



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 21,277,644 shares of the registrant's Common Stock issued and outstanding as of November 10, 2016.



CareDx, Inc.

TABLE OF CONTENTS

	Page No.
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Unaudited Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2016 and 2015</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2016 and 2015</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015</u>	6
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	34
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	51
<u>Item 4. Controls and Procedures</u>	52
 <u>PART II. OTHER INFORMATION</u>	 53
<u>Item 1. Legal Proceedings</u>	53
<u>Item 1A. Risk Factors</u>	54
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	87
<u>Item 3. Defaults Upon Senior Securities</u>	87
<u>Item 4. Mine Safety Disclosures</u>	87
<u>Item 5. Other Information</u>	87
<u>Item 6. Exhibits</u>	87
<u>Signatures</u>	88
<u>Exhibit Index</u>	89

## PART I. FINANCIAL INFORMATION

## ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CareDx, Inc.

## Condensed Consolidated Balance Sheets

(Unaudited)

(In thousands, except share data)

	September 30, 2016	December 31, 2015 (Note 2)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$22,265	\$29,888
Accounts receivable	4,568	2,367
Inventory	7,444	766
Prepaid and other assets	846	1,341
Total current assets	35,123	34,362
Property and equipment, net	3,305	2,425
Intangible assets, net	35,444	6,650
Goodwill	28,047	12,005
Restricted cash	143	147
Other noncurrent assets	30	49
Total assets	\$102,092	\$55,638
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$3,464	\$1,644
Accrued payroll liabilities	3,725	2,366
Accrued and other liabilities	8,204	2,892
Accrued royalties	310	242
Deferred revenue	58	142
Deferred purchase consideration	5,942	—
Current portion of long-term debt	17,902	2,866
Total current liabilities	39,605	10,152
Deferred rent, net of current portion	1,190	1,426
Deferred revenue, net of current portion	744	703
Deferred tax liability	6,896	—
Long-term debt, net of current portion	8,496	12,887
Contingent consideration	526	948
Common stock warrant liability	6,736	—
Other liabilities	1,119	28
Total liabilities	65,312	26,144
Commitments and contingencies (Note 9)		
Stockholders' equity:		

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Preferred stock: \$0.001 par value; 10,000,000 shares authorized at September 30, 2016

and December 31, 2015; no shares issued and outstanding at September 30, 2016

and December 31, 2015

Common stock: \$0.001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015; 21,226,343 shares and 11,902,346 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Additional paid-in capital	235,087	202,564
Accumulated other comprehensive loss	(1,831 )	—
Accumulated deficit	(197,071)	(173,082)
Total CareDx, Inc. stockholders' equity	36,206	29,494
Noncontrolling interest	574	—
Total stockholders' equity	36,780	29,494
Total liabilities and stockholders' equity	\$ 102,092	\$ 55,638

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

CareDx, Inc.

## Condensed Consolidated Statements of Operations

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Revenue:</b>				
Testing revenue	\$ 8,613	\$ 7,007	\$ 22,317	\$ 21,147
Product revenue	3,754	—	7,228	—
Collaboration, license and other revenue	108	144	226	349
<b>Total revenue</b>	<b>12,475</b>	<b>7,151</b>	<b>29,771</b>	<b>21,496</b>
<b>Operating expenses:</b>				
Cost of testing	2,604	2,568	8,228	7,786
Cost of product	3,355	—	6,411	—
Research and development	2,930	2,698	9,231	6,629
Sales and marketing	3,451	2,062	8,544	6,453
General and administrative	5,180	3,361	16,250	8,553
Change in estimated fair value of contingent consideration	(112 )	(345 )	(422 )	(456 )
<b>Total operating expenses</b>	<b>17,408</b>	<b>10,344</b>	<b>48,242</b>	<b>28,965</b>
<b>Loss from operations</b>	<b>(4,933 )</b>	<b>(3,193 )</b>	<b>(18,471 )</b>	<b>(7,469 )</b>
Interest expense	(568 )	(251 )	(1,351 )	(1,334 )
Other expense	(133 )	(45 )	(3,334 )	(142 )
Change in estimated fair value of common stock warrant liability	1,386	—	(1,779 )	—
<b>Loss before income taxes</b>	<b>(4,248 )</b>	<b>(3,489 )</b>	<b>(24,935 )</b>	<b>(8,945 )</b>
Income tax benefit	449	—	888	—
<b>Net loss</b>	<b>(3,799 )</b>	<b>(3,489 )</b>	<b>(24,047 )</b>	<b>(8,945 )</b>
Net loss attributable to noncontrolling interest	35	—	58	—
<b>Net loss attributable to CareDx, Inc.</b>	<b>\$ (3,764 )</b>	<b>\$ (3,489 )</b>	<b>\$ (23,989 )</b>	<b>\$ (8,945 )</b>
<b>Net loss per share attributable to CareDx, Inc. (Note 3):</b>				
Basic	\$ (0.20 )	\$ (0.29 )	\$ (1.61 )	\$ (0.76 )
Diluted	\$ (0.26 )	\$ (0.29 )	\$ (1.61 )	\$ (0.76 )
<b>Weighted average shares used to compute net loss per share</b>				
<b>attributable to CareDx, Inc.:</b>				
Basic	19,098,626	11,890,057	14,894,218	11,846,921
Diluted	19,481,424	11,890,057	14,894,218	11,846,921

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





CareDx, Inc.

## Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net loss	\$ (3,799 )	\$ (3,489 )	\$ (24,047 )	\$ (8,945 )
Other comprehensive loss:				
Foreign currency translation adjustments	(423 )	—	(1,831 )	—
Net Comprehensive loss	(4,222 )	(3,489 )	(25,878 )	(8,945 )
Comprehensive loss attributable to noncontrolling interest	35	—	58	—
Comprehensive loss attributable to CareDx, Inc.	\$ (4,187 )	\$ (3,489 )	\$ (25,820 )	\$ (8,945 )

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

CareDx, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities:		
Net loss	\$ (24,047 )	\$ (8,945 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,195	575
Amortization of inventory fair market value adjustment	2,738	—
Stock-based compensation	1,511	1,028
Amortization of deferred revenue	(43 )	(115 )
Amortization of debt discount and noncash interest expense	354	204
Revaluation of contingent consideration to estimated fair value	(422 )	(456 )
Revaluation of common stock warrant liability to estimated fair value	1,779	—
Changes in operating assets and liabilities:		
Accounts receivable	(690 )	446
Inventory	325	(129 )
Prepaid and other assets	1,290	(393 )
Accounts payable	(990 )	791
Accrued payroll liabilities	824	508
Accrued royalties	68	11
	2,593	699

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Accrued and other liabilities		
Change in deferred taxes	(947 )	—
Net cash used in operating activities	(13,462 )	(5,776 )
Investing activities:		
Purchase of property and equipment	(627 )	(1,123 )
Acquisition of business, net of cash acquired	(20,567 )	—
Net cash used in investing activities	(21,194 )	(1,123 )
Financing activities:		
Proceeds from debt, net of issuance costs	—	15,625
Proceeds from issuance of common stock, net of issuance costs	8,293	—
Proceeds from private placement and subsequent financing, net of issuance costs	20,625	—
Proceeds from issuance of common stock under employee stock purchase plan	304	203
Principal payments on debt and capital lease obligations	(2,170 )	(11,451 )
Proceeds from exercise of stock options	9	45
Net cash provided by financing activities	27,061	4,422
Effect of exchange rate changes on cash and cash equivalents	(28 )	—
Net decrease in cash and cash equivalents	(7,623 )	(2,477 )
Cash and cash equivalents at beginning of period	29,888	36,431

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Cash and cash equivalents at end of period	\$ 22,265	\$ 33,954
Supplemental disclosure of cash flow information:		
Common stock issuance costs accrued, not paid	\$ 461	\$ —
Deferred purchase consideration	\$ 5,700	\$ —
Debt assumed as part of acquisition	\$ 13,421	\$ —
Common shares issued as part of acquisition	\$ 7,205	\$ —

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

CareDx, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

## 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. (“CareDx” or the “Company”) together with its subsidiary Allenex AB (“Allenex” or “Olerup”) and its subsidiaries, is a global transplant diagnostics company with product offerings along the pre- and post-transplant continuum. The Company focuses on discovery, development and commercialization of clinically differentiated, high-value diagnostic surveillance solutions for transplant patients. In post-transplant diagnostics, the Company offers AlloMap®, which is a heart transplant molecular test (“AlloMap”). In pre-transplant diagnostics, the Company offers Olerup SSP®, a set of Human Leukocyte Antigen (“HLA”) typing used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation.

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 to severe acute cellular rejection. Since 2008, the Company has sought to expand the adoption and utilization of its 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 its 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. The Company believes 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, the Company believes AlloMap can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. AlloMap has received 510(k) clearance from the U.S. Food and Drug Administration (the “FDA”) for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe acute cellular rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test. The Company is also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure®, its proprietary next-generation sequencing-based test to detect donor-derived cell-free DNA (“dd-cfDNA”) after transplantation. Through the acquisition of ImmuMetrix, Inc. (“IMX”), a privately held development-stage company working on dd-cfDNA-based solutions in transplantation and other fields, the Company added to its existing know-how, expertise, and intellectual property the ability to apply dd-cfDNA technology to the surveillance of transplant recipients, which has contributed to the development of AlloSure.

With the acquisition of Allenex, the Company develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP is used to type HLA alleles based on the sequence specific primer (“SSP”) technology and has a market in Europe and selected other markets for pre-transplant solutions. The Company also offers XM-ONE®, a standardized test that identifies a patient’s antigens against HLA Class I or Class II, as well as antibodies against a donor’s endothelium. This cross-match test has primarily been used prior to kidney transplants. The Company, by way of Olerup’s sales and distribution agreement with Conexio Genomics (since acquired by Illumina, Inc.) offers a complete product range for sequence-based typing (“SBT”) of HLA alleles. SBT Resolver is a test kit for sequence based HLA typing, while AssignSBT is the companion software for sequence analysis. Because this SBT technology

is primarily used in larger typing laboratories, it is a good complement to SSP technology, which is more appropriate for smaller centers. In 2014, Olerup began active development of a new HLA typing product, QTYPE, that uses real-time polymerase chain reaction (“PCR”) methodology. QTYPE was commercially launched at the end of September 2016. This technology is based on SSP technology, which Olerup was well-situated to develop.

The Company’s headquarters are in Brisbane, California; and primary operations are in Brisbane and Stockholm, Sweden; and it operates in two reportable segments.

#### 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 \$197.1 million at September 30, 2016. As of September 30, 2016, the Company had cash and cash equivalents of \$22.3 million, and \$26.8 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. Allenex had 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 aggregate purchase consideration paid by the Company was approximately \$34.1 million and consisted of (i) \$26.9 million of cash, of which approximately \$5.7 million was deferred purchase consideration and payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB (collectively, the “Majority Shareholders”) by no later than March 31, 2017, and (ii) the issuance of 1,375,029 shares of the Company’s common stock valued at \$7.2 million. Of the total cash consideration, \$8.0 million of cash payable to the Majority Shareholders was deposited into an escrow account by the Company and subsequently invested in the Company by the Majority Shareholders through a purchase of the Company’s equity securities in a financing that was completed on June 15, 2016 (the “Subsequent Financing”). Upon the completion of the Subsequent Financing, certain contingencies in the Conditional Share Purchase Agreements were waived, and the deferred purchase consideration is due to the Majority Shareholders by no later than March 31, 2017. The Company determined at the date of the acquisition that these contingencies would be waived. The Company intends to complete compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. On June 8, 2016, the Company delisted Allenex’s common stock from Nasdaq Stockholm. See Note 5 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. Each Unit was comprised of (i) one share of the Company’s 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 the Company’s common stock. The aggregate gross proceeds to the Company from the Private Placement were approximately \$14.2 million. Concurrently, the Company also entered into commitment letters (the “Commitment Letters”) pursuant to which the Majority Shareholders purchased the Company’s equity securities in the Subsequent Financing. 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, including submitting the Private Placement to the Company’s stockholders for approval pursuant to the rules of The NASDAQ Stock Market LLC (the “Requisite Stockholder Approval”), which was obtained on June 16, 2016, and granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3. Upon obtaining the Requisite Stockholder Approval on June 16, 2016, each share of Series A Preferred was converted into one share of the Company’s common stock. On May 27, 2016, the Company filed a registration statement on Form S-3 (the “2016 Form S-3”) with the Securities and Exchange Commission (the “SEC”) to register for resale the shares of common stock issued or issuable upon conversion of the Series A Preferred and upon exercise of the warrants sold in the Private Placement. The 2016 Form S-3 was declared effective by the SEC on July 12, 2016. On June 15, 2016, the Company completed the Subsequent Financing for the sale of an additional 334,169 Units to the Majority Shareholders. The aggregate gross proceeds to the Company from the Subsequent Financing were \$8.0 million. Securities issued in the Subsequent Financing were issued and sold at the same price and upon substantially the same terms as the Units issued in the Private Placement. See Note 12 for more detail about the Private Placement and Subsequent Financing.

On September 26, 2016, the Company completed an underwritten public offering pursuant to which the Company issued and sold an aggregate of 2,250,000 shares of common stock at a public offering price of \$4.00 per share (the “Public Offering”). The aggregate gross proceeds were \$9.0 million, and \$7.8 million net of issuance costs.

The Company will require additional financing and/or refinancing of its current debt obligations to fund working capital, repay debt and pay its obligations. 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. Additional financing might include one or more offerings and one or more of a combination of discounted or at-the-market common stock, securities convertible into or exchangeable for shares of common stock, warrants or other rights to purchase or acquire

common stock.

Due to insufficient working capital in Allenex, a debt covenant in the Company's Term Loan Facility Agreement (the "Term Loan Facility") with Danske Bank A/S ("Danske") relating to maintaining an adequate leverage ratio was violated at each of June 30, 2016 and September 30, 2016. The Company obtained waivers from Danske for each of these violations of the debt covenant. While Allenex received waivers from Danske for these violations as of June 30, 2016 and September 30, 2016, due to continuing liquidity matters, Allenex has determined that it is not probable that it will be in compliance with this covenant in future periods. For these reasons, the long-term debt due to Danske is classified as a current liability in the condensed consolidated balance sheet as of September 30, 2016. Additionally, if the loan was no longer available or Danske demanded repayment of the debt, the Company may not have sufficient capital to operate and there would be substantial doubt about its ability to continue as a going concern.

On June 10, 2016, CMS announced its proposed gapfill pricing from the MACs ("Medicare Administrative Carriers") for patients covered by Medicare, which initially proposed that reimbursement for AlloMap be reduced from the current rate of \$2,821 to \$732. On September 30, 2016, CMS published a final gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would be \$1,921. This reimbursement rate, determined by gapfill submissions from the MACs, is open to



reconsideration submissions until October 31, 2016. The Company submitted a request for reconsideration of the reimbursement rate determined by the MACs. Given the significant portion of payments to the Company represented by Medicare, any resulting lower test revenue would have a material adverse effect on the Company's operations and financial condition.

Absent additional and sufficient financing, in addition to Danske not demanding repayment of the outstanding debt, the Company will likely exhaust its cash and cash equivalents in the quarter ending March 2017 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. Moreover, the Company does not believe that it will have sufficient cash to meet its projected operating requirements for the next 12 months from the condensed consolidated balance sheet date included in the Quarterly Report on Form 10-Q unless it raises additional financing. If the Company is unsuccessful in its efforts to raise outside financing or refinance the Company's indebtedness 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 consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), and follow the requirements of the 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 consolidated 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 and nine months ended September 30, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated. Since the Company owns less than 100% of the shares of Allenex, the Company records net loss attributable to noncontrolling interest in its condensed consolidated statements of operations equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties.

## Use of Estimates

The preparation of unaudited condensed consolidated 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 consolidated 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) inventory valuation, (vii) the valuation of warrants, Series A Preferred, and common stock issued in the Private Placement and Subsequent Financing, (viii) the fair value of contingent consideration in a business acquisition, (ix) the fair value of embedded derivatives, (x) measurement of stock-based compensation expense, (xi) the determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (xii) any impairment of long-lived assets, including in-process technology and goodwill, and (xiii) 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. As of September 30, 2016, these financial instruments were held in Company accounts at eight 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 primarily in the U.S. and billed to various third-party payers, and sales of Olerup SSP products to distributors, strategic partners and end customers in Europe, Middle East and Africa, the U.S., and Latin America and other. The Company has not experienced any significant credit losses and does not generally require collateral on receivables. For the nine months ended September 30, 2016 and 2015, approximately 45% and 50%, respectively, of testing revenue was derived from Medicare. No other payers represented more than 10% of testing revenue for these periods. Product revenue accounted for 30% and 24% of total revenue for the three and nine months ended September 30, 2016, respectively. At September 30, 2016, Medicare accounted for approximately 20% of accounts receivable. At December 31, 2015, Medicare and Aetna accounted for approximately 35% and 21% of accounts receivable, respectively. No other payers or customers represented more than 10% of accounts receivable at either September 30, 2016 or 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

Amortizable intangible assets include customer relationships, developed technology, trademarks, contracts and in-process research and development (“IPR&D”) identified intangible assets acquired as part of a business combination. Intangible assets subject to amortization are amortized over their estimated useful lives. Acquired intangible assets with indefinite useful lives are related to 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 research and development 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 an 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 recognizes an impairment loss when the total estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. 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 two reportable segments associated with the delivery of diagnostic tests and the development and commercialization of diagnostic products. In the event the Company determines that it is more likely than not that the carrying value of a 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.

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

During the three and nine months ended September 30, 2016, the Company changed its method of revenue recognition from one and three of its payers, respectively, from the cash basis to the accrual basis based on its consistent history of obtaining timely reimbursement from such payers. The Company also changed its method of revenue recognition from the cash basis to the accrual basis with respect to one and four of its payers, respectively, during the three and nine months ended September 30, 2015 based on the Company's consistent history of obtaining timely reimbursement from such payers. The impact of this change in accounting estimate was to increase revenues by \$0.1 million and \$0.4 million for the three and nine months ended September 30, 2016, respectively, and to reduce net loss per share by less than one cent and \$0.02 for the three and nine months ended September 30, 2016, respectively. For the three and nine months ended September 30, 2015, the impact of this change in accounting estimate was to increase revenues by \$0.1 million and \$0.2 million, respectively, and to reduce net loss per share by less than one cent for each of the three and

nine months ended September 30, 2015.

#### Product Revenue

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when persuasive evidence of an arrangement exists, the product is complete and tested and has been shipped or delivered, as required to transfer title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and the Company does not have significant obligations for future performance. When collectability is not reasonably assured, the Company defers the revenue until the cash is received. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts given to the buyer.

11

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## Collaboration, License and Other Revenue

The Company has generated 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 its 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 revenue connected with milestones during the three and nine months ended September 30, 2016 and 2015.

## 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 on-site, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Costs associated with performing tests (except royalties) are recorded as the test is processed regardless of whether and when the testing revenue is recognized with respect to that test. As a result, the Company's cost of testing as a percentage of revenue may vary significantly from period to period because the Company does 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.

## Cost of Product

Cost of product reflects the aggregate costs incurred in delivering the Company's products to customers. The components of cost of product are materials costs, manufacturing and kit assembly costs, direct labor costs, including equipment and infrastructure expenses associated with preparing kitted products for shipment, shipping, and allocated overhead including rent, information technology, equipment depreciation, and utilities. Cost of product also includes amortization of acquired developed technology and adjustments to inventory values, including write-down of impaired, slow moving or obsolete inventory.

## 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 Financial Accounting Standards Board (“FASB”) Accounting Standards Codification Topic 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 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 using 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 using the Company's expectations and historical data. The fair value of each restricted stock unit is calculated based upon the closing price of the Company's common stock on the date of the grant.

