maag
Peter Maag
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Charles Constanti
Charles Constanti
Chief Financial Officer
(Principal Accounting and Financial Officer)

EXHIBIT INDEX

Exhibit

Number

- 10.1(1) Amendment to Conditional Share Purchase Agreement between CareDx and Midroc Invest AB, dated as of February 8, 2016.
- 10.2(1) Amendment to Conditional Share Purchase Agreement between CareDx and FastPartner AB, dated as of February 8, 2016.
- 10.3(1) Amendment to Conditional Share Purchase Agreement between CareDx and Xenella Holding AB, dated as of February 8, 2016.
- 10.4(2) Offer letter, dated February 29, 2016 by and between CareDx and Todd Whitson.
- 31.1* Certification of Periodic Report by Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification of Periodic Report by Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1** Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the Securities and Exchange Commission on February 8, 2016.

(2) Incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-K/A filed with the Securities and Exchange Commission on April 25, 2016.

* Filed herewith.

** Furnished herewith.