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

On April 14, 2016 and June 15, 2016, the Company completed the Private Placement and Subsequent Financing, respectively (as described in Note 13), which included the issuance of freestanding warrants to certain accredited investors and placement agents to purchase shares of the Company's common stock. The exercisability of the warrants was contingent upon the receipt of the Requisite Stockholder Approval, which occurred on June 16, 2016.

The freestanding warrants issued pursuant to the Private Placement and Subsequent Financing are contingently redeemable and classified as liabilities on the condensed consolidated balance sheet and recorded at their estimated fair value. The warrants were remeasured on September 30, 2016 and will be remeasured at each subsequent balance sheet date with changes recorded in change in estimated fair value of common stock warrant liability on the condensed consolidated statements of operations.

### Foreign Currency Translation

The functional currency of the Company's foreign subsidiaries is the local currency for each entity, including the Swedish Krona and the Euro. The revenue and expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Assets and liabilities have been translated at the rates of exchange on the balance sheet date. The resulting cumulative translation adjustments are reported in other comprehensive loss. Foreign currency transaction gains and losses are recognized in current operations.

### Comprehensive Loss

Comprehensive loss consists of net loss and other gains and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net income or loss. For the Company, such items consist of foreign currency translation losses.

### Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update (“ASU”) 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 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 No. 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 (i) prospectively to all arrangements entered into or materially modified after the effective date or (ii) 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 date of adoption.

In November 2015, the FASB issued ASU No. 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 on January 1, 2017 with early adoption permitted as of the beginning of any interim or annual reporting period, and it may be applied either (i) prospectively to all deferred tax assets and liabilities, or (ii) 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 is required to 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. As of September 30, 2016, the Company had a net noncurrent deferred tax liability of approximately \$6.9 million attributable to the acquisition of Allenex. The adoption of this guidance did not result in any material impact on the Company's condensed financial statements.

In February 2016, the FASB issued ASU No. 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 No. 2016-09, Improvements to Employee Share-Based Payment Accounting (Topic 718), to simplify various aspects of share-based payment accounting and presentation. The new standard requires entities to record all of the tax effects related to share-based payments at settlement (or expiration) through the income statement. This will require the Company to reclassify tax benefits in excess of compensation cost ("windfalls") and tax deficiencies ("shortfalls") to the extent of previous windfalls from Capital in excess of par value to Provision for income tax expense. This change is required to be applied prospectively to all excess tax benefits and tax deficiencies resulting from settlements after the date of adoption of the ASU. The standard eliminates the requirement to delay recognition of a windfall tax benefit until it reduces current taxes payable. This change is required to be applied on a modified retrospective basis, with a cumulative-effect adjustment to opening retained earnings. In addition, all income tax-related cash flows resulting from share-based payments are required to be reported as operating activities on the statement of cash flows as opposed to the current presentation as an inflow from financing activities and an outflow from operating activities. Either prospective or retrospective transition of this provision is permitted. Finally, the standard clarifies that all cash payments made to taxing authorities on the employees' behalf for withheld shares should be presented as financing activities on the statement of cash flows. This change will be applied retrospectively. This guidance is effective for annual reporting periods beginning after December 15, 2016 and interim periods within that reporting period. Early adoption is permitted, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company is continuing to review the requirements of this standard and any potential

impact it may have on the Company's financial position, results of operations, or cash flows.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing ("ASU 2016-10"). In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net) ("ASU 2016-08"). These amendments provide additional clarification and implementation guidance on the previously issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASU 2014-09"), 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 required 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 (i) retrospectively to each prior period presented, or (ii) 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.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments, to reduce the diversity in practice with respect to the presentation of certain cash flows. The ASU is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. Adoption of the ASU is retrospective. The Company is currently assessing the impact of the ASU on its condensed consolidated 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Numerator:</b>				
Net loss attributable to CareDx, Inc. used to compute basic				
net loss per share	\$ (3,764 )	\$ (3,489 )	\$ (23,989 )	\$ (8,945 )
Less: Gain on private placement warrants	(1,386 )	—	—	—
Net loss attributable to CareDx, Inc. used to compute diluted				
net loss per share	\$ (5,150 )	\$ (3,489 )	\$ (23,989 )	\$ (8,945 )
<b>Denominator:</b>				
Weighted-average shares used to compute basic net loss per				
share attributable to CareDx, Inc.	19,098,626	11,890,057	14,894,218	11,846,921
Add: Private placement warrant shares	382,798	—	—	—
Weighted-average shares used to compute diluted				
net loss per share attributable to CareDx, Inc.	19,481,424	11,890,057	14,894,218	11,846,921
Net loss per share attributable to CareDx, Inc.:				
Basic	\$ (0.20 )	\$ (0.29 )	\$ (1.61 )	\$ (0.76 )
Diluted	\$ (0.26 )	\$ (0.29 )	\$ (1.61 )	\$ (0.76 )

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Shares of common stock subject to outstanding options	1,851,232	1,510,479	1,851,232	1,510,479
Shares of common stock subject to outstanding common stock warrants	283,415	301,069	3,261,502	301,069
Restricted stock units	314,115	110,300	314,115	110,300
Total common stock equivalents	2,448,762	1,921,848	5,426,849	1,921,848

The Company issued 2,959,300 shares of preferred stock pursuant to the Private Placement and Subsequent Financing, which were completed on April 14, 2016 and June 15, 2016, respectively. All of the preferred stock was converted to common stock upon receipt of the Requisite Stockholder Approval on June 16, 2016. As of September 30, 2016, there was no preferred stock outstanding. On September 26, 2016, the Company completed the Public Offering pursuant to which the Company issued and sold an aggregate of 2,250,000 shares of common stock.

#### 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 1 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):

	September 30, 2016			Total
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Balance
<b>Assets</b>				
Money market funds	\$19,039	\$ —	\$ —	\$19,039
<b>Liabilities</b>				
Contingent consideration	\$—	\$ —	\$ 526	\$526
Warrants to purchase common stock	—	—	6,736	6,736
Total liabilities	\$—	\$ —	\$ 7,262	\$7,262

	December 31, 2015			Total
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Balance
<b>Assets</b>				
Money market funds	\$28,774	\$ —	\$ —	\$28,774
<b>Liabilities</b>				
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	Warrants to			
Consideration	Purchase			
Liability	Common Stock		Total	

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Balance as of December 31, 2015	\$948	—	\$948
Warrants issued in conjunction with Private Placement and Subsequent Financing on April 14, 2016 and June 15, 2016, respectively, and Placement Agent Warrants	—	4,957	4,957
Change in estimated fair value	(422)	1,779	1,357
Balance as of September 30, 2016	\$526	\$ 6,736	\$7,262

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 each of September 30, 2016 and December 31, 2015, money market funds were included on the balance sheets in cash and cash equivalents.

16

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Contingent consideration - As of September 30, 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 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 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 estimate at September 30, 2016 and December 31, 2015 of the probability of success, which management estimated to be 65%. 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 at 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 fair value of the contingent consideration decreased by \$0.1 million and \$0.4 million in the three and nine months ended September 30, 2016, respectively, as a result of the decreases in the fair market value of the Company's common stock price during these periods. There was no change during these periods in management's 65% estimate of the probability of completing the specified commercial tests.

Warrants to purchase common stock – As of September 30, 2016, the Company had warrants to purchase 2,978,087 shares of common stock outstanding that it issued to certain accredited investors and its placement agents following the closing of the Private Placement on April 14, 2016 and Subsequent Financing on June 15, 2016. The common stock warrants are classified as liabilities within Level 3. The Company utilized a binomial-lattice pricing model (the Monte Carlo simulation model) that involved a market condition to estimate the fair value of the warrants. The application of the Monte Carlo simulation model required the use of a number of complex assumptions including the Company's stock price, expected life of the warrants, stock price volatility determined from the Company's historical stock prices and stock prices of peer companies in the diagnostics industry, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of the warrants. The estimated fair value of the warrants was subsequently remeasured at September 30, 2016, and the change in estimated fair value of common stock warrant liability was recorded on the Company's condensed consolidated statements of operations.

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

The carrying values of the Company's debt approximates its fair value at September 30, 2016 because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The estimated fair value of the Company's debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input.

## 5. BUSINESS COMBINATION

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. The acquisition of Allenex creates an international transplant diagnostics company with product offerings along the pre- and post-transplant continuum. The combined company has a presence and direct distribution channels in the U.S. and Europe, with additional third party distributors in Europe and other markets around the world. 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 aggregate purchase consideration paid by the Company was approximately \$34.1 million and consisted of (i) \$26.9 million of cash, of which approximately \$5.7 million was deferred purchase consideration payable to the Majority Shareholders by no later than March 31, 2017, and (ii) the issuance of 1,375,029 shares of the Company's common stock valued at \$7.2 million. Of the total cash consideration, \$8.0 million of cash payable to the Majority Shareholders was deposited into an escrow account by the Company and subsequently invested in the Company by the Majority Shareholders through a purchase of the Company's equity securities in the Subsequent Financing. Upon the completion of the Subsequent Financing, certain contingencies in the Conditional Share Purchase Agreements were waived, and the deferred purchase consideration is due to the Majority Shareholders by no later than March 31, 2017. The Company determined at the date of the acquisition that these contingencies would be waived. The Company intends to complete compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. On June 8, 2016, the Company delisted Allenex's common stock from Nasdaq Stockholm.

The cash portion of the acquisition purchase price was paid from the Company's general working capital. The acquisition of Allenex required, and the Company obtained, a consent from East West Bank (the "Consent"), as the lender under the Company's Loan and Security Agreement, dated January 30, 2015, as amended (the "Loan Agreement"). The Consent was contingent upon the closing of a private placement financing for aggregate cash proceeds of at least \$12.0 million and separately depositing into an escrow account cash of \$8.0 million relating to a commitment by the Majority Shareholders to purchase the Company's equity securities in the Subsequent Financing, all of which occurred on April 14, 2016. Pursuant to the Consent, the Company is also required to raise another \$20.0 million through one or more equity financings by March 31, 2017, of which \$9.0 million was raised on September 26, 2016 in the Public Offering, prior to paying the approximately \$5.7 million of deferred purchase price consideration to the Majority Shareholders, which has a carrying value of \$5.9 million as of September 30, 2016.

The Company has accounted for this transaction as a business combination in exchange for total consideration of approximately \$34.1 million. Under business combination accounting, the total purchase price was allocated to Allenex's net tangible and identifiable intangible assets based on their estimated fair values as of April 14, 2016 as set forth in the table below. The excess of the purchase price over the net tangible and identifiable intangible assets was recorded as goodwill. The preliminary allocation of the purchase price was based upon a valuation, and the Company's estimates and assumptions are subject to change. The primary areas of the purchase price allocation that are not yet finalized relate to valuation of acquired inventory, income and non-income based taxes and residual goodwill. Total acquisition-related expenses for the three and nine months ended September 30, 2016 were \$0.5 million and \$4.3 million, respectively.

The amounts recorded for certain assets and liabilities are preliminary in nature and are subject to adjustment as additional information is obtained about the facts and circumstances that existed as of the acquisition date. The final determination of the fair values of certain assets and liabilities will be completed within the measurement period of up to one year from the acquisition date, as permitted under U.S. GAAP. Any potential adjustments made could be material in relation to the values presented in the table below.

The preliminary fair values of the assets acquired and liabilities assumed are as follows (in thousands):

	Total
Cash	\$596
Accounts receivable	1,608
Prepaid and other assets	1,092
Inventory	9,636
Property, plant and equipment	1,057
Intangible assets	31,560
Goodwill	16,940
Deferred tax liability	(8,505 )
Assumed liabilities	(19,910)
Total preliminary acquisition consideration	\$34,074

The fair value of the remaining 1.7% of noncontrolling interest in Allenex was estimated to be approximately SEK 5,100,000, or approximately \$0.6 million in U.S. dollars, as of April 14, 2016. The fair value of the noncontrolling interest was determined based on the number of outstanding shares comprising the noncontrolling interest and Allenex's stock price of SEK 2.48 per share as of the acquisition date. The noncontrolling interest was presented as a component of stockholders' equity on the Company's condensed consolidated balance sheets. During the three months

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ended September 30, 2016, the Company recorded a measurement period adjustment related to inventory, tax and accruals recorded in the preliminary purchase price allocation, with a corresponding adjustment to goodwill.

Noncontrolling interest as of September 30, 2016 was as follows (in thousands):

	September 30, 2016
Beginning noncontrolling interest	\$ —
Noncontrolling interest investment	634
Foreign currency effect	(2 )
Loss attributable to noncontrolling interest	(58 )
Ending noncontrolling interest	\$ 574

The following table presents details of the identified intangible assets acquired at the acquisition date (in thousands):

	Estimated	Estimated Useful
	Fair Value	Life (Years)
Customer relationships	\$ 12,650	15
Developed technology	11,650	10
Acquired in-process technology	4,510	15
Trademarks	2,260	15
Acquired contracts	490	2
Total	\$ 31,560	

Goodwill recorded from the acquisition of Allenex is primarily related to expected synergies. The goodwill resulting from the acquisition is not deductible for tax purposes.

Allenex's post-acquisition results of operations for the period from April 14, 2016 through September 30, 2016 are included in the Company's condensed consolidated statements of operations. Since the acquisition date, total revenue of Allenex for the period from April 14, 2016 through September 30, 2016 was \$7.2 million. Net loss for Allenex for the period from April 14, 2016 through September 30, 2016 was \$3.4 million, including \$1.1 million of costs for the amortization of acquisition related intangible assets, net of tax effects.

#### Pro Forma Impact of the Acquisition of Allenex

The following table presents pro forma results of operations and gives effect to the Allenex transaction as if the transaction had been consummated on January 1, 2015. The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or operating efficiencies resulting from combining the two companies (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Revenue:</b>				
Testing revenue	\$ 8,613	7,007	22,310	21,147
Product revenue	3,754	3,806	11,642	11,867
Other revenue	108	237	396	593
<b>Total revenue</b>	<b>\$ 12,475</b>	<b>11,050</b>	<b>34,348</b>	<b>33,607</b>
Net loss	\$ (2,491 )	(4,563 )	(17,597 )	(13,091 )

The unaudited pro forma financial information for the three and nine months ended September 30, 2016 and 2015 is prepared using the acquisition method of accounting and has been adjusted to give effect to the pro forma events that

are: (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) expected to have a continuing impact on the combined results. The pro forma adjustments directly attributable to the acquisition exclude acquisition-related expenses of \$4.3 million and debt financing costs of \$2.9 million relating to a six-month bridge loan with Oberland Capital SA Davos LLC (“Oberland”) that did not materialize, together with the consequential tax effects.

## 6. GOODWILL AND INTANGIBLE ASSETS

## Goodwill

Goodwill is recorded when the purchase price of an acquisition exceeds the fair value of the net tangible and identified intangible assets acquired.

The following table presents details of the Company's goodwill for the nine months ended September 30, 2016 (in thousands):

	CareDx	Allenex	Total
Balance as of December 31, 2015	\$12,005	\$—	\$12,005
Goodwill acquired	—	16,940	16,940
Foreign currency translation adjustments	—	(898 )	(898 )
Balance as of September 30, 2016	\$12,005	\$16,042	28,047

The gross carrying amount of goodwill may change due to the effects of foreign currency fluctuations as a result of acquiring an entity with a functional currency other than the U.S. dollar.

## Intangible Assets

The following tables present details of the Company's intangible assets as of September 30, 2016 (in thousands):

	September 30, 2016				Weighted Average Remaining Useful Life (In Years)
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	
<b>Intangible assets with finite lives:</b>					
Customer relationships	\$12,650	\$ (377 )	\$ (678 )	\$ 11,595	14.3
Developed technology	11,650	(526 )	(623 )	10,501	9.3
Acquired technology – QTYPE (a)	4,510	—	(241 )	4,269	14.3
Trademarks	2,260	(107 )	(121 )	2,032	14.3
Acquired contracts	490	(67 )	(26 )	397	1.5
Total intangible assets with finite lives	31,560	(1,077 )	(1,689 )	28,794	
Acquired in-process technology dd-cfDNA	6,650	—	—	6,650	—
Total intangible assets	\$38,210	\$ (1,077 )	\$ (1,689 )	\$ 35,444	

(a) QTYPE was initially classified as acquired in-process technology on acquisition of Allenex on April 14, 2016, but reclassified as an intangible asset with a finite life when QTYPE was commercially launched at the end of September 2016.

The gross carrying amount of intangible assets and the related amortization expense of intangible assets may change due to the effects of foreign currency fluctuations as a result of acquiring an entity with a functional currency other than the U.S. dollar. Amortization expenses were \$0.6 million and \$1.1 million for the three and nine months ended September 30, 2016, respectively, of which \$0.3 million and \$0.6 million were amortized to cost of product for the three and nine months ended September 30, 2016, respectively. There was no amortization recorded for the three and nine months ended September 30, 2015, as the Company only had an intangible asset related to acquired in-process technology with an indefinite useful live in that period.

Intangible assets are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of product and sales and marketing. Acquired IPR&D of \$6.7 million has not reached technological feasibility as of September 30, 2016 and is therefore not subject to amortization. As such, the Company excluded amortization of acquired in-process technology from the future amortization expense table below.



The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2016 (in thousands):

Years Ending December 31,	Cost of Product	Sales and Marketing	Total
Remainder of 2016	\$416	\$ 240	\$656
2017	1,666	959	2,625
2018	1,502	959	2,461
2019	1,435	959	2,394
2020	1,435	959	2,394
2021	1,435	959	2,394
Thereafter	7,237	8,633	15,870
Total future amortization expense	\$15,126	\$ 13,668	\$28,794

## 7. INVENTORIES

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

	September 30, 2016	December 31, 2015
Finished goods	\$ 6,244	\$ 237
Raw materials	1,200	529
Total inventory	\$ 7,444	\$ 766

## 8. ACCRUED AND OTHER LIABILITIES

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

	September 30, 2016	December 31, 2015
Debt financing fees	\$ 1,384	\$ —
Common stock issuance costs	333	—
Transaction related fees	685	589
Software implementation costs	302	—
Accrued interest payable on debt	832	—
Tax, audit and compliance related fees	662	89
Test sample processing fees	490	426
Accrued overpayments and refunds	293	163
Clinical studies	1,196	756

Accrued inventory payable	324	—
Deferred rent – current portion	300	258
Capital leases – current portion	175	71
Other accrued expenses	1,228	540
Total accrued and other liabilities	\$ 8,204	\$ 2,892

## 9. COMMITMENTS AND CONTINGENCIES

### Royalty Commitments

In November 2004, the Company entered into a license agreement with Roche Molecular Systems, Inc. (“Roche”), that grants the Company the right to use certain Roche technology relating to polymerase chain reaction (“PCR”), and quantitative real-time PCR, in clinical laboratory services, including in connection with AlloMap. This is a non-exclusive license agreement in the U.S. 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. Commencing as of July 1, 2011, the Company fully accrues the unpaid royalties on its balance sheets, and the amount of the unpaid royalties is reflected as an expense in the Company’s statements of operations in the periods revenue is recorded and 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 to Roche in connection with 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 condensed consolidated statements of operations. For each of the three months ended September 30, 2016 and 2015, royalty expenses in connection with the Roche agreement were \$0.3 million. For each of the nine months ended September 30, 2016 and 2015, royalty expenses in connection with the Roche agreement were \$0.8 million.

#### Operating Lease

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in California, Pennsylvania and Stockholm, Sweden. The lease for the Company's facility in Vienna, Austria is on a month-to-month basis. The leases expire at various dates through 2020. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

As of September 30, 2016, future minimum lease payments due under operating leases were as follows (in thousands):

Years Ending December 31,	Amount
Remainder of 2016	\$ 507
2017	2,044
2018	2,017
2019	2,003
2020	1,964
2021 and thereafter	—
<b>Total future minimum lease payments</b>	<b>\$ 8,535</b>

#### Contingencies

On April 25, 2016, Oberland filed a breach of contract claim against the Company in the Supreme Court of the State of New York, County of New York (the "Oberland Complaint"), alleging, among other things, that the Company breached certain provisions of the amended and restated commitment letter and the restated fee letter that it entered into with Oberland on February 8, 2016. Pursuant to the Oberland Complaint, Oberland is seeking damages against the Company in the amount of at least \$1.4 million, plus costs and expenses, including the fees and expenses of Oberland's attorneys. On July 15, 2016, the Company filed an answer and made counterclaims against Oberland (the

“Answer”), generally denying the claims asserted by Oberland in the Oberland Complaint and asserting fraudulent inducement and breach of contract counterclaims against Oberland. Pursuant to the Answer, the Company is seeking dismissal of the Oberland Complaint in its entirety, rescission of all agreements with Oberland and damages of not less than \$1.3 million, together with interest and punitive damages, if deemed appropriate under applicable law, and costs and disbursements of the action, including reasonable attorneys’ fees. On August 4, 2016, Oberland filed a motion to dismiss the Company’s counterclaims and affirmative defenses asserted in the Answer. Oral arguments for this motion are scheduled for December 8, 2016. The Company believes that it has meritorious defenses to the claims asserted in the Oberland Complaint and that the counterclaims asserted by it in the Answer have merit. The Company intends to vigorously defend against the claims asserted by Oberland and vigorously pursue the counterclaims set forth in the Answer. However, there is no guarantee that the Company will prevail in this suit or recover damages from its counterclaims or other relief if it does prevail. As a result, the Company has accrued the amount being claimed by Oberland of \$1.4 million.

In addition, on June 15, 2016, the Company received a letter from Nasdaq OMX Stockholm AB (the “Exchange”) regarding the Company’s compliance with the requirements of the Nasdaq Stockholm Takeover Rules (the “Takeover Rules”) and good practice in the securities market in Sweden in connection with the Company’s recently completed acquisition of Allenex AB. The Exchange

concluded that the Company violated certain technical provisions of the Takeover Rules and acted contrary to good practice in the securities market in Sweden, and gave the Company the opportunity to submit the Company's views before it decided whether to refer the matter to its Disciplinary Committee. On July 11, 2016, the Company submitted a response, which was considered by the Exchange in making a final determination whether to refer the matter to its Disciplinary Committee for further assessment. On September 21, 2016, the Company received notice from the Exchange that, by letter dated September 20, 2016 from the Exchange to its Disciplinary Committee, the Exchange has referred the matter to the Disciplinary Committee and is seeking a ruling from the Disciplinary Committee regarding disciplinary sanction. The Disciplinary Committee has the authority to impose a fine and/or sanctions. The Company has been granted an opportunity to submit documents in support of its position to the Disciplinary Committee. This submission must be completed by November 24, 2016. A hearing before the Disciplinary Committee is currently scheduled for December 9, 2016. Takeover Rules authorize the Exchange to impose a special fine ranging between SEK 50,000 (approximately \$6,000 in U.S. dollars) and SEK 100 million (approximately \$12.0 million in U.S. dollars). The Company cannot predict the outcome of any Disciplinary Committee review. Accordingly, no provisions have been recorded related to this violation. An adverse determination by the Disciplinary Committee could have a material adverse effect on the Company.

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

## 10. 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 agreed to 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 percentage 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. The Company sold the shares of DHT common stock 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 of the AlloMap test began in the EEA in June 2014. Total revenues recognized from this arrangement for the three months ended September 30, 2016 and 2015 were \$2,000 and \$8,000, respectively. Total revenues recognized from this arrangement for the nine months ended September 30, 2016 and 2015 were \$12,000 and \$41,000, 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 to certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company in an amount equal to 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. Initially, the Company recognized royalty revenues when earned. Commencing with the fourth quarter of 2015, the Company recognizes royalty revenues when payments are received as it was assessed that collection was not reasonably assured prior to receipt of payment. Royalty revenues for the three months ended September 30, 2016 and 2015 were \$98,000 and \$96,000, respectively. Royalty revenues for the nine months ended September 30, 2016 and 2015 were \$0.2 million and \$0.3 million, respectively, and are included in collaboration and license revenue on the condensed consolidated statements of operations. The Company had no receivable balance from CDX at September 30, 2016 and December 31, 2015.

## 11. DEBT

On January 30, 2015, the Company entered into the Loan Agreement with East West Bank as the lender (“the Lender”), which provides the Company with 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 began 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 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 both September 30, 2016 and December 31, 2015 were \$0.2 million. Debt discount and issuance costs, non-current, as of both September 30, 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 5.00% 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 principle by the Lender 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 September 30, 2016, the Company was in compliance with its debt covenants under the Loan Agreement.

In April 2016, the Lender consented to the acquisition of Allenex by the Company (the “Consent”). The Consent was contingent upon the closing of a private placement financing for aggregate cash proceeds of at least \$12.0 million and separately depositing into an escrow account cash of \$8.0 million relating to a commitment by the Majority

Shareholders to purchase the Company's equity securities in the Subsequent Financing, all of which occurred on April 14, 2016. Pursuant to the Consent, the Company is also required to raise another \$20.0 million through one or more equity financings by March 31, 2017, of which \$9.0 million was raised on September 26, 2016 in the Public Offering, prior to paying the \$6.2 million of deferred purchase price consideration to the Majority Shareholders, which had a carrying amount of \$5.9 million as of September 30, 2016.

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 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, but in the interim a charge of \$2.9 million was recorded in the nine months ended September 30, 2016 to expense financing costs associated with this bridge loan (see the Oberland Complaint in Note 9). These costs have been included as a component of other expense on the Company's condensed consolidated statements of operations.

On May 12, 2016, the Company entered into a First Amendment to Loan and Security Agreement (the "First Amendment"), which amended the Loan Agreement. The First Amendment, among other things, amended the Loan Agreement by modifying certain financial covenants, adding an equity financing covenant, and restricting certain transactions between the Company and its subsidiaries. On June 27, 2016, the Company entered into a Second Amendment to Loan and Security Agreement (the "Second Amendment"). The Second Amendment, among other things, amended the Loan Agreement to permit certain transactions between the Company and its subsidiaries and to add intellectual property as collateral security.



On June 25, 2013, Allenex entered into the Term Loan Facility with Danske in an aggregate principal amount of up to SEK 71,000,000 (approximately \$8.3 million in U.S. dollars). The Term Loan Facility is available for utilization in advances of a minimum of SEK 5,000,000 (approximately \$0.6 million in U.S. dollars) and if more, integral multiples of SEK 1,000,000 (approximately \$0.1 million in U.S. dollars). The interest rate applicable to each advance shall be the percentage rate per annum calculated as the aggregate of (i) Stockholm Interbank Offered Rate (“STIBOR”) (as defined in the Term Loan Facility) and (ii) the Margin (as described in the Term Loan Facility) at 3% conditional on the fulfillment of certain criteria. In March 2015, Allenex entered into a first amendment to the Term Loan Facility, pursuant to which additional loans were granted. In August 2015, Allenex entered into a second amendment to the Term Loan Facility, pursuant to which the term of the Term Loan Facility was extended. In December 2015, Allenex entered into a waiver and amendment agreement relating to the Term Loan Facility, pursuant to which the change of control provision was waived and amended. In March 2016, Allenex entered into another amendment to the Term Loan Facility, which modified the repayment schedule for advances under the Term Loan Facility. Under this Term Loan Facility, SEK 63,500,000 (approximately \$7.4 million in U.S. dollars) was outstanding as of September 30, 2016, and a quarterly payment of SEK 1,500,000 (approximately \$0.2 million in U.S. dollars) is payable in the quarter ended December 31, 2016, and six quarterly payments of SEK 3,000,000 (approximately \$0.4 million in U.S. dollars) are payable in 2017 and the first half of 2018, and the remaining balance of SEK 44,000,000 (approximately \$5.1 million in U.S. dollars) is due in June 2018. Notwithstanding the repayment schedule provided by the Term Loan Facility, the full outstanding balance was reclassified to current liabilities due to the insufficient working capital in Allenex.

On June 18, 2015, Allenex also entered into a short term credit facility with Danske with total available credit of SEK 8,000,000 (approximately \$0.9 million in U.S. dollars). As of August 4, 2016, the available credit under the short term credit facility with Danske was increased to SEK 10,000,000 (approximately \$1.2 million in U.S. dollars). As of September 30, 2016, the total outstanding balance due to Danske under the short term credit facility was SEK 5,200,000 (approximately \$0.6 million in U.S. dollars), and is due on December 31, 2016, unless it is rolled over.

Due to insufficient working capital in Allenex, a debt covenant in the Term Loan Facility relating to maintaining an adequate leverage ratio was violated at each of June 30, 2016 and September 30, 2016. The Company obtained waivers from Danske for each of these violations of the debt covenant. While Allenex received waivers from Danske for each of these violations as of June 30, 2016 and September 30, 2016, due to continuing liquidity matters, Allenex has determined that it is not probable that it will be in compliance with this covenant in future periods. For these reasons, the long-term debt due to Danske was classified as a current liability in the condensed consolidated balance sheet as of September 30, 2016. Additionally, if the loan was no longer available or Danske demanded repayment of the debt, the Company may not have sufficient capital to operate.

On June 28, 2013, Allenex issued a SEK 9,400,000 (approximately \$1.1 million in U.S. dollars) subordinated promissory note to FastPartner AB (“FastPartner”), which provides for an annual interest rate of 10.00%. Principal payments of SEK 1,000,000 (approximately \$0.1 million in U.S. dollars) and accrued interest are payable quarterly at September 30, December 31, March 31 and June 30 and subject to working capital requirements that had not been met in fiscal years 2014 and 2015, nor the nine months ended September 30, 2016. The full amount of the promissory note was outstanding as of September 30, 2016, and will mature on December 31, 2016. However, pursuant to an intercreditor agreement among Allenex, Danske, FastPartner, Mohammed Al Amoudi and Olerup SSP AB, dated June 25, 2013 (the “Intercreditor Agreement”), until the Term Loan Facility with Danske is repaid, FastPartner may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex’s obligations under the subordinated promissory note, without Danske’s prior written consent. Allenex’s obligations under the promissory note is secured by a pledge of Allenex shares to FastPartner. As of September 30, 2016, FastPartner had beneficial ownership of 5% or more of the outstanding shares of the Company’s common stock and was considered a related party (See Note 17).

On June 28, 2013, Allenex issued a SEK 10,600,000 (approximately \$1.2 million in U.S. dollars) subordinated promissory note to Mohammed Al Amoudi, which provides for an annual interest rate of 10.00%. Principal payments of SEK 1,000,000 (approximately \$0.1 million in U.S. dollars) and accrued interest are payable quarterly at September 30, December 31, March 31 and June 30, subject to meeting certain requirements for working capital. The promissory note had an initial maturity date of June 28, 2016. On December 16, 2015, the maturity date was extended until December 31, 2016. However, pursuant to the Intercreditor Agreement, until the Term Loan Facility with Danske is repaid, Mohammed Al Amoudi may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. The full amount of the promissory note was outstanding as of September 30, 2016. Allenex's obligations under the promissory note is secured by a pledge of Allenex shares to Mohammed Al Amoudi. As of September 30, 2016, Mohammed Al Amoudi had beneficial ownership of 5% or more of the outstanding shares of the Company's common stock and was considered a related party (see Note 17).

On February 25, 2015, Allenex entered into a SEK 14,000,000 (approximately \$1.6 million in U.S. dollars) loan agreement with SSP Primers Aktieboulag, pursuant to which SEK 4,000,000 (approximately \$0.5 million in U.S. dollars) has been paid and SEK 5,000,000 (approximately \$0.6 million in U.S. dollars) is payable on February 27, 2017, and SEK 5,000,000 (approximately \$0.6 million in U.S. dollars) is payable on February 26, 2018. The loan amount outstanding as of September 30, 2016 is SEK 10,000,000 (approximately \$1.2 million in U.S. dollars) and has an annual interest rate of 3% payable in conjunction with each principal payment.

On December 29, 2015, Allenex issued a SEK 2,000,000 (approximately \$0.2 million in U.S. dollars) subordinated promissory note to FastPartner, a related party, which matures on December 31, 2016 and has an annual interest rate of 10.00%. Principal and accrued interest are payable on the maturity date and subject to working capital requirements that had not been met in fiscal year 2015, nor the nine months ended September 30, 2016. However, pursuant to the Intercreditor Agreement, until the Term Loan Facility with Danske is repaid, FastPartner may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. Allenex's obligations under the promissory note is secured by a pledge of Allenex shares to FastPartner. The full amount of subordinated promissory note was outstanding as of September 30, 2016.

On March 7, 2016, Allenex issued a SEK 4,000,000 (approximately \$0.5 million in U.S. dollars) subordinated promissory note to FastPartner, a related party, which matures on December 31, 2016 and has an annual interest rate of 10.00%. Principal and accrued interest are payable on the maturity date and subject to working capital requirements that had not been met during the nine months ended September 30, 2016. However, pursuant to the Intercreditor Agreement, until the Term Loan Facility with Danske is repaid, FastPartner may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. Allenex's obligations under the promissory note is secured by a pledge of Allenex shares to FastPartner. The full amount of the subordinated promissory note was outstanding as of September 30, 2016.

Interest of \$0.7 million on shareholder loans had been accrued as of September 30, 2016.

As of September 30, 2016, future debt maturities were as follows (in thousands):

Years Ending December 31,	Amount
Remainder of 2016	\$12,662
2017	6,984
2018	6,984
Total debt maturities	26,630
Less: debt discount and issuance costs	(232 )
Total debt maturities, net of debt discount and issuance costs	26,398
Less: current portion of long-term debt	(17,902)
Long-term debt, net carrying value	\$8,496

## 12. STOCKHOLDERS' EQUITY

On April 14, 2016, the Company completed a Private Placement transaction for the offering of 591,860 Units. Each Unit was comprised of: (i) one share of common stock, (ii) five shares of 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 gross proceeds to the Company from the Private Placement were approximately \$14.2 million, of which \$1.8 million was paid in satisfaction of placement agents, escrow agent, legal fees as well as other direct issuance costs. The Company and

certain stockholders representing a majority of the Company's outstanding shares of common stock entered into voting agreements on April 14, 2016, pursuant to which each stockholder agreed to vote certain of its shares of the Company's common stock in favor of granting the Company the Requisite Stockholder Approval.

Upon obtaining the Requisite Stockholder Approval on June 16, 2016, each share of Series A Preferred was converted into one share of the Company's common stock. In addition to the warrants issued to certain accredited investors in the Private Placement, on April 14, 2016, the Company issued warrants to purchase an aggregate of 200,000 shares of common stock to certain of its placement agents (the "Placement Agent Warrants"). All of the warrants issued in the Private Placement and the Placement Agent Warrants became exercisable once the Company obtained the Requisite Stockholder Approval on June 16, 2016.

The proceeds from the Private Placement were allocated between the common stock, preferred stock and warrants issued based on their relative fair values. The estimated fair values of the common stock, preferred stock and warrants were \$1.9 million, \$9.3 million and \$3.0 million, respectively, as of the transaction date. The warrants were recorded as a liability and are subject to ongoing remeasurement. The shares of Series A Preferred were initially recorded as temporary equity upon the closing of the Private Placement and subsequently reclassified to common stock after their conversion to common stock on June 16, 2016. See Note 13 for a description of the accounting of for the warrants.

Concurrent to the Private Placement, the Company also entered into Commitment Letters pursuant to which the Majority Shareholders agreed to purchase the Company's equity securities in the Subsequent Financing (as described in Note 1), which investment was completed on June 15, 2016. In the Subsequent Financing, the Company issued to the Majority Shareholders 334,169 Units, which consisted of (i) an aggregate of 334,169 shares of common stock, (ii) an aggregate of 1,670,845 shares of Series A Preferred that were all converted into shares of the Company's common stock upon obtaining the Requisite Stockholder Approval on June 16, 2016, and (iii) 1,002,507 warrants, each of which is exercisable for one share of the Company's common stock.

The proceeds from the Subsequent Financing were allocated between the common stock, preferred stock and warrants issued based on their relative fair values. The estimated fair values of the common stock, preferred stock and warrants were \$1.0 million, \$5.3 million and \$1.7 million, respectively, as of the transaction date. The warrants were recorded as a liability and are subject to ongoing remeasurement. The shares of Series A Preferred were initially recorded as temporary equity upon the closing of the Subsequent Financing and subsequently reclassified to common stock after their conversion to common stock on June 16, 2016.

Following the closing of the Private Placement, the Company agreed to a number of requirements, including submitting the Private Placement to the Company's stockholders for approval, which was obtained on June 16, 2016, and granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3. On May 27, 2016, the Company filed a registration statement on Form S-3 with the SEC to register for resale the shares of common stock issued or issuable upon conversion of the Series A Preferred and upon exercise of the warrants sold in the Private Placement. The Form S-3 was declared effective by the SEC on July 12, 2016.

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 the Private Placement and Subsequent Financing of the Company's common stock and the consummation of any private placement of its securities 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, the Company considered M.M. Dillon to be a related party. 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.

On September 26, 2016, the Company completed the Public Offering pursuant to which the Company issued and sold an aggregate of 2,250,000 shares of common stock at a public offering price of \$4.00 per share. The aggregate gross proceeds were \$9.0 million, and \$7.8 million net of issuance costs.

In connection with the Public Offering, in accordance with the anti-dilution provisions in the warrants issued in connection with the Private Placement and the Subsequent Financing, the exercise price of the 1,775,580 and 1,002,507 Private Placement and Subsequent Financing warrants, respectively, was adjusted from \$4.98 per share to \$4.00 per share, which was the price paid by investors in the Public Offering.

### 13. WARRANTS

The warrants issued in the Private Placement and the Placement Agent Warrants (as described in Note 12) are considered freestanding instruments that are contingently redeemable and classified as liabilities on the Company's

condensed consolidated balance sheet as of September 30, 2016. The warrants became exercisable to purchase common stock after the Company obtained the Requisite Stockholder Approval on June 16, 2016. Upon the closing of the Private Placement on April 14, 2016, the Company recorded an estimated fair value of \$3.3 million relating to warrants to purchase 1,975,580 shares of common stock that were issued in the Private Placement. The warrants were comprised of warrants to purchase 1,775,580 shares of common stock that were issued to certain accredited investors measured at an estimated fair value of \$3.0 million, and Placement Agent Warrants to purchase 200,000 shares of common stock measured at an estimated fair value of \$0.3 million. The Placement Agent Warrants were issued for services performed by placement agents as part of the Private Placement and were treated as equity issuance costs and were recorded in stockholders' equity on the Company's condensed consolidated balance sheets to offset the Private Placement proceeds allocated to the Series A Preferred and common stock.

Additional warrants were issued on June 15, 2016 to the Majority Shareholders upon the closing of the Subsequent Financing (as described in Note 12). The warrants issued in the Subsequent Financing were also considered freestanding instruments being accounted for using the same methodology as described above. On June 15, 2016, the Company recorded an estimated fair value of \$1.7 million for warrants to purchase an aggregate of 1,002,507 shares of common stock issued in the Subsequent Financing.

The Company utilizes a Monte Carlo simulation model to estimate the fair value of the warrants issued in the Private Placement and the Subsequent Financing, and the Placement Agent Warrants and the Subsequent Financing. The Monte Carlo simulation model uses multiple input variables to estimate the probability that market conditions will be achieved. These variables include the Company's stock price, the expected term of the warrants, the volatility of the Company's and its peers' stock prices over such expected term, and the risk-free interest rate for the expected term of the warrants. The variables used in this simulation model are reviewed on a quarterly basis and adjusted, as needed. If the Company issues common stock at a price lower than the exercise price or issues stock options or other securities (other than securities issued pursuant to the Company's stock or option plans or employment agreements, securities issued or issuable upon exercise or exchange of convertible securities outstanding as of the date the warrants were issued or securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company) with an exercise price that is lower than the current exercise price of the warrants, the exercise price of the warrants shall be adjusted to be equal to such lower price. As a result of the anti-dilution provisions in the warrants issued in connection with the Private Placement and the Subsequent Financing, the exercise price of the 1,775,580 and 1,002,507 Private Placement and Subsequent Financing warrants, respectively, was adjusted from \$4.98 per share to \$4.00 per share, which was the price paid by investors in the Public Offering. The number of warrants outstanding did not change.

The initial total estimated fair value of the warrant liability was \$5.0 million following the closings of the Private Placement, the issuance of Placement Agent Warrants and the Subsequent Financing on April 14, 2016. As of September 30, 2016, the total estimated fair value of the warrant liability was \$6.7 million and the corresponding remeasurement gain of \$1.4 million and loss of \$1.8 million for the three and nine month periods ending September 30, 2016, respectively, was recorded in change in estimated fair value of common stock warrant liability on the Company's condensed consolidated statement of operations. The increase in the fair value of the warrant liability was attributable to events that had occurred between the initial fair value measurement and September 30, 2016, including obtaining the Requisite Stockholder Approval, which occurred on June 16, 2016, granting certain registration rights, including rights regarding the registration of shares issuable upon exercise of the warrants issued in the Private Placement and the Subsequent Financing and the Placement Agent Warrants. The registration of the shares impacted the exercisability of the warrants and resulted in an increase in the fair value of the warrant liability.

As of September 30, 2016, outstanding warrants to purchase Common Stock were:

		Exercise	Number of
	Original Term	Price	Shares
			Underlying
			Warrants
Original issue date:			
November 2006	10 years	\$ 31.72	1,576
February 2008	10 years	\$ 35.07	22,792
August 2009	10 years	\$ 21.78	33,473
July 2010	9 years	\$ 21.78	6,694
December 2010	7 years	\$ 21.78	17,215
August 2012	7 years	\$ 21.78	167,182
January 2015	5 years	\$ 6.96	34,483
April 2016 (a)	7 years	\$ 4.00	1,775,580

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April 2016 (b)	5 years	\$ 3.99	200,000
June 2016 (c)	7 years	\$ 4.00	1,002,507
			3,261,502

- (a) Issued on April 14, 2016 in connection with the Private Placement to certain accredited investors. The exercise price was reset from \$4.98 to \$4.00 as a result of the Public Offering that closed on September 26, 2016. In accordance with the anti-dilution provisions, the exercise price of the warrants issued in connection with the Private Placement reset from \$4.98 per share to \$4.00 per share, which was the price paid by investors in the Public Offering, which closed on September 26, 2016.
- (b) Issued on April 14, 2016 in connection with the Private Placement to placement agents.
- (c) Issued on June 15, 2016 in connection with the Subsequent Financing. The exercise price was reset from \$4.98 to \$4.00 as a result of the Public Offering that closed on September 26, 2016. In accordance with the anti-dilution provisions, the exercise price of the warrants issued in connection with the Subsequent Financing reset from \$4.98 per share to \$4.00 per share, which was the price paid by investors in the Public Offering, which closed on September 26, 2016.



## 14. STOCK INCENTIVE PLANS

## 2014 Equity Incentive Plan

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:

- 37,075 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.

## 2016 Inducement Plan

On April 21, 2016, the Company’s board of directors, including its independent directors, adopted the Company’s 2016 Inducement Equity Incentive Plan (the “Inducement Plan”), pursuant to which the Company may grant stock awards of up to a total of 155,500 shares of common stock to new employees of the Company. The Inducement Plan was adopted to accommodate a reserve of additional shares of common stock for issuance to new employees hired by the Company from Allenex. The terms in the Inducement Plan are substantially similar to the Company’s 2014 Plan. The Inducement 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 pursuant to the Inducement Plan starting June 2016.

## Stock Options Under the 2014 Plan

The following table summarizes option activity and related information:

	Shares	Weighted-
	Underlying	average
	Stock	Exercise
	Options	Price
	Outstanding	
Balance—December 31, 2015	1,577,317	\$ 6.87
Granted	558,170	5.00
Exercised	(2,770 )	3.14
Forfeited	(215,087 )	6.90
Expired	(66,398 )	9.87
Balance—September 30, 2016	1,851,232	6.20

Options outstanding that have vested or are expected to vest as of September 30, 2016 are as follows:

	Number of	Weighted Average	Weighted Average	Aggregate
	Shares Issued	Exercise Price	Contractual	Intrinsic Value
			Life (Years)	(In Thousands)
Vested	952,608	\$ 5.99	6.54	\$ 678
Expected to vest	767,518	6.42	8.87	7
Total	1,720,126	6.18	7.58	\$ 685

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at September 30, 2016 for stock options that were in-the-money. The fair market value of the Company's common stock as of September 30, 2016 was \$3.55 per share.

#### Restricted Stock Units

The Company's 2014 Plan and Inducement Plan allow RSUs to be granted in addition to stock options. The RSUs vest annually over four years in equal increments. The Company began granting RSUs under the 2014 Plan in March 2015 and under the Inducement Plan in June 2016.

Unvested RSU activity for the nine months ended September 30, 2016 is summarized below:

	Number of Shares	Weighted- Average Grant Date Fair Value
Unvested balance—December 31, 2015	106,200	\$ 6.49
Granted	287,900	5.50
Vested	(26,550 )	6.49
Forfeited	(53,485 )	5.88
Unvested balance—September 30, 2016	314,065	5.69

#### Shares Available for Grant Under the 2014 Plan and 2016 Inducement Plan

The following table summarizes shares available for grant under the 2014 Plan and the Inducement Plan:

	Shares Available for Grant
Balance—December 31, 2015	404,692
Additional shares authorized for options and RSUs	498,075
Options granted	(558,170)
Options forfeited	215,087
Options expired	66,398
RSUs granted	(287,900)
RSUs forfeited	53,485
Balance—September 30, 2016	391,667

## 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. The ESPP was made available to its employees on January 1, 2015. The first offering period in 2016 began on January 1, 2016 and ended on June 30, 2016. During the first offering period in 2016, 35,024 shares were purchased for aggregate proceeds of \$0.1 million from the issuance of shares, which occurred on July 1, 2016.

The option price per share of common stock to be paid by a participant 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 September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
<b>Employee stock options</b>				
Expected term (in years)	5.5	6.0	5.9	6.0
Expected volatility	46.27 %	39.10 %	41.80 %	40.74 %
Risk-free interest rate	1.20 %	1.90 %	1.52 %	1.87 %
Expected dividend yield	— %	— %	— %	— %
<b>Employee stock purchase plan</b>				
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	54.48 %	39.10 %	61.18 %	35.61 %
Risk-free interest rate	0.37 %	0.11 %	0.45 %	0.11 %
Expected dividend yield	— %	— %	— %	— %

The weighted-average grant-date fair value of options granted during the three months ended September 30, 2016 and 2015 using the Black-Scholes Model was \$2.18 and \$2.81 per share, respectively, and \$2.08 per share and \$2.63 per share during the nine months ended September 30, 2016 and 2015, respectively.

## 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 and nine months ended September 30, 2016 and 2015, included in the statements of operations as follows (in thousands):

	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2015	
	2016	2015	2016	2015
Cost of testing	\$ 38	\$ 22	\$ 105	\$ 91
Research and development	109	79	321	215
Sales and marketing	47	37	118	93
General and administrative	336	198	967	629
<b>Total</b>	<b>\$ 530</b>	<b>\$ 336</b>	<b>\$ 1,511</b>	<b>\$ 1,028</b>

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.

As of September 30, 2016, there was approximately \$2.0 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 2.33 years.

As of September 30, 2016, there was approximately \$1.4 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 3.05 years.

## 15. INCOME TAXES

The Company's effective tax rate may vary from the U.S. federal statutory tax rate due to the change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits, and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income. For the three and nine months ended September 30, 2016, the Company recorded an income tax benefit of \$0.4 million and \$0.9 million, respectively, compared to no income tax benefit or provision for each of the three and nine months ended September 30, 2015. The income tax benefit of \$0.4 million and \$0.9 million for the three and nine months ended September 30, 2016, respectively, is largely due to the reversal of net deferred tax liabilities

resulting from the amortization of acquired inventory and intangible assets. In connection with the acquisition of Allenex during the quarter, net deferred tax liabilities were established on the acquired identifiable intangible assets and step up to fair market value of acquired inventory.

The increase in the gross unrecognized tax benefits is primarily a result of the acquisition of Allenex. The Company will continue to reevaluate the tax impact of the Allenex acquisition as information is obtained with regards to the estimated values of the assets and liabilities acquired with any adjustments to the preliminary estimates being recorded to goodwill, provided that it is within the measurement period.

## 16. SEGMENT REPORTING

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker (“CODM”), or decision making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its chief executive officer as the CODM. In determining its reportable segments, the Company considered the markets and types of customers served and the products or services provided in those markets.

Prior to the acquisition of Allenex, the Company operated as a single reportable segment. Subsequent to the acquisition of Allenex, the Company has identified the following two reportable segments, which are the same as its operating segments:

• **CareDx:** This segment focuses on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. Its first commercialized testing solution, 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.

• **Olerup:** This segment develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Its Olerup SSP product line, which addresses HLA typing, is used prior to hematopoietic stem cell/bone marrow and organ transplantations to match donors with recipients.

There were no intersegment sales for the three and nine months ended September 30, 2016. The following table summarizes the operating results of the Company’s reportable segments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Total segments</b>				
Net revenues	\$ 12,475	\$ 7,151	\$ 29,771	\$ 21,496
Operating loss	(4,933 )	(3,193 )	(18,471 )	(7,469 )
Depreciation and amortization	1,068	217	2,172	575
<b>CareDx</b>				
Net revenues	\$ 8,721	\$ 7,151	\$ 22,543	\$ 21,496
Operating loss	(2,910 )	(3,193 )	(14,724 )	(7,469 )
Depreciation and amortization	301	217	861	575
<b>Olerup</b>				

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Net revenues	\$ 3,754	\$ —	\$ 7,228	\$ —
Operating loss	(2,023 )	—	(3,747 )	—
Depreciation and amortization	767	—	1,311	—

	September 30, 2016	December 31, 2015
<b>Assets:</b>		
CareDx	\$ 47,455	\$ 55,638
Olerup	54,637	—
Total assets	\$ 102,092	\$ 55,638



Revenues by geographic regions are based upon the customers' ship-to address or headquarters location. The following table summarizes reportable revenues by geographic regions (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
<b>Revenues:</b>				
United States	\$ 10,007	\$ 7,151	\$ 26,149	\$ 21,496
Europe, Middle East and Africa	2,313	—	3,168	—
Latin America and Canada	155	—	454	—
<b>Total</b>	<b>\$ 12,475</b>	<b>\$ 7,151</b>	<b>\$ 29,771</b>	<b>\$ 21,496</b>

The following table summarizes long-lived assets, consisting of property and equipment, net, by geographic regions (in thousands):

	September 30, 2016	December 31, 2015
<b>Long-lived assets:</b>		
United States	\$ 2,184	\$ 2,425
Europe	1,121	—
<b>Total</b>	<b>\$ 3,305</b>	<b>\$ 2,425</b>

## 17. RELATED PARTY TRANSACTIONS

On April 14, 2016, the Company completed the Private Placement (as described in Note 12), pursuant to which it issued and sold to certain investors an aggregate of 591,860 Units, for aggregate gross proceeds to the Company of approximately \$14.2 million, of which \$1.8 million was paid in satisfaction of placement agents, escrow agent and legal fees as well as other direct issuance costs.

FastPartner, Midroc Invest AB and Xenella Holding AB, the three Majority Shareholders, each beneficially owned 566,962 shares, 636,838 shares and 162,928 shares, respectively, of the Company's outstanding shares of common stock prior to the closing of the Subsequent Financing (as described in Note 12).

The Company has loans outstanding with both FastPartner AB and Mr. Mohammed Al Amoudi as of September 30, 2016 (as described in Note 11). A member of the Company's board of directors is a managing director of M.M. Dillon, and as such, the Company considered M.M. Dillon to be a related party. M.M. Dillon acted as one of the Company's financial advisors and placement agents in connection with the Private Placement and Subsequent Financing (as described in Note 12).



## 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 consolidated 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 amended, as filed originally with the Securities and Exchange Commission, or the SEC, on March 29, 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 post-transplant solutions, if any, and our ability to increase the commercial success of AlloMap;
- our ability to generate revenue from sales of Olerup SSP products, sequence-based typing, or SBT Resolver, XM-ONE, and future pre-transplant solutions, if any, and our ability to increase the commercial success of these pre-transplant products;
- our plans and ability to develop and commercialize new solutions, including donor-derived cell-free DNA, or dd-cfDNA (which includes our AlloSure test), and solutions for the surveillance of heart, kidney, and other solid organ transplant recipients;
- our plans and ability to continue updating our sequence specific primer, or SSP, products and technology to maintain our leading position in the SSP market;
- our plans and ability to develop, commercialize, and/or distribute new Human Leukocyte Antigen, or HLA, typing, such as a real-time PCR, or q-PCR, methodology (which includes QTYPE) and possibly Next Generation Sequencing technology and pre-transplant solutions;
- our ability to obtain additional financing;
- our ability to integrate our business with the business of Allenex and to realize the anticipated benefits of the acquisition;
- our ability to obtain, maintain and expand reimbursement coverage from payers for AlloMap, AlloSure and other future solutions, if any;
- the outcome or success of our clinical trial collaborations and observational studies;
- our dependence on certain of our suppliers, service providers, and other distribution partners;
- our compliance with federal, state and foreign regulatory requirements;
- the favorable review of our pre- and post-transplant offerings, 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;
- our ability to meet our obligations under our debt agreements;

• 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;

34

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- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our pending litigation and review and hearing with the Disciplinary Committee of Nasdaq OMX Stockholm AB;
- our ability to expand internationally;
- our ability to remediate the two material weaknesses in our internal control over financial reporting; and
- our ability to comply with the requirements of being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled “Risk Factors” in 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 and adversely 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 global transplant diagnostics company with product offerings along the pre- and post-transplant continuum. We focus on 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-to-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 avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. AlloMap has received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe acute cellular rejection. We are also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, our proprietary next-generation sequencing-based test to detect donor derived cell-free DNA, or dd-cfDNA, after transplantation. Through our 2014 acquisition of ImmuMetrix, Inc., or

IMX, a privately held development-stage company working on dd-cfDNA-based solutions in transplantation and other fields, we added to our existing know-how, expertise, and intellectual property the ability to apply dd-cfDNA technology to the surveillance of transplant recipients, which has contributed to the development of AlloSure.

In April 2016, we acquired Allenex AB, or Allenex. Through the Allenex acquisition, we also develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP, a set of Human Leukocyte Antigen, or HLA, typing, is used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. Olerup SSP is used to type HLA alleles based on sequence-specific primer, or SSP, technology, is one of the market leaders, and has long been a well-established brand name in Europe and select other markets for pre-transplant solutions. We frequently update typing kits to include newly discovered alleles, resulting in what we believe is one of the most up-to-date and comprehensive allele libraries for the SSP technology. We also offer XM-ONE®, which we believe is the first

standardized test that quickly identifies a patient's antigens against HLA Class I or Class II, as well as antibodies against a donor's endothelium. This crossmatch test has primarily been used prior to kidney transplants, and more recent clinical trials are further demonstrating its value as a complement to traditional antibody testing prior to these types of transplants. In 2014, Allenex began active development of a new HLA typing product, QTYPE, and commercially launched the product at the end of September 2016. QTYPE uses real-time PCR, or q-PCR, methodology. This technology is based on SSP technology.

Since 2011, Allenex, through Olerup SSB AB, is the exclusive global distributor of the HLA sequence-based typing products SBT Resolver and Assign SBT from Conexio Genomics, or Conexio, which is an Australian-based company that specializes in the development of sequencing of HLA typing, among other technologies. The distribution agreement continues until April 2018. The focus has been on introducing this new product line to the largest and most automated HLA laboratories in the U.S. and Europe. We recently received a notice that Conexio's SBT products will be discontinued by December 31, 2016. Conexio was acquired by Illumina, Inc. and we are currently negotiating the continuation of our ability to offer SBT products.

Since the launch of AlloMap in January 2005, we have performed more than 91,000 commercial AlloMap tests, including 10,577 tests during the first nine months of 2016, in our Brisbane, California laboratory. Since the commercial launch of AlloMap through September 30, 2016, we have received net proceeds of approximately \$181.1 million from AlloMap testing revenues. During the first nine months of 2016, AlloMap was used in 120 of the approximately 130 heart transplant centers in the United States. As of September 30, 2016, significantly all of our testing and product revenues came from the United States and Europe, and significantly all of our assets and operations are located in the United States and Sweden. In 2013, we began a partnership with Diaxonhit, or DHT, the leading French provider of specialty in-vitro diagnostic solutions for transplantation, to expand our AlloMap offering in Europe for which we have secured a dedicated laboratory. On May 25, 2016, DHT announced that it had entered into a services agreement with University Hospital of Strasbourg to open a center dedicated to AlloMap testing. The lab meets all of the quality and safety requirements to ensure the accuracy and reproducibility of the results of AlloMap. Further, its Strasbourg location is in the heart of Europe, which is ideal for servicing heart transplant centers throughout Europe. As a result of our acquisition of Allenex, we have further increased our international presence.

In addition to our current offering of surveillance solutions, 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 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 solid organs, irrespective of the type of organ transplanted. In late 2015, we announced the completion of analytical validation of AlloSure. Samples used in the analytical validation included donor recipient pairs with unrelated as well as closely related family members.

As part of our efforts to demonstrate the clinical utility of AlloSure, we initiated the DART trial in May 2015. 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. We completed the first analysis of the data from DART in June 2016. By the time of completion of the first analysis, over 400 patients had enrolled in DART in 14 centers and we had collected specimens from over 1,248 patient visits before enrollment was closed. The study demonstrated increased levels of dd-cfDNA in acute rejection using the non-invasive AlloSure assay. Based on the analytical validity and first analysis clinical validation data, we, in collaboration with clinical investigators, submitted two manuscripts for scientific peer-review.

With the relevant information from the first analysis, we are developing a study design for a second clinical trial to establish the clinical utility of our dd-cfDNA kidney solution and engage with payers in an effort to ensure future access to and reimbursement for this novel non-invasive test for transplant surveillance.

We expect the Centers for Medicare and Medicaid Services, or CMS, to publish a final Clinical Lab Fee Schedule in late November or early December 2016, for reimbursement rates beginning January 1, 2017, including reimbursement for AlloMap. CMS is using a process referred to as “gapfill” to establish reimbursement rates for 2017. The gapfill process consists of a number of steps, including: (i) CMS obtaining preliminary proposed reimbursement for AlloMap from the eight Medicare Administrative Contractors, or MACs; (ii) CMS obtaining final reimbursement submission for AlloMap from the eight MACs; and (iii) a reconsideration period, with requests for reconsideration due by October 31, 2016. On June 10, 2016, CMS announced the proposed gapfill pricing from the MACs for patients covered by Medicare, which initially proposed that reimbursement for AlloMap be reduced from the current rate of \$2,821 to \$732. On September 30, 2016, CMS published a final gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would be \$1,921. This reimbursement rate, determined by gapfill submissions from the MACs, is open to reconsideration submissions until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the MACs. If an AlloMap reimbursement rate of \$1,921 is published in the Clinical Lab Fee Schedule for 2017, it could cause us to discontinue AlloMap testing for Medicare patients because providing AlloMap tests at that reimbursement rate may



not be economically viable. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations. Additionally, some hospitals may reduce the use of AlloMap if it is not available to all patients, and only to non-Medicare recipients.

#### 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 with 58 employees that develops, manufactures, and sells products that help match donor organs with potential recipients prior to transplantation. Our combination with Allenex creates an international transplant diagnostics company with product offerings along the pre- and post-transplant continuum. Allenex's Olerup SSP line, which addresses HLA testing, is well recognized by the transplant community. As a result of the acquisition we now have a presence and direct distribution channels in the U.S. and Europe, with additional third party distributors in Europe and other markets around the world. 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 aggregate purchase consideration paid by us was approximately \$34.1 million and consisted of (i) \$26.9 million of cash, of which approximately \$5.7 million was deferred purchase consideration payable to the Midroc Invest AB, FastPartner AB and Xenella Holding AB, or the Majority Shareholders, by no later than March 31, 2017, and (ii) the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Of the total cash consideration, \$8.0 million of cash due to the Majority Shareholders, was deposited into an escrow account by us and subsequently invested in us by the Majority Shareholders through a purchase of our equity securities in a subsequent financing completed on June 15, 2016, or the Subsequent Financing. The Subsequent Financing was completed on June 15, 2016 and is described under the heading "—Private Placement" below. Upon the completion of the Subsequent Financing, certain contingencies in the Conditional Share Purchase Agreements were waived, and the deferred purchase consideration is due to the Majority Shareholders by March 31, 2017. We determined at the date of the acquisition that those contingencies would be waived. We intend to complete compulsory acquisition proceedings under Swedish law to purchase the remaining 1.7% of the outstanding shares of common stock of Allenex. On June 8, 2016, we delisted Allenex's common stock from Nasdaq Stockholm.

On May 12, 2016, we entered into a First Amendment to the Loan and Security Agreement, or the First Amendment, which amended the Loan and Security Agreement, dated January 30, 2015, by and between us and East West Bank, as the lender, or, as amended or restated from time to time, the Loan Agreement. The First Amendment, among other things, amended the Loan Agreement by modifying certain financial covenants, adding an equity financing covenant, and restricting certain transactions between us and our subsidiaries. On June 27, 2016, we entered into a Second Amendment to Loan and Security Agreement, or the Second Amendment. The Second Amendment, among other things, amended the Loan Agreement to permit certain transactions between us and our subsidiaries and to add intellectual property as collateral security.

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 we have recorded a charge of \$2.9 million in the nine months ended September 30, 2016 to expense financing costs associated with this bridge loan. These costs have been included as a component of other expense on our condensed consolidated statements of operations. As a result, the cash portion of the acquisition purchase price was paid from our general working capital.

On April 25, 2016, Oberland Capital SA Davos LLC, or Oberland, filed a breach of contract claim against us in the Supreme Court of the State of New York, County of New York, or the Oberland Complaint, alleging, among other things, that we breached certain provisions of the amended and restated commitment letter and the restated fee letter that we entered into with Oberland on February 8, 2016. On July 15, 2016, we filed an answer and made

counterclaims against Oberland, or the Answer, generally denying the claims asserted by Oberland in the Oberland Complaint and asserting fraudulent inducement and breach of contract counterclaims against Oberland. On August 4, 2016, Oberland filed a motion to dismiss our counterclaims. Oral arguments for this motion are scheduled for December 8, 2016. We intend to vigorously defend against the claims asserted by Oberland and vigorously pursue the counterclaims set forth in the Answer. However, there is no guarantee that we will prevail in this suit or recover damages from our counterclaims or other relief if we do prevail. As a result, we accrued the amount being claimed by Oberland of \$1.4 million. See Note 9 of the unaudited condensed consolidated financial statements included elsewhere in Item 1 of Part 1 and Legal Proceedings included in Item 1 of Part II of this Quarterly Report on Form 10-Q for additional information.

#### Private Placement

On April 14, 2016, we completed a private placement transaction pursuant to which we issued and sold an aggregate of 591,860 Units, or the Private Placement. Each Unit was comprised of: (i) one share of our common stock, (ii) five shares of our Series A Mandatorily Convertible Preferred Stock, or Series A Preferred, and (iii) three warrants, each of which is exercisable for one share of our common stock at an exercise price of \$4.98 per share. If the Company issues common stock at a price lower than the exercise price or issues

stock options or other securities (other than securities issued pursuant to the Company's stock or option plans or employment agreements, securities issued or issuable upon exercise or exchange of convertible securities outstanding as of the date the warrants were issued or securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company) with an exercise price that is lower than the current exercise price of the warrants, the exercise price of the warrants shall be adjusted to be equal to such lower price. 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 our acquisition of Allenex, the consent of East West Bank, as the lender under the Loan Agreement, to the acquisition of Allenex, and certain other customary closing conditions, all of which occurred on April 14, 2016. The aggregate gross proceeds to us from the Private Placement were approximately \$14.2 million, of which \$1.8 million was paid in satisfaction of placement agent, escrow agent and legal fees as well as other direct issuance costs. Following the closing of the Private Placement, we agreed to a number of requirements, including submitting the Private Placement to our stockholders for approval pursuant to the rules of The NASDAQ Stock Market LLC, or the Requisite Stockholder Approval, and granting certain registration rights, including the registration of the shares of common stock sold in the Private Placement on a registration statement on Form S-3. On April 14, 2016, we and certain of our stockholders representing a majority of our outstanding shares of common stock entered into voting agreements, pursuant to which each such stockholder agreed to vote certain of our shares of common stock in favor of granting us the Requisite Stockholder Approval. The Requisite Stockholder Approval was obtained on June 16, 2016. On May 27, 2016, we filed a registration statement on Form S-3 with the SEC to register for resale the shares of common stock issued or issuable upon conversion of the Series A Preferred and upon exercise of the warrants sold in the Private Placement, or the 2016 Form S-3. The 2016 Form S-3 was declared effective by the SEC on July 12, 2016.

Upon obtaining the Requisite Stockholder Approval on June 16, 2016, each share of Series A Preferred was converted into one share of our common stock. In addition to the warrants issued to certain accredited investors in the Private Placement, on April 14, 2016, we also issued warrants to purchase an aggregate of 200,000 shares of our common stock to certain of our placement agents, or the Placement Agent Warrants. All of the Private Placement warrants and Placement Agent Warrants became exercisable after we obtained the Requisite Stockholder Approval on June 16, 2016. The Placement Agent Warrants are exercisable at an exercise price of \$3.99 per share.

Concurrently, we also entered into Commitment Letters pursuant to which the Majority Shareholders agreed to purchase our equity securities in a subsequent financing, or the Subsequent Financing, which investment was completed on June 15, 2016. Pursuant to the Subsequent Financing, we issued to the Majority Shareholders an additional 334,169 Units, which consisted of (i) an aggregate of 334,169 shares of our common stock, (ii) an aggregate of 1,670,845 shares of Series A Preferred that were all converted into shares of our common stock upon obtaining the Requisite Stockholder Approval on June 16, 2016, and (iii) 1,002,507 warrants, each of which is exercisable for one share of our common stock at the same price per share as the Private Placement warrants.

M.M. Dillon & Co. Group, or M.M. Dillon, an investment banking firm, acted as one of our financial advisors and placement agents in connection with the Private Placement and the Subsequent Financing. A member of our board of directors is a managing director of M.M. Dillon, and, as such, we consider M.M. Dillon to be a related party. 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.

#### Public Offering

On September 26, 2016, we completed an underwritten public offering pursuant to which we issued and sold an aggregate of 2,250,000 shares of our common stock at a public offering price of \$4.00 per share, or the Public Offering. The aggregate gross proceeds to us were approximately \$9.0 million, and \$7.8 million net of issuance costs.

The Public Offering was made pursuant to our registration statement on Form S-3, which was declared effective by the SEC on December 4, 2015, a base prospectus dated December 4, 2015 and a prospectus supplement dated September 21, 2016. Piper Jaffray & Co. acted as the sole underwriter for the Public Offering.

In connection with the Public Offering, in accordance with the anti-dilution provisions in the warrants issued in connection with the Private Placement and the Subsequent Financing, the exercise price of the 1,775,580 warrants and 1,002,507 warrants from the Private Placement and the Subsequent Financing warrants, respectively, was adjusted from \$4.98 per share to \$4.00 per share, which was the price paid by investors in the Public Offering.

We expect to use the proceeds from the Private Placement and other private financing activities, the Subsequent Financing and the Public Offering to fund the continued development of AlloSure, including a clinical utility trial and commercialization efforts, and for additional working capital and general corporate purposes.

## SEC Comment Letter

On October 17, 2016, we received a comment letter from the staff of the Division of Corporation Finance of the Securities and Exchange Commission, or the “Staff”. The comments from the Staff were issued with respect to its review of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2016 and June 30, 2016. We responded to the letter on October 28, 2016 and are awaiting a response from the Staff.

## Financial Operations Overview

### Testing Revenue

Our testing revenue is derived from AlloMap tests, which represented 69% and 75% of our total revenues for the three and nine months ended September 30, 2016, respectively, and 98% of our total revenues for each of the three and nine months ended September 30, 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 September 30, 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. Additionally, CMS recently announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the gapfill fee schedule for 2017, which is in the reconsideration period, AlloMap reimbursement for patients covered by Medicare would be reduced from \$2,821 to \$1,921, effective January 1, 2017. However, this rate is subject to requests for reconsideration until October 31, 2016 and we have submitted such a request. If the \$1,921 rate is finalized, it could cause us to discontinue AlloMap testing for Medicare patients because providing AlloMap tests at that reimbursement rate may not be economically viable. Given the significant portion of payments to us represented by Medicare, the lower test revenue would have a material adverse effect on our operations and financial condition. 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.

### Product Revenue

We began recognizing product revenue following the acquisition of Allenex in the second quarter of 2016. Our product revenue is derived primarily from sales of Olerup SSP products and other related product lines. Product revenue represented 30% and 24% of total revenue for the three and nine months ended September 30, 2016, respectively. We recognize product revenue from the sale of products to end-users, distributors and strategic partners when persuasive evidence of a sale exists, the product is complete and tested and has been shipped, which coincides with transfer of title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and we do not have significant obligations for future performance. When collectability is not reasonably assured, we defer the revenue over the cash collection period. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts given to the buyer.

Collaboration, License and Other Revenue

Revenue from our collaboration and license agreements was insignificant to 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 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 on-site, 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. As a result, our cost of testing as a percentage of revenue may vary significantly from period to period because we do not recognize all revenue in the period in which the associated costs are incurred. Royalties for licensed technology, calculated as a percentage of test revenues, are recorded as license fees in cost of testing at the time the test revenues are recognized.

Royalties 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 of certain technology relating to polymerase chain reaction, or PCR, and quantitative real-time PCR in clinical laboratory services from Roche Molecular Systems, Inc., or 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.

### Cost of Product

Cost of product reflects the aggregate costs incurred in delivering our products to customers. The components of cost of product are material costs, manufacturing and kit assembly costs, direct labor costs, including equipment and infrastructure expenses associated with preparing kitted products for shipment, shipping, distributorship agreements, and allocated overhead including rent, information technology, equipment depreciation and utilities. Cost of product also includes amortization of acquired developed technology and adjustments to inventory values, including write-down of impaired, slow moving or obsolete inventory.

### Research and Development Expenses

Research and development expenses represent costs incurred to develop new pre- and post-transplant diagnostic solutions as well as continued efforts related to improving our existing product lines. 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 and a clinical utility study for AlloSure.

### Sales and Marketing Expenses

Sales and marketing expenses represent costs incurred to sell, promote and increase awareness of our existing product lines to clinicians, hospital laboratories, and payers. These efforts also include education of patients, clinicians, payers, and other relevant decision makers. 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 periodic 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 transplant diagnostic marketplace.

## 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 continue 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 SEC and The NASDAQ Stock Market LLC, additional insurance expenses, investor relations activities and other administrative and professional services. For the three and nine months ended September 30, 2016, general and administrative expenses also included transaction related fees and expenses associated with the acquisition of Allenex and completion of the Private Placement and Subsequent Financing. Following the completion of the acquisition of Allenex and excluding costs incurred in connection with the acquisition of Allenex, we expect our general and administrative expenses will increase as we incur additional costs to finance our operations and growth, to integrate Allenex's business with ours, 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, which occurred in June 2014, 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 consolidated statements of operations.

## Interest Expense

Interest expense is associated with borrowings under our loan agreements.

## Other Expense

For the three and nine months ended September 30, 2016, other expense primarily consisted of state franchise taxes and the impact of from changes in foreign currency exchange rates, in addition to a charge recorded to expense financing costs associated with a proposed six-month bridge loan with Oberland based on our determination that it was not probable that the bridge loan would be consummated. For the three and nine months ended September 30, 2015, other expense primarily consisted of state franchise taxes.

## Change in Estimated Fair Value of Common Stock Warrant Liability

The freestanding warrants issued in connection with the Private Placement, Subsequent Financing and Placement Agent Warrants are recorded at their estimated fair value. The warrants were remeasured on September 30, 2016 and will be remeasured at each subsequent balance sheet date with changes recorded to change in estimated fair value of common stock warrant liability on the condensed consolidated statements of operations.

## Results of Operations

## Comparison of the Three Months Ended September 30, 2016 and 2015

(In thousands, except for AlloMap test results delivered)

	Three Months Ended September 30,	
	2016	2015
AlloMap test results delivered	3,616	3,423
Revenue:		
Testing revenue	\$8,613	\$7,007
Product revenue	3,754	—
Collaboration, license and other revenue	108	144
Total revenue	12,475	7,151
Operating expenses:		
Cost of testing	2,604	2,568
Cost of product	3,355	—
Research and development	2,930	2,698

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Sales and marketing	3,451	2,062
General and administrative	5,180	3,361
Change in estimated fair value of contingent consideration	(112 )	(345 )
Total operating expenses	17,408	10,344
Loss from operations	(4,933 )	(3,193 )
Interest expense	(568 )	(251 )
Other expense	(133 )	(45 )
Change in estimated fair value of common stock warrant liability	1,386	—
Income tax benefit	449	—
Net loss attributable to noncontrolling interest	35	—
Net loss attributable to CareDx, Inc.	\$(3,764 )	\$(3,489 )

41

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### Testing Revenue

AlloMap test results delivered increased by 193, or 6%, for the three months ended September 30, 2016 as compared to the same period of 2015. Testing revenue increased by \$1.6 million, or 23%, for the three months ended September 30, 2016 as compared to the same period of 2015. The increase in testing revenue of \$1.6 million reflects increased revenue corresponding to the 6% increase in test results delivered and was also due to an increase in cash basis revenue of \$1.4 million compared to the same period of 2015. The increase in cash basis revenue reflects collections progress following the hiring of additional full-time and temporary billing employees in 2016, as part of a plan to increase our rate of collections.

### Product Revenue

The product revenue reported for the three months ended September 30, 2016 was generated by Allenex following our acquisition of Allenex on April 14, 2016, and represents our sales of the Olerup SSP products and other Allenex products.

### Collaboration, License and Other Revenue

Collaboration, license and other revenue decreased by approximately \$36,000 for the three months ended September 30, 2016 as compared to the same period of 2015 due to a decrease in royalties received under our services agreement with CardioDx, Inc.

### Cost of Testing

Cost of testing increased by \$36,000, or 1%, for the three months ended September 30, 2016 as compared to the same period of 2015. The increase reflects an increase in expenditures on laboratory materials.

### Cost of Product

Cost of product reported for the three months ended September 30, 2016 was incurred by us as a result of the acquisition of Allenex on April 14, 2016, and represents cost of product from our sales of Olerup SSP products and other Allenex products. Cost of product includes \$1.4 million of amortization of the acquisition-related mark-up in the value of inventory and \$0.3 million of acquisition-related amortization of intangible assets.

### Research and Development

Research and development expenses increased by \$0.2 million, or 9%, for the three months ended September 30, 2016 as compared to the same period of 2015. The increase reflects our acquisition of Allenex on April 14, 2016. We incurred approximately \$0.3 million of research and development expenses related to the Allenex business, primarily for the development of QTYPE subsequent to the acquisition.

### Sales and Marketing

Sales and marketing expenses increased by approximately \$1.4 million, or 69%, for the three months ended September 30, 2016 as compared to the same period of 2015. This increase reflects our acquisition of Allenex on April 14, 2016. We incurred approximately \$1.5 million of sales and marketing expenses related to the Allenex business, including costs for trade shows and marketing efforts for the commercial launch of QTYPE at the end of

September 2016 and includes \$0.2 million of acquisition-related amortization of purchased intangible assets.

#### General and Administrative

General and administrative expenses increased by approximately \$1.8 million, or 53%, for the three months ended September 30, 2016 as compared to the same period of 2015. The increase reflects approximately \$0.7 million of general and administrative expenses incurred by our Allenex business subsequent to the acquisition. The increase also reflects \$0.5 million of audit, legal, tax and other professional and consulting fees incurred in connection with our acquisition of Allenex. The remaining increase reflects employee-related costs, fees for consulting, and professional service fees and financial advice related to the first corporate consolidation of Allenex.

## Change in Estimated Fair Value of Contingent Consideration

The consideration for our business combination with IMX, which occurred in June 2014, 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 each of the three months ended September 30, 2016 and 2015 and recorded non-cash gains of \$0.1 million and \$0.4 million in our condensed consolidated statements of operations, respectively, as a result of changes in the market value of our common stock.

## Interest Expense

Interest expense increased by \$0.3 million, or 126%, for the three months ended September 30, 2016 as compared to the same period of 2015. In connection with our acquisition of Allenex, we assumed its existing debt and incurred interest expense of \$0.2 million following the acquisition. In addition, we incurred interest expense of \$0.1 million on the deferred purchase consideration payable to the Majority Shareholders following our acquisition of Allenex.

## Other Expense

Other expense for the three months ended September 30, 2016 increased by \$0.1 million as compared to the same period of 2015. This expense is related to foreign currency transactions charges during the three months ended September 30, 2016.

## Change in Estimated Fair Value of Common Stock Warrant Liability

During the three months ended September 30, 2016, we recorded a \$1.4 million non-cash gain for the remeasurement of the fair value of warrants issued in the Private Placement, Subsequent Financing and Placement Agent Warrants as a result of a decrease in the market value of our common stock.

## Comparison of the Nine Months Ended September 30, 2016 and 2015

(In thousands, except for AlloMap test results delivered)

	Nine Months Ended September 30,	
	2016	2015
AlloMap test results delivered	10,577	9,793
Revenue:		
Testing revenue	\$22,317	\$21,147
Product revenue	7,228	—
Collaboration, license and other revenue	226	349
Total revenue	29,771	21,496
Operating expenses:		
Cost of testing	8,228	7,786
Cost of product	6,411	—
Research and development	9,231	6,629
Sales and marketing	8,544	6,453
General and administrative	16,250	8,553

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Change in estimated fair value of contingent		
Consideration	(422 )	(456 )
Total operating expenses	48,242	28,965
Loss from operations	(18,471)	(7,469)
Interest expense	(1,351)	(1,334)
Other expense	(3,334)	(142)
Change in estimated fair value of common stock		
warrant liability	(1,779)	—
Income tax benefit	888	—
Net loss attributable to noncontrolling interest	58	—
Net loss attributable to CareDx, Inc.	\$(23,989)	\$(8,945)

### Testing Revenue

Testing revenue increased by \$1.2 million, or 6%, for the nine months ended September 30, 2016 as compared to the same period of 2015. AlloMap test results delivered increased by 784, or 8%, for the nine months ended September 30, 2016 as compared to the same period of 2015. The increase in testing revenue during the nine months ended September 30, 2016 reflects \$0.6 million of increased revenue corresponding to the 6% increase in test results delivered and an increase in cash basis revenue of \$0.9 million. The increase in cash basis revenue reflects collections progress following the hiring of additional full-time and temporary billing employees during the three months ended June 30, 2016, as part of a plan to increase our rate of collections.

### Product Revenue

The product revenue reported for the nine months ended September 30, 2016 was generated by Allenex following our acquisition of Allenex on April 14, 2016, and represents our sales of the Olerup SSP products and other Allenex products.

### Collaboration, License and Other Revenue

Collaboration, license and other revenue decreased by approximately \$0.1 million, or 35%, during the nine months ended September 30, 2016 as compared to the same period of 2015 due to a decrease in royalties received under our services agreement with CardioDx, Inc.

### Cost of Testing

Cost of testing increased by approximately \$0.4 million, or 6%, during the nine months ended September 30, 2016 as compared to the same period of 2015. The increase reflects an increase in our expenditures on laboratory materials to support the increase in testing volume.

### Cost of Product

Cost of product reported for the nine months ended September 30, 2016 was incurred due to our acquisition of Allenex on April 14, 2016, and represents cost of product from the sale of the Olerup SSP products and other Allenex products. Cost of product includes \$2.6 million of amortization of the acquisition-related mark-up in the value of inventory and \$0.6 million of acquisition-related amortization of intangible assets.

### Research and Development

Research and development expenses increased by \$2.6 million, or 39%, for the nine months ended September 30, 2016 as compared to the same period of 2015. The increase reflects higher headcount related expenses of \$0.7 million and additional expenditures of \$0.9 million for our dd-cfDNA clinical trials. The increase also reflects our acquisition of Allenex on April 14, 2016. We incurred approximately \$0.6 million of research and development expenses related to the Allenex business subsequent to the acquisition, primarily for the development of QTYPE subsequent to the acquisition.

### Sales and Marketing

Sales and marketing expenses increased by approximately \$2.1 million, or 33%, for the nine months ended September 30, 2016 as compared to the same period of 2015. This increase is mainly due to our acquisition of Allenex on April 14, 2016. We incurred approximately \$2.6 million of sales and marketing expenses related to the Allenex business

subsequent to the acquisition, including approximately \$0.5 million of acquisition-related amortization of purchased intangible assets. This increase was partially offset by reduced spending on discretionary marketing activities.

#### General and Administrative

General and administrative expenses increased by approximately \$7.7 million, or 90%, for the nine months ended September 30, 2016 as compared to the same period of 2015. This increase includes approximately \$1.4 million of general and administrative expenses incurred by our Allenex business subsequent to the acquisition. The increase also reflects approximately \$4.3 million of audit, legal, tax and other professional and consulting fees incurred in connection with our acquisition of Allenex. The remaining increase reflects employee-related costs, fees for consulting, and professional service fees and financial advice related to the integration of Allenex.



## Change in Estimated Fair Value of Contingent Consideration

The consideration for our business combination with IMX, which occurred in June 2014, 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 nine months ended September 30, 2016 and 2015 and recognized non-cash gains of \$0.4 million and \$0.5 million, respectively, in our condensed consolidated statements of operations as a result of changes in the market value of our common stock during those periods.

## Interest Expense

Interest expense increased by less than \$0.1 million, or 1%, for the nine months ended September 30, 2016 as compared to the same period of 2015. A loss on extinguishment of debt of \$0.6 million resulting from our pay-off of a term loan in January 2015 was offset by higher interest expenses of \$0.6 million connected with our acquisition of Allenex on April 14, 2016. In connection with our acquisition of Allenex, we assumed its existing debt and incurred interest expense of \$0.4 million on the assumed debt following the acquisition. In addition, we incurred interest expense of \$0.2 million on the deferred purchase consideration payable to the Majority Shareholders following our acquisition of Allenex.

## Other Expense

Other expense for the nine months ended September 30, 2016 increased by \$3.2 million as compared to the same period of 2015. The increase reflects a \$2.9 million charge to expense financing costs associated with a six-month bridge loan with Oberland that did not materialize and based on our determination that it was not probable that the bridge would be consummated. Additionally, we incurred \$0.2 million of foreign currency transactions charges. Other expense for nine months ended September 30, 2015 was \$0.1 million, which primarily consisted of state franchise taxes.

## Change in Estimated Fair Value of Common Stock Warrant Liability

During the nine months ended September 30, 2016, we incurred a \$1.8 million charge for the remeasurement of the fair value of the warrants issued in the Private Placement, Subsequent Financing and Placement Agent Warrants.

## Cash Flows for the Nine Months Ended September 30, 2016 and 2015

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

	Nine Months Ended September 30, 2016      2015 (in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(13,462)	\$(5,776)
Investing activities	(21,194)	(1,123)
Financing activities	27,061	4,422
Effect of exchange rate changes on cash and cash equivalents	(28)	—

Net decrease in cash and cash equivalents	\$(7,623 ) \$(2,477)
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### 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 nine months ended September 30, 2016 was \$13.5 million. Our net loss for the period of \$24.0 million was the primary use of our cash and included \$4.3 million of fees and expenses incurred in connection with our acquisition of Allenex. The net loss also included a number of noncash items including a \$1.8 million charge for the remeasurement of the fair value of warrants, a charge of \$2.9 million to expense financing charges, stock-based compensation expense of \$1.5 million, depreciation and amortization of \$2.2 million, amortization of an inventory fair market value adjustment of \$2.7 million, and a revaluation gain of \$0.4 million on a contingent consideration liability remeasurement. Net operating assets and liabilities increased by \$2.5 million, which was primarily caused by an increase in accrued and other liabilities.

Cash used in operating activities for the nine months ended September 30, 2015 was \$5.8 million. Our net loss of \$8.9 million was the primary use of cash, which included AlloSure development costs, expansion of our sales and marketing activities, and increased general and administrative costs. Our net loss for the period included \$1.2 million of net non-cash expenses, including stock-based

compensation expense of \$1.0 million, depreciation and amortization expense of \$0.6 million non-cash, a contingent liability gain of \$0.5 million and interest expenses for the amortization of debt issuance costs associated with new debt, and a loss on extinguishment from a previous debt. Cash used in operating activities also included a decrease in our net operating assets of \$1.9 million, including a decrease in accounts receivable of \$0.4 million, an increase in accounts payable and accrued and other liabilities of \$1.5 million, an increase in payroll liabilities of \$0.5 million as a result of accrued employee bonuses, and an increase in inventory, prepaid expenses and other assets of \$0.5 million.

#### Investing Activities

During the nine months ended September 30, 2016, net cash used in investing activities was \$21.2 million, which was mainly the cash paid to acquire Allenex of \$20.6 million, net of cash acquired of \$0.6 million. Net cash used in investing activities during the nine months ended September 30, 2016 also included \$0.6 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.

During the nine months ended September 30, 2015, net cash used in investing activities was \$1.1 million for purchases of property and equipment.

#### Financing Activities

For the nine months ended September 30, 2016, net cash provided by financing activities was \$27.1 million primarily due to net proceeds received from the Public Offering of \$8.3 million, net of issuance cost, from the issuance of securities in private financing transactions of \$20.6 million, and \$0.3 million from the issuance of common stock under the employee stock purchase plan, offset by \$2.2 million of principal payments on debt and capital lease obligations.

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

#### Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$197.1 million at September 30, 2016. As of September 30, 2016, we had cash and cash equivalents of \$22.3 million, and \$26.8 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 for an aggregate purchase consideration of approximately \$34.1 million which consisted of (i) \$26.9 million of cash, of which approximately \$5.7 million was deferred purchase consideration payable to the Majority Shareholders by no later than March 31, 2017, and (ii) the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Of the total cash consideration, \$8.0 million of cash payable to the Majority Shareholders was deposited into an escrow account by us and subsequently invested in us by the Majority Shareholders through a purchase of our equity securities in the Subsequent Financing, which was completed on June 15, 2016. We intend to complete compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. On June 8, 2016, we delisted Allenex's common stock from Nasdaq Stockholm.

On April 14, 2016, we completed a private placement, or the Private Placement, pursuant to which we received aggregate gross proceeds of approximately \$14.2 million. We 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 Private Placement and Subsequent Financing. On June 15, 2016, we completed the Subsequent Financing with aggregate gross proceeds of \$8.0 million. Securities issued in the Subsequent Financing were issued and sold at the same price and upon substantially the same terms as securities issued in the Private Placement.

On September 26, 2016, we completed the Public Offering pursuant to which we issued and sold an aggregate of 2,250,000 shares of our common stock at a public offering price of \$4.00 per share. The aggregate gross proceeds to us were \$9.0 million and the net proceeds after debt issuance costs was approximately \$7.8 million. The Public Offering was made pursuant to our registration statement on Form S-3, which was declared effective by the SEC on December 4, 2015, a base prospectus dated December 4, 2015 and a prospectus supplement dated September 21, 2016. Piper Jaffray & Co. acted as the sole underwriter for the Public Offering.

Due to insufficient working capital in Allenex, a debt covenant in the Danske Bank A/S, or Danske, loan facility, relating to maintaining an adequate leverage ratio was violated at each of June 30, 2016 and September 30, 2016. While Allenex received a

waiver from Danske for these violations, due to continuing liquidity matters, we determined that it is not probable that Allenex will be in compliance with this covenant in future periods. For these reasons, the long-term debt due to Danske was classified as a current liability in the condensed consolidated balance sheet as of September 30, 2016. Additionally, if the loan was no longer available or Danske demanded repayment of the debt, we may not have sufficient capital to operate.

We expect CMS to publish a final Clinical Lab Fee Schedule in late November or early December 2016, for reimbursement rates beginning January 1, 2017, including reimbursement for AlloMap. CMS is using a process referred to as “gapfill” to establish reimbursement rates for 2017. The gapfill process consists of a number of steps, including: (i) CMS obtaining preliminary proposed reimbursement for AlloMap from the eight Medicare Administrative Contractors, or MACs; (ii) CMS obtaining final reimbursement submission for AlloMap from the eight MACs; and (iii) a reconsideration period, with requests for reconsideration due by October 31, 2016. On June 10, 2016, CMS announced the proposed gapfill pricing from the MACs for patients covered by Medicare, which initially proposed that reimbursement for AlloMap be reduced from the current rate of \$2,821 to \$732. On September 30, 2016, CMS published a final gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would be \$1,921. This reimbursement rate, determined by gapfill submissions from the MACs, is open to reconsideration submissions until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the MACs. If an AlloMap reimbursement rate of \$1,921 is published in the Clinical Lab Fee Schedule for 2017, it could cause us to discontinue AlloMap testing for Medicare patients because providing AlloMap tests at that reimbursement rate may not be economically viable. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations. Additionally, some hospitals may reduce the use of AlloMap if it is not available to all patients, and only to non-Medicare recipients.

We will require additional financing and/or refinancing of our current debt obligations to fund working capital, repay debt and pay our obligations. We may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities. Additional financing might include one or more offerings and one or more of a combination of discounted or at-the-market common stock, securities convertible into or exchangeable for shares of common stock, warrants or other rights to purchase or acquire common stock.

Absent additional and sufficient financing and provided that Danske does not demand repayment of debt, we will exhaust our cash and cash equivalents in the quarter ending March 2017 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, which raises substantial doubt about our ability to continue as a going concern. Moreover, we do not believe that we will have sufficient cash to meet our projected operating requirements for the next 12 months from the condensed consolidated balance sheet date included in this Quarterly Report on Form 10-Q unless we raise additional financing. If we are unsuccessful in our efforts to raise sufficient outside financing or refinancing in the near term, we will be required to significantly reduce or cease operations.

#### 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 consolidated 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 consolidated 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 consolidated 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.

#### Product Revenue

We recognize product revenue from the sale of products to end-users, distributors and strategic partners when persuasive evidence of an arrangement exists, the product is complete and tested and has been shipped or delivered, as required to transfer title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and we do not have significant obligations for future performance. When collectability is not reasonably assured, we defer the revenue until the cash is received. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts given to the buyer.

### Finite-lived Intangible Assets

Our finite-lived intangible assets resulted from the acquisition of Allenex. We amortize finite-lived intangible assets using the straight-line method, over their estimated useful lives. The estimated useful lives range from two years to fifteen years and are based on management's estimate of the extent of the economic benefit resulting from these assets. We test for impairment on an annual basis and in between annual tests if we become 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.

### Warrants

On April 14, 2016 and June 15, 2016, we completed the Private Placement and Subsequent Financing, respectively, which included the issuance of freestanding warrants to certain accredited investors and placement agents to purchase shares of our common stock.

The freestanding warrants issued pursuant to the Private Placement and Subsequent Financing are classified as liabilities on the condensed consolidated balance sheet and recorded at their estimated fair value. The warrants are remeasured each reporting period with changes recorded in change in estimated fair value of common stock warrant liability on the condensed consolidated statements of operations.

We utilize a Monte Carlo simulation model to estimate the fair value of the warrants issued in the Private Placement and the Subsequent Financing, and the Placement Agent Warrants. The Monte Carlo simulation model uses multiple input variables to estimate the probability that market conditions will be achieved. These variables include our stock price, the expected term of the warrants, the volatility of our stock prices and our peers' stock prices over such expected term, and the risk-free interest rate for the expected term of the warrants. The variables used in this simulation model are reviewed on a quarterly basis and adjusted, as needed. If we issues common stock at a price lower than the exercise price or issues stock options or other securities (other than securities issued pursuant to our stock or option plans or employment agreements, securities issued or issuable upon exercise or exchange of convertible securities outstanding as of the date the warrants were issued or securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors) with an exercise price that is lower than the current exercise price of the warrants, the exercise price of the warrants shall be adjusted to be equal to such lower price.

### Segment Information

We use the management approach for segment disclosure, which designates our internal organization used by our management for making operating decisions and assessing performance as the source of our reportable segments. We manage our business on the basis of two reportable segments as CareDx, a segment focused on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients, and Allenex, a segment that develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs.

Other than the policies noted above, there have been no other material changes in our critical accounting policies and estimates during the nine months ended September 30, 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 for the fiscal year ended December 31, 2015, as amended, originally 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, damage in transit or other causes. We incur costs in connection with collecting and shipping all samples and a portion of the costs when we cannot ultimately issue a score report. As a result, the number of samples received largely correlates directly to the number of score reports.

#### The Number of Pre-Transplant Diagnostic Products We Sell

The growth of our pre-transplant business is tied to the marketing and sales of the Olerup SSP, SBT Resolver, and XM-ONE product lines. Traditionally, under the Allenex umbrella, the sales organization has been housed internally at Allenex's Stockholm headquarters and at subsidiaries based in Vienna, Austria and West Chester, Pennsylvania. The sales organization also relied on distributors in close to 40 countries. The sales efforts for these products still rely on these entities, including the worldwide distributors.



## How We Recognize Revenue

We recognize revenues for tests and products 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.

For testing revenue, the first criterion is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with us for the test. The second criterion is satisfied when we perform the test and deliver 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 our 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 of the 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 us for tests performed, we recognize revenue on the cash basis in the period in which the payment is received.

Revenue for tests performed is recognized on the accrual basis net of adjustments for differences between amounts billed and the estimated receipts from payers. The amount we expect 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.

Following the criteria above, Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allow us to recognize the related revenue on an accrual basis under U.S. GAAP. For the nine months ended September 30, 2016 and 2015, 35% and 33%, respectively, of our AlloMap 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, if and when we commercialize new post-transplant products such as AlloSure, we will need to achieve our revenue recognition criteria for each payer for each new product prior to being able to recognize related revenue on an accrual basis. Because the timing and amount of cash payments received from payers are difficult to predict, we expect our revenue will 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.

Our Olerup products are sold in the form of lab kits either directly to labs involved in pre-transplant testing or to distributors who sell to labs. Revenue from the sale of these products is recognized on an accrual basis when the risk and benefits of owning the lab kits are transferred to the customer and this occurs either upon shipment or receipt as determined by the contractual terms with customers that cover the transfer of ownership.

## Continued Adoption of and Reimbursement for AlloMap

AlloMap test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap, as Medicare provided reimbursement and payers adopt coverage policies and fewer payers consider AlloMap to be 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 maintain Medicare reimbursement, achieve broader reimbursement from third party payers and to expand the number of tests per patient and the base of ordering physicians.

On June 10, 2016, CMS announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the gapfill reimbursement rate for 2017, which is in the reconsideration period with publication of the Clinical Lab Fee Schedule for 2017 pending, AlloMap reimbursement for patients covered by Medicare would be reduced from \$2,821 to \$1,921, effective January 1, 2017. However, this rate is subject to requests for reconsideration until October 31, 2016 and we have submitted such a request.

## Development of Additional Products

We rely on sales of AlloMap, Olerup SSP, SBT Resolver and XM-ONE to generate the majority of our revenue. Our product development pipeline includes other transplant diagnostic solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. Currently, our product development pipeline includes new products such as AlloSure. QTYPE was commercially launched at the end of September 2016. 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 expend funds 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 will affect our financial results. We conduct clinical studies to validate our new products, such as AlloSure 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

	Total	Payments Due by Period			
		Remainder of 2016	Fiscal 2017 to 2018	Fiscal 2019 to 2021	Fiscal 2022 and Beyond
	(in thousands)				
Debt obligations	\$26,630	\$12,662	\$13,968	\$—	\$—
Deferred purchase consideration	6,200	—	6,200	—	—
Operating lease obligations	8,535	507	4,061	3,967	—
Capital lease obligations	339	63	195	81	—
Inventory purchase commitment	930	930	—	—	—
Software purchase commitment	324	25	299	—	—
<b>Total</b>	<b>\$42,958</b>	<b>\$14,187</b>	<b>\$24,723</b>	<b>\$4,048</b>	<b>\$—</b>

Pursuant to the terms of the Loan Agreement, the maturity date of the amounts loaned to us by East West Bank is December 1, 2018. Our obligation to make principal payments under the Loan Agreement commenced on July 1, 2016, and the loan is payable in 30 equal monthly installments. The First Amendment modified certain financial covenants of the Loan Agreement, added an equity financing covenant to the Loan Agreement and provided for restrictions on certain transactions between us and our subsidiaries. The Second Amendment, among other things, amended the Loan Agreement to permit certain transactions between us and our subsidiaries and to add intellectual property as collateral security. As of September 30, 2016, we were in compliance with our debt covenants with East West Bank.

The acquisition of Allenex required, and, we obtained consent from East West Bank as our lender. East West Bank's consent was contingent upon the closing of a private placement financing for aggregate cash proceeds of at least \$12.0 million and separately depositing into an escrow account cash of \$8.0 million relating to a commitment by the Majority Shareholders to purchase our equity securities in the Subsequent Financing, all of which occurred on April 14, 2016. We are also required to raise another \$20.0 million through one or more equity financings by March 31, 2017, prior to paying the fully accreted value of \$6.2 million of deferred purchase price consideration to the Majority Shareholders.

Pursuant to the terms of promissory notes that Allenex issued to FastPartner AB, we owe principal totaling SEK 15,400,000, or approximately \$1.8 million in U.S. dollars. This debt was outstanding as of September 30, 2016, and is payable in a lump sum on December 31, 2016. However, pursuant to an intercreditor agreement among Allenex, Danske, FastPartner AB, Mohammed Al Amoudi and Olerup SSP AB, dated June 25, 2013, or the Intercreditor Agreement, until the term loan facility with Danske, or the Term Loan Facility, is repaid, FastPartner AB may not demand or receive payment of its subordinated promissory notes, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory notes, without Danske's prior written consent. Allenex's obligations under the promissory note is secured by a pledge of Allenex shares to FastPartner AB. FastPartner AB is one of the three Majority Shareholders and a related party to us.

Pursuant to the terms of a promissory note that Allenex issued to Mohammad Al Amoudi, we owe principal in the amount of SEK 10,600,000, or approximately \$1.2 million in U.S. dollars. This debt was outstanding as of September 30, 2016, and is payable in a lump sum on December 31, 2016. However, pursuant to the Intercreditor Agreement, until the Term Loan Facility with Danske is repaid, Mohammed Al Amoudi may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. Allenex's obligations under the promissory note is secured by a pledge of Allenex shares to Mohammad Al Amoudi. Mohammed Al Amoudi is affiliated with Midroc Invest AB and Xenella Holding AB, which are two of the three Majority Shareholders. Mohammed Al Amoudi is a related party to us.

Pursuant to the terms of a loan agreement that Allenex entered into with SSP Primers Aktieboulag, SEK 10,000,000, or approximately \$1.2 million in U.S. dollars, was outstanding as of September 30, 2016, and is payable in two equal payments of SEK 5,000,000, or approximately \$0.6 million in U.S. dollars, in February 2017 and February 2018.

Pursuant to the Term Loan Facility, SEK 63,500,000, or approximately \$7.4million in U.S. dollars, was outstanding as of September 30, 2016, and one quarterly payment of SEK 1,500,000, or approximately \$0.2 million in U.S. dollars, are payable in the fourth quarter of 2016, and six quarterly payments of SEK 3,000,000, or approximately \$0.4 million in U.S. dollars, are payable in 2017 and the first half of 2018, and the remaining balance of SEK 44,000,000, or approximately \$5.1 million in U.S. dollars, is due in June 2018. Notwithstanding the repayment schedule provided by the Term Loan Facility, the full outstanding balance was reclassified to current liabilities due to the end of the quarterly roll-over provisions on December 31, 2016.

Due to insufficient working capital in Allenex, a debt covenant in the Term Loan Facility relating to maintaining an adequate leverage ratio was violated at each of June 30, 2016 and September 30, 2016. We obtained waivers from Danske for each of these violations of the debt covenant. Although each of these violations of the leverage ratio covenant may be resolved upon the next measurement date of December 31, 2016, Danske has the ability to demand repayment of the debt if the violation is not resolved. For these reasons, the long-term debt due to Danske was classified as a current liability in the condensed consolidated balance sheet as of September 30, 2016. Additionally, if the loan was no longer available or Danske demanded repayment of the debt, we may not have sufficient capital to operate.

Pursuant to a short term credit facility that Allenex entered into with Danske, we have total available credit of SEK 10,000,000, or approximately \$1.2 million in U.S. dollars. As of September 30, 2016, our outstanding balance was SEK 5,200,000, or approximately \$0.6 million in U.S. dollars, and pursuant to a quarterly roll-over provision is due on December 31, 2016.

#### 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.

## Foreign Operations

The accompanying balance sheets contain certain recorded assets in foreign countries, primarily Sweden and Austria. Although these countries are considered economically stable and we have experienced no notable burden from foreign exchange transactions, export duties or government regulations, unanticipated events in foreign countries could have a material adverse effect on our operations.

## 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 \$22.3 million and \$34.0 million at September 30, 2016 and 2015, respectively, which consisted of bank deposits and money market funds. Additionally, we had debt of \$26.4 million and \$15.7 million as of September 30, 2016 and 2015, respectively. Most of our current debt arrangements bear 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 increase or decrease in interest rates, which is approximately a 10% increase or decrease, as applicable, in the cost of borrowing, during any of the periods presented would not have a material impact on our unaudited condensed consolidated 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.

Following the acquisition of Allenex on April 14, 2016, with operations in Sweden and other countries in Europe, we are subject to significant foreign currency exposures, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in Swedish Krona and Euro and to a lesser extent in U.S. dollars. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona and the Euro, which is also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at September 30, 2016, would have negatively impacted our annual financial results by \$1.5 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

#### 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 Rules 13a-15(b) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended), 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, and as a result of the material weaknesses described below, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective at the reasonable assurance level and are not 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.

##### Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected and corrected on a timely basis. During the quarter ended June 30, 2016, we identified material weaknesses in our internal control over financial reporting relating to: (i) certain areas of our financial statement close process, specifically with respect to an incorrect classification of the deferred consideration payable to the Majority Shareholders within our consolidated statement of cash flows following the Allenex acquisition, and (ii) a failure in the design and implementation of controls over our accounting for business combinations, specifically we did not design and implement transaction level or management review controls for the oversight, integration and consolidation of the acquired entities or controls to assess the completeness and accuracy of information, including key inputs and assumptions used by third party specialists, used in estimating the fair value of assets acquired and liabilities assumed. These control deficiencies resulted in the incorrect valuation of inventories and certain intangible assets acquired. These errors were corrected in the consolidated financial statements included in the Company's Form 10-Q for the quarter ending June 30, 2016.

Despite the existence of these material weaknesses, we believe that the consolidated financial statements included in this Quarterly Report on Form 10-Q present, in all material respects, our financial position, results of operations, comprehensive loss and cash flows for the periods presented in conformity with U.S. GAAP.



#### Remediation Efforts to Address Material Weaknesses

We have prepared a preliminary remediation plan to address the underlying causes of the material weaknesses described above. The preliminary remediation plan includes, among other things, reassessing the design and operation of internal controls over our financial statement close process and the related accounting staffing levels and experience; and designing and implementing effective internal controls related to business combination, including management's review of the completeness and accuracy of information and key inputs and assumptions used to estimate the fair value of assets acquired and liabilities assumed. We cannot assure you that the measures we may take in response to these material weaknesses will be sufficient to remediate such material weaknesses or to avoid potential future material weaknesses.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred 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, other than with respect to the material weakness and the preliminary remediation plan noted above.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

On April 25, 2016, Oberland filed a breach of contract claim against us in the Supreme Court of the State of New York, County of New York, or the Oberland Complaint, alleging, among other things, that we breached certain provisions of the amended and restated commitment letter and the restated fee letter that we entered into with Oberland on February 8, 2016. Pursuant to the Oberland Complaint, Oberland is seeking damages against us in the amount of at least \$1.4 million, plus costs and expenses, including the fees and expenses of Oberland's attorneys. On July 15, 2016, we filed an answer and made counterclaims against Oberland, or the Answer, generally denying the claims asserted by Oberland in the Oberland Complaint and asserting fraudulent inducement and breach of contract counterclaims against Oberland. Pursuant to the Answer, we are seeking dismissal of the Oberland Complaint in its entirety, recession of all agreements with Oberland and damages of not less than \$1.3 million, together with interest and punitive damages, if deemed appropriate under applicable law, and costs and disbursements of the action, including reasonable attorneys' fees. On August 4, 2016, Oberland filed a motion to dismiss our counterclaims and affirmative defenses asserted in the Answer. We believe that we have meritorious defenses to the claims asserted in the Oberland Complaint and that the counterclaims asserted by us in the Answer have merit. We intend to vigorously defend against the claims asserted by Oberland and vigorously pursue the counterclaims set forth in the Answer. Oral arguments for this motion are scheduled for December 8, 2016. However, there is no guarantee that we will prevail in this suit or recover damages from our counterclaims or other relief if we do prevail. As a result, we had accrued the amount being claimed by Oberland of \$1.4 million. See Note 9 of the unaudited condensed consolidated financial statements included elsewhere in Item 1 of Part 1 of this Quarterly Report on Form 10-Q for additional information.

In addition, on June 15, 2016, we received a letter from Nasdaq OMX Stockholm AB, or the Exchange, regarding our compliance with the requirements of the Nasdaq Stockholm Takeover Rules, or the Takeover Rules, and good practice in the securities market in Sweden in connection with our recently completed acquisition of Allenex AB. The Exchange concluded that we violated certain technical provisions of the Takeover Rules and acted contrary to good practice in the securities market in Sweden, and gave us the opportunity to submit our views before it decided whether to refer the matter to its Disciplinary Committee. On July 11, 2016, we submitted a response, which was considered by the Exchange in making a final determination whether to refer the matter to its Disciplinary Committee for further assessment. On September 21, 2016, we received notice from the Exchange that, by letter dated September 20, 2016 from the Exchange to its Disciplinary Committee, the Exchange has referred the matter to the Disciplinary Committee and is seeking a ruling from the Disciplinary Committee regarding disciplinary sanction. The Disciplinary Committee has the authority to impose a fine and/or sanctions. We have been granted an opportunity to submit documents in support of our position to the Disciplinary Committee. This submission must be completed by November 24, 2016. A hearing before the Disciplinary Committee is currently scheduled for December 9, 2016. Takeover Rules authorize the Exchange to impose a special fine ranging between SEK 50,000 (approximately \$6,000) and SEK 100 million (approximately \$12.0 million). We cannot predict the outcome of the Disciplinary Committee review. An adverse determination by the Disciplinary Committee could have a material adverse effect on us.

From time to time, we may become subject to legal proceedings and claims that arise in the ordinary course of business. Although 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, 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 Securities and Exchange Commission, or 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, as amended, originally filed on March 29, 2016 with the SEC, which is incorporated herein by reference. 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.

Risk factors marked with an asterisk (\*) below include a change from or an update to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2015, as amended, originally filed with the SEC on March 29, 2016.

### Risks Related to Our Business

\*We have a history of losses, and we expect to incur net losses for the next several years.

We have incurred substantial net losses since our inception, and we expect to continue to incur additional losses for the next several years. For the nine months ended September 30, 2016 and September 30, 2015, our net loss was \$24.0 million and \$8.9 million, respectively. As of September 30, 2016, we had an accumulated deficit of \$197.1 million. For the year ended December 31, 2015, our net loss was \$13.7 million. As of December 31, 2015, we had an accumulated deficit of \$173.1 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new diagnostic solutions, including additional expenses in connection with our continuing development of AlloSure and other future diagnostic solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of integrating the Allenex business and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel; and
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a public company.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. For a detailed discussion of our financial condition and results of operations, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

\*We will require additional financing.

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex AB, or Allenex. 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 aggregate purchase consideration paid by us was approximately \$34.1 million and consisted of (i) \$26.9 million of cash, of which approximately \$5.7 million was deferred purchase consideration payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB, or the Majority Shareholders, by no later than March 31, 2017, and (ii) the issuance of 1,375,029 shares of our common stock valued at \$7.2 million. Of the total cash consideration, \$8.0 million of cash payable to the Majority Shareholders was deposited into an escrow account by us and subsequently invested in us by the Majority Shareholders through a purchase of our equity securities in a subsequent financing, or the Subsequent Financing. Upon the completion

of the Subsequent Financing, certain contingencies in the Conditional Share Purchase Agreements were waived, and the deferred purchase consideration is due to the Majority Shareholders by no later than March 31, 2017. Our deferred purchase consideration obligations are secured by a pledge of shares of Allenex. We determined at the date of the acquisition that these contingencies would be waived. We intend to complete compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. On June 8, 2016, we delisted Allenex's common stock from Nasdaq Stockholm.

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, or the Private Placement. The aggregate gross proceeds to us from the Private Placement were approximately \$14.2 million. Concurrently, we also entered into Commitment Letters pursuant to which the Majority Shareholders agreed to purchase our equity securities in the Subsequent Financing. 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. On June 15, 2016, we completed the Subsequent Financing for the sale of an additional 334,169 Units to the Majority Shareholders. The aggregate gross proceeds to us from the Subsequent Financing were approximately \$8.0 million. Securities issued in the Subsequent Financing were issued and sold at the same price and on substantially the same terms as the securities issued in the Private Placement.

On September 26, 2016, we completed the Public Offering pursuant to which we issued and sold an aggregate of 2,250,000 shares of our common stock at a public offering price of \$4.00 per share, or the Public Offering. The aggregate gross proceeds to us were approximately \$9.0 million, and \$7.8 million net of issuance costs. The Public Offering was made pursuant to our registration statement on Form S-3, which was declared effective by the SEC on December 4, 2015, a base prospectus dated December 4, 2015 and a prospectus supplement dated September 21, 2016. Piper Jaffray & Co. acted as the sole underwriter for the Public Offering.

Notwithstanding the prior transactions, we will require additional financing and/or refinancing of our current debt obligations to fund working capital, repay debt and to pay our obligations, including our year-end obligations under a term loan facility, or the Term Loan Facility, with Danske Bank A/B, or Danske, and our obligations to FastPartner AB and Mohammed Al Amoudi under our outstanding promissory notes with such parties. Our obligations under the promissory notes are secured by a pledge of shares of Allenex. We may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities. Additional financing might include one or more offerings and one or more of a combination of discounted or at-the-market common stock, securities convertible into or exchangeable for shares of common stock, warrants or other rights to purchase or acquire common stock.

Absent the receipt of additional financing and provided that Danske, does not demand repayment of debt, we expect that we will exhaust our cash and cash equivalents in the quarter ended March 31, 2017 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 our indebtedness in the near term, we will be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements as of and for each of the three years in the period ended December 31, 2015, included in our Annual Report on Form 10-K for the year ended December 31, 2015, included a "going concern" explanatory paragraph indicating that our recurring losses from operations and need for additional capital raise substantial doubt about our ability to continue as a going concern.

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

For the past three months and nine months ended September 30, 2016, payments from Medicare for AlloMap represented 45% of post-transplant testing revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

We expect the Centers for Medicare and Medicaid Services, or CMS, to publish a final Clinical Lab Fee Schedule in late November or early December 2016, for reimbursement rates beginning January 1, 2017, including reimbursement for AlloMap. CMS is using a process referred to as “gapfill” to establish reimbursement rates for 2017. The gapfill process consists of a number of steps, including: (i) CMS obtaining preliminary proposed reimbursement for AlloMap from the eight Medicare Administrative Contractors, or MACs; (ii) CMS obtaining final reimbursement submission for AlloMap from the eight MACs; and (iii) a reconsideration period, with requests for reconsideration due by October 31, 2016. On June 10, 2016, CMS announced the proposed gapfill pricing from the MACs for patients covered by Medicare, which initially proposed that reimbursement for AlloMap be reduced from the current rate of \$2,821 to \$732. On September 30, 2016, CMS published a final gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would be \$1,921. This reimbursement rate, determined by gapfill submissions from the MACs, is open to reconsideration submissions until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the MACs. If an AlloMap reimbursement rate of \$1,921 is published in the Clinical Lab Fee Schedule for 2017, it could cause us to discontinue AlloMap testing for Medicare patients because providing AlloMap tests at that reimbursement rate may not be economically viable. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations. Additionally, some hospitals may reduce the use of AlloMap if it is not available to all patients, and only to non-Medicare recipients.

Even if the reimbursement levels are increased from the rate posted on September 30, 2016, if they are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. We may also not be able to maintain or increase the portion of our tests reimbursed by Medicare for a variety of other reasons, including changes in reimbursement practices and general policy shifts.

On a five-year rotational basis, Medicare requests bids for its regional MAC, services. Medicare reimbursement for AlloMap began in 2006 and has continued through three successive MACs. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U.S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloMap at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloMap could impact the coverage or payment amount for our test and our ability to obtain Medicare coverage for any products we may launch in the future.

Any decision by CMS or its local contractors to reduce or deny coverage for our test would have a significant adverse effect on our revenue and results of operations. Any such decision could also cause affected clinicians treating Medicare covered patients to reduce or discontinue the use of our AlloMap test.

\*Our financial results currently are largely dependent on sales of one post-transplant test, AlloMap, and Allenex’s current Olerup SSP products for pre-transplant matching, and we will need to generate sufficient revenues from these and other solutions and tests we develop to grow our business.

A majority of our revenue is currently dependent on sales of AlloMap for heart transplant recipients and secondarily from sales of Olerup SSP products for pre-transplant matching of donors and recipients. We expect that sales of AlloMap and Olerup SSP products will account for a substantial portion of our revenue for at least the next two years. Although we are working to commercialize AlloSure, our dd-cfDNA-based solution for solid organ transplant recipients, and QTYPE for more rapid testing of pre-transplant organs and tissues, even if we are successful in developing these new tests, we expect that adoption will take many quarters during which our financial results will depend on the performance of our existing solutions and test. While we are in the process of commercializing AlloSure for kidney transplant recipients, the first group of patients the test will be available for, even if we are successful in developing this test, we do not expect to receive approval for reimbursement of this test, which will drive its value as a contributor to our revenue stream, for at least the next several fiscal quarters. If we are unable to increase sales of AlloMap or Olerup SSP products or successfully develop and commercialize other solutions, tests or enhancements, such as QTYPE, which was commercially launched at the end of September 2016, our revenues and our ability to achieve profitability would be impaired, and the market price of our common stock could decline.



\*We are subject to legal proceedings that could be time consuming, result in costly litigation and settlements/judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business, financial condition and results of operations.

We are currently involved in, and from time to time in the future may become involved in, lawsuits, claims and proceedings incident to the ordinary course of or otherwise in connection with our business. Litigation is inherently unpredictable. For example, on June 14, 2016, Oberland Capital SA Davos LLC, or Oberland, filed a breach of contract claim against us in the Supreme Court of the State of New York, County of New York, or the Oberland Complaint, alleging, among other things, that we breached certain provisions of the amended and restated commitment letter and the restated fee letter that we entered into with Oberland on February 8, 2016. Pursuant to the Oberland Complaint, Oberland is seeking a monetary judgment against us in the amount of at least \$1.4 million, plus costs and expenses, including the fees and expenses of Oberland's attorneys. On July 15, 2016, we filed an answer and counterclaims against Oberland, or the Answer, generally denying the claims asserted in the Oberland Complaint and asserting fraudulent inducement and breach of contract counterclaims against Oberland. Pursuant to the Answer, we are seeking dismissal of the Oberland Complaint in its entirety, rescission of all agreements with Oberland and damages of not less than \$1.3 million, together with interest and punitive damages, if deemed appropriate under applicable law, and costs and disbursements of the action, including reasonable attorneys' fees. On August 4, 2016, Oberland filed a motion to dismiss our counterclaims and affirmative defenses asserted in the Answer. Oral arguments on this motion are scheduled for December 8, 2016. There is no guarantee that we will prevail in this suit or receive any damages or other relief if we do prevail. Moreover, our defense of this lawsuit and others that may be brought against us in the future may be time consuming, result in costly litigation, require significant amounts of management time and result in the diversion of significant operational resources, each of which may adversely affect our business, financial condition and results of operations.

In addition, on June 15, 2016, we received a letter from Nasdaq OMX Stockholm AB (the "Exchange") regarding our compliance with the requirements of the Nasdaq Stockholm Takeover Rules (the "Takeover Rules") and good practice in the securities market in Sweden in connection with our recently completed acquisition of Allenex AB. The Exchange concluded that we violated certain technical provisions of the Takeover Rules and acted contrary to good practice in the securities market in Sweden, and gave us the opportunity to submit our views before it decided whether to refer the matter to its Disciplinary Committee. On July 11, 2016, we submitted a response, which was considered by the Exchange in making a final determination whether to refer the matter to its Disciplinary Committee for further assessment. On September 21, 2016, we received notice from the Exchange that, by letter dated September 20, 2016 from the Exchange to its Disciplinary Committee, the Exchange has referred the matter to the Disciplinary Committee and is seeking a ruling from the Disciplinary Committee regarding disciplinary sanction. The Disciplinary Committee has the authority to impose a fine and/or sanctions. We have been granted an opportunity to submit documents in support of our position to the Disciplinary Committee. This submission must be completed by November 24, 2016. A hearing before the Disciplinary Committee is currently scheduled for December 9, 2016. Takeover Rules authorize the Exchange to impose a special fine ranging between SEK 50,000 (approximately \$6,000) and SEK 100 million (approximately \$12.0 million). We cannot predict the outcome of the Disciplinary Committee review. An adverse determination by the Disciplinary Committee could have a material adverse effect on us.

\*The development and commercialization of additional diagnostic solutions, including solutions related to the acquisition of Allenex, are a key to our growth strategy. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize additional diagnostic solutions.

Key elements of our strategy are to discover, develop, validate and commercialize a portfolio of new diagnostic solutions in addition to AlloMap and Olerup SSP. While we have engaged in discovery and development activity for AlloSure, our dd-cfDNA solution for solid organ transplant recipients, we will be required to devote considerable additional efforts and resources to the further research and development of this test to demonstrate its clinical validity

and utility before it will be fully adopted for use in recipients of various types of donated organs. Our planned new diagnostic solutions for organs other than the heart or kidney, are at much earlier stages of development. dd-cfDNA solutions are a novel technology, and to date have not been used commercially in the field of transplantation surveillance. In connection with the acquisition of Allenex, we acquired two new potential commercial opportunities, QTYPE and XM-ONE, to address pre-transplantation testing needs. In 2014 and 2015, Allenex expended significant resources to develop QTYPE. QTYPE was commercially launched at the end of September 2016. XM-ONE is a research product for larger medical centers and we are working to establish broader commercial use. We cannot assure you that we will be able to successfully complete development of or commercialize any of our planned future or recently launched solutions, or that they will prove to be capable of reliably being used for organ surveillance in the heart or in other types of organs. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;
- obtain the necessary testing samples and related data;
- conduct clinical validation studies;

57

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- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from ordering clinicians at a larger number of transplant centers;
- gain acceptance from ordering laboratories associated with transplant centers; and
- seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations.

This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization efforts may be delayed or fail for many reasons, including:

- failure of the test at the research or development stage;
- difficulty in accessing suitable testing samples, especially testing samples with known clinical results;
- 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, or third-party payers.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new diagnostic solutions, or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those new diagnostic solutions. In addition, as we develop diagnostic solutions, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a test is abandoned or delayed. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical trial, which could harm our business.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of additional diagnostic solutions by us may be delayed and, as a result, our business will suffer and our stock price may decline.

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. In addition, we have included a discussion of a number of anticipated targets in our Annual Report on Form 10-K for the year ended December 31, 2015, as amended, as originally filed with the SEC on March 29, 2016. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

\*The field of diagnostic testing in transplantation is evolving and is subject to rapid technological change. If we are unable to develop solutions to keep pace with rapid medical and scientific change, our operating results could be harmed.

The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations which could make AlloMap, Olerup SSP products, and our solutions in development, outdated. We must continually innovate and expand our test offerings to address unmet needs in monitoring transplant related conditions and in pre-transplant testing. AlloMap, Olerup SSP products and our solutions under development could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloMap, Olerup SSP

products and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our solutions and tests could decline, which would harm our business and financial results.

\*If clinicians, hospital administrators, medical centers and laboratories do not adopt our diagnostic solutions, we will not achieve future sales growth.

Clinicians and healthcare administrators are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we continue to educate clinicians, administrators and laboratory directors about AlloMap, AlloSure, Allenex's SSP product line and, subject to their development, our other solutions, and demonstrate the clinical and diagnostic benefits of these solutions and products. We believe that clinicians, transplant centers and laboratories may not use our solutions unless they determine, based on published peer-reviewed journal articles, the experience of other clinicians or laboratory verification, that our solutions provide accurate, reliable and cost-effective information that is useful in pre-transplant matching and monitoring their post-transplant recipients.

We estimate that there are approximately 130 centers managing heart transplant recipients in the United States. In 2015, AlloMap was used in 120 of these centers. However, not all clinicians in these centers are currently using our test. In order for AlloMap sales to grow, we must continue to market to and educate clinicians and administrators at treatment centers that have used our test to increase the number of clinicians ordering our test, the number of recipients tested and the number of tests per recipient. In addition, we must actively solicit additional treatment centers to establish policies and procedures for ordering our test and to encourage clinicians at those centers to incorporate our test into their standard clinical practice. Some of the challenges that our sales team must overcome include explaining the clinical benefits of AlloMap, which is a highly technical product, and changing a 30-year patient management paradigm of using biopsy as the basis of transplant recipient monitoring.

Our Olerup SSP pre-transplant tests are sold to hundreds of laboratories mainly in Europe and the U.S. Laboratories order pre-transplant testing products based on the accuracy, speed and cost of the test together with the cost and availability of equipment on which to run the test. Switching to or adopting our Olerup SSP product often requires the purchase of new and costly testing equipment. To attract new laboratory customers, the performance of our Olerup SSP products must provide an accuracy, speed and/or cost advantage over similar products sold by our competitors.

If clinicians, hospital administrators and laboratories do not adopt and continue to use AlloMap, Olerup SSP products or our future solutions and tests, our business and financial results will suffer.

\*Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Historically, our financial results have been, and we expect that our operating results will continue to be, subject to quarterly fluctuations. Our net income (loss) and other operating results will be affected by numerous factors, including:

- our ability to successfully market and sell AlloMap and Olerup SSP products;
- our ability to commercialize new diagnostic solutions and tests such as AlloSure and QTYPE, which was commercially launched at the end of September 2016;
- the amount of our research and development expenditures;
- the timing of cash collections from third-party payers;
- the extent to which our current test and future solutions, if any, are eligible for coverage and reimbursement from third-party payers;
- the process of integrating new acquisitions, such as Allenex, and the associated potential disruption to our business;
- changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business;
  - any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved or that otherwise may affect our intellectual property position;

announcements by our competitors of new or competitive products;  
regulatory or legal developments affecting our test or competing products;  
total operating expenses; and  
changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts.

59

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If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

\*If the utility of AlloMap, AlloSure and our other solutions is not supported by studies published in peer-reviewed medical publications, and then periodically supplemented with additional support in peer-reviewed journals, the rate of adoption of our current and future solutions by clinicians and treatment centers and the rate of reimbursement of our current and future solutions by payers may be negatively affected.

The results of our clinical trials involving AlloMap have been presented at major medical society congresses and published in peer-reviewed publications in leading medical journals. We need to maintain a continued presence in peer-reviewed publications to promote clinician adoption and favorable reimbursement decisions. We believe that peer-reviewed journal articles that provide evidence of the utility of our solutions or the technology underlying AlloMap or our other solutions are very important to the commercial success of our solutions. Clinicians typically take a significant amount of time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about AlloMap, AlloSure and our future solutions, and demonstrate the clinical benefits of these solutions. Clinicians may not adopt, and third-party payers may not cover or adequately reimburse for, our current and future solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our diagnostic current and future solutions provide accurate, reliable and cost-effective information that is useful in monitoring transplant recipients and making informed and timely treatment decisions.

The administration of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our current and future solutions would suffer and our business would be harmed. While we have had success in generating peer-reviewed publications regarding AlloMap, peer-reviewed publications regarding AlloSure and our future solutions may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies that would be the subject of the article. If our current and future solutions or the technology underlying AlloMap, AlloSure or our future solutions do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption and positive reimbursement coverage decisions could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for diagnostic solutions such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

We are in the process of completing clinical trials demonstrating the clinical validity of AlloSure, our development stage transplant surveillance solution, and clinical performance characteristics of dd-cfDNA. To ensure the success of AlloSure and future tests based on dd-cfDNA, we will need to continue our efforts to complete and publicize research and trials that provide evidence of the utility of dd-cfDNA and validate AlloSure as a solution.

Transplant centers may not adopt AlloMap or our other solutions due to historical practices or due to more favorable reimbursement policies associated with other means of monitoring transplants.

Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute cellular rejection in heart transplant recipients by utilizing biopsies. Many clinicians use AlloMap in parallel with biopsies rather than as an alternative to biopsies. While we do not

market AlloMap as a biopsy alternative, per se, if treatment center administrators view our test as an alternative to a biopsy and believe they would derive more revenue from the performance of biopsies, such administrators may be motivated to reduce or avoid the use of our test. We cannot provide assurance that our efforts will increase the use of our test by new or existing customers. Our failure to increase the frequency of use of our test by new and existing customers would adversely affect our growth and revenues.

\*If we are unable to successfully compete with larger and more established players in the clinical surveillance of the transplantation field, we may be unable to increase or sustain our revenues or achieve profitability.

Our AlloMap solution for heart transplant recipients competes against existing diagnostic tests utilized by pathologists, which, in the case of heart transplant rejection, generally involve evaluating biopsy samples to determine the presence or absence of rejection. This practice has been the standard of care in the United States for many years, and we will need to continue to educate clinicians, transplant recipients and payers about the various benefits of our test in order to change clinical practice.



Competition for kidney surveillance diagnostics can also come from biopsies. However, because of the risks and discomforts of the invasive kidney biopsy procedure, as well as the expense and relatively low rate of finding moderate to severe grade rejection, biopsy is not a standard practice for surveillance of transplanted kidneys. Additional competition for kidney surveillance diagnostics currently comes from general, non-specific clinical chemistry tests such as serum creatinine, urine protein, complete blood count, lipid profile and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs.

We expect the competition for pre- and post-transplant surveillance to increase as there are numerous established and startup companies in the process of developing novel products and services for the transplant market which may directly or indirectly compete with AlloMap or our development pipeline. Allenex has a well-established business with well-known products in the field of HLA typing based on Olerup SSP. However, competition from other companies, especially those with an eye toward transitioning to more automated typing processes, could impact Allenex's ability to maintain market share and its current margins. In addition to companies focused on pre-transplantation such as Thermo Fisher Scientific Inc.'s One Lambda and Immucor, Inc.'s LIFECODES businesses, companies who have not historically focused on transplantation, but with existing knowledge of dd-cfDNA technology have indicated they are considering this market.

The field of clinical surveillance of transplantation is evolving. New and well established companies are devoting substantial resources to the application of molecular diagnostics to the treatment of medical conditions. Some of these companies may elect to develop and market diagnostic solutions in the post-transplant surveillance market.

Many of our potential competitors have greater brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by clinicians and payers as functionally equivalent to our AlloMap test, which could force us to lower the current list price of our test and impact our operating margins and our ability to achieve profitability. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of AlloMap and our future solutions, which could prevent us from increasing or sustaining our revenues or achieving profitability and could cause the market price of our common stock to decline.

\*If we are unable to successfully and continually update our Olerup SSP typing kits on a timely basis, our ability to attract and retain patients could be impaired and our competitive position could be harmed.

We operate in an environment characterized by rapid development and continuing innovation. We will need to continue to maintain the value of our Olerup SSP offering. To compete successfully, we must continually update our product range and produce continually updated HLA test kits. The failure to maintain the quality of our products or inability to keep pace with this innovation could render our existing or future solutions obsolete or less attractive to patients. Any failure to anticipate or develop new or enhanced solutions in a timely manner could result in decreased revenue and harm to our business and prospects. If we fail to introduce new or enhanced solutions that meet the needs of our patients, we will lose market share and our business, operating results and prospects will be adversely affected.

\*Our research and development efforts will be hindered if we are not able to acquire or contract with third parties for access to additional tissue and blood samples.

Our clinical development relies on our ability to secure access to tissue and blood samples, as well as recipient information including biopsy results and clinical outcomes from the same patient. Furthermore, the studies through which our future solutions are developed may rely on access to multiple samples from the same recipient over a period of time as opposed to samples at a single point in time or archived samples. We will require additional samples and recipient data for future research, development and validation. Access to recipients and samples on a real-time, or non-archived, basis is limited and often on an exclusive basis, and there is no guarantee that initiatives such as the

DART study will be successful in obtaining and validating additional samples. Additionally, the process of negotiating access to new and archived donor and recipient data and samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues, such as usage rights, institutional review board approval, recipient consent, privacy rights and informed consent of recipients, publication rights, intellectual property ownership and research parameters. If we are not able to acquire or negotiate access to new and archived donor and recipient data and tissue and blood samples with source institutions, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future solutions such as AlloSure will be limited or delayed.

\*If we cannot maintain existing new clinical collaborations and enter into new ones, our efforts to commercialize AlloMap and QTYPE and our development of new products such as AlloSure could be delayed.

In the past, we have entered into clinical trial collaborations with highly regarded academic institutions and leading treatment centers in the transplant field. Our success in the future may depend in part on our ability to enter into agreements with other leading institutions in the transplant field. Securing these agreements can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. In addition to completing clinical trial collaborations, publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining coverage and reimbursement for solutions such as ours. Our inability to control when, if ever, results of such studies are published may delay or limit our ability to derive sufficient revenues from any test that may result from a collaboration.

From time to time we expect to engage in discussions with potential clinical collaborators, which may or may not lead to collaborations. We cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies which may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations become known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the other entity's announcement of a collaboration with an entity other than us may result in adverse speculation about us, our current and future solutions or our technology, resulting in harm to our reputation and our business.

If we are unable to successfully manage our growth and support demand for our tests, our business may suffer.

As the volume of the tests that we perform grows, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements and expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products are developed, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. We plan to expand our sales force to support additional products. There is significant competition for qualified, productive sales personnel with advanced sales skills and technical knowledge in our field. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training, and retaining sufficient qualified sales personnel.

The value of AlloMap depends, in large part, on our ability to perform AlloMap on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new equipment or processes or to hire new personnel could result in higher costs of processing or an inability to meet market demand in a timely manner. There can be no assurance that we will be able to perform AlloMap or our future solutions, if any, on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand for our current and future solutions, our reputation could be harmed and our future prospects and our business could suffer.

In addition, our growth may place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage

our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

\*Our past testing revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline.

From 2014 to 2015, our testing revenue grew from \$25.8 million to \$27.9 million, which represents annual growth of 8%. For the nine months ended September 30, 2015 versus September 30, 2016, our testing revenue increased from \$21.1 million to \$22.3 million, which represents an increase of 6%. In the future, our revenue may not grow at all and it may decline. We believe that our future revenue will depend on, among other factors:

- the continued usage and acceptance of our current and future solutions;
- demand for our products and services;
- the introduction and acceptance of new or enhanced products or services by us or by competitors;
- our ability to maintain reimbursement for AlloMap and secure reimbursement for our future solutions;

62

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our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies;  
our ability to attract, retain and motivate qualified personnel;  
the initiation, renewal or expiration of significant contracts with our commercial partners;  
pricing changes by us, our suppliers or our competitors; and  
general economic conditions and other factors.

We may not be successful in our efforts to manage any of the foregoing, and any failure to be successful in these efforts could materially and adversely affect revenue growth. You should not consider our past revenue growth to be indicative of future growth.

If our sole laboratory facility in the U.S. becomes inoperable, we will be unable to perform AlloMap and future testing solutions, if any, and our business will be harmed.

We perform all of our diagnostic services for the U.S. in our laboratory located in Brisbane, California. Additionally, through our partnership with Diaxonhit we have recently validated a dedicated laboratory for AlloMap testing in Europe through the Strasbourg University Hospital Central Immunology Laboratory. We do not have redundant laboratory facilities. Brisbane, California is situated on or near earthquake fault lines. Our facility and the equipment we use to perform AlloMap would be costly to replace and could require substantial lead time to repair or replace, if damaged or destroyed. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, flooding and power outages, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us in the U.S. would be required to be certified under the Clinical Laboratory Improvement Amendments, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including California, Florida, Maryland, New York and Pennsylvania, which can take a significant amount of time and result in delays in our ability to begin operations at that facility. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform AlloMap or future solutions following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing or able to adopt AlloMap or future solutions and comply with the required procedures, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

Any additional laboratories opened in Europe would need to undergo a multi-step validation process demonstrating that AlloMap test results provided from such laboratory are equivalent to AlloMap results generated by our Brisbane, California laboratory. Training and other preparation is required before the laboratory is operational, and any commercial partner in Europe may encounter unanticipated obstacles. We do not have access to redundant facilities in Europe and our exclusive arrangement with Diaxonhit precludes the engagement by us of another collaboration partner whose laboratories we could use in the event that our primary facility is harmed or rendered inoperable. Without immediate access to an alternative facility, any disruption to our European partner's laboratory may result in delays in the delivery of test results, patient claims, loss of customers or harm to our reputation.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of recipient samples to our laboratory and enhanced tracking of these recipient samples. Should a carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our recipient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis.

Our ability to commercialize the diagnostic solutions that we develop is dependent on our relationships with laboratory services providers and their willingness to support our current and future solutions.

We rely on third-party laboratory services providers to draw the recipient blood samples that are analyzed in our Brisbane, California laboratory. Our business will suffer if these service providers do not support AlloMap or the other solutions that we may develop. For example, these laboratories may determine that the effort to process the samples for our solutions requires too much additional effort. Additionally, if transplant facilities have relationships with large reference laboratories that will not process and send out our specimens, the clinicians at these facilities may deem ordering our tests outside of these relationships too inconvenient for their patients. A lack of acceptance of our current and future solutions by these service providers could result in lower test volume.

\*If we are unable to raise additional capital on acceptable terms in the future, it may limit our ability to develop and commercialize new diagnostic solutions and technologies, and we may have to curtail or cease operations.

We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- complete development of AlloSure, our proposed dd-cfDNA test for heart and kidney, or develop other solutions for clinical surveillance in transplantation;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of AlloMap and our pre-transplant tests or enhancements to those tests;
- acquire or license products or technologies including through acquisitions; and
  - finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our dd-cfDNA test for heart and kidney transplant recipients and additional solutions for the surveillance of transplantation of other organs and our new HLA typing product, QTYPE, commercially launched at the end of September 2016 that reduces the time required to match donor organs and tissue with potential recipients prior to transplantation and uses real-time PCR;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional FDA or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. For example, we have the ability to sell additional shares of our common stock to the public through an “at the market” offering and a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. Any shares of common stock issued in the at-the-market offering will result in dilution to the existing stockholders. 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, and the terms of the debt securities issued could impose significant restrictions on our operations. 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 may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.



\*Our debt agreements contain restrictive and financial covenants that may limit our operating flexibility.

Our existing debt agreements with East West Bank and Danske contain certain restrictive covenants that limit our ability to merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements, incur additional indebtedness or enter into various specified transactions. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate our existing debt agreements. Our debt agreements also contain certain financial covenants, including minimum revenue requirements, a cap on expenses, a minimum cash flow to debt service ratio and maximum leverage and solvency ratios and are secured by substantially all of our assets. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under our debt agreements or to satisfy all of the financial covenants. For example, as of February 29, 2016, we were in violation of one of our financial covenants under our loan agreement with East West Bank. This violation was waived and memorialized in a written amendment to the loan agreement dated May 12, 2016 and, as of September 30, 2016, we were in compliance with our debt covenants under our loan agreement with East West Bank. However, as of September 30, 2016, we were in violation of the leverage ratio covenant under our term loan facility with Danske. Danske waived this violation, but there is no assurance that we will be able to comply with the leverage ratio covenant by the next measurement date of December 31, 2016, and Danske has the ability to demand repayment of the debt if the violation is not resolved. If Danske demands repayment of the debt, we may not have sufficient capital to operate. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under our debt agreements.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and laboratory and field personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes and as we attempt to transition to a company with more than one commercialized test. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, biostatisticians, engineers, licensed laboratory technicians and chemists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities, public and private research institutions and other organizations in recruiting and retaining highly qualified scientific personnel.

In addition, our success depends on our ability to attract and retain laboratory and field personnel with extensive experience in post-transplant recipient care and surveillance and close relationships with clinicians, pathologists and other hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of AlloMap or our future solutions, if any. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development, verification and commercialization programs.

\*Recent and future acquisitions and investments could disrupt our business, harm our financial condition and operating results, dilute your ownership of us and increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements to expand our existing know-how, expertise and intellectual property in other fields, including for the development of other commercial tests. Examples include our 2014 acquisition of ImmuMetrix, Inc., a privately held development-stage company working on dd-cfDNA-based solutions in transplantation and other fields, and our recent acquisition of Allenex in April 2016. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our test offerings or distribution. 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 identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not successfully complete acquisitions that we target in the future. The risks we face in connection with acquisitions, including our acquisition of ImmuMetrix, Inc. and our recent acquisition of Allenex, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- reduction of available cash reserves, assumption of debt or dilutive issuances of equity securities due to payment of consideration;
- coordination of research and development and sales and marketing functions;

65

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- integration of product and service offerings;
- acquired technology or research and development expectations prove unsuccessful;
- retention of key personnel from the acquired company;
- financial reporting, revenue recognition or other financial control deficiencies of the acquired company that we do not adequately address and that cause our reported results to be incorrect or delayed;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties;
- integrating a global workforce of the acquired company into our business;
- obtaining the approval of minority shareholders to complete an acquisition; and
- commercialization of new products being developed by the acquired company.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally. For example, we completed our acquisition of ImmuMetrix, Inc. in June 2014, and some risks remain, including the risks that the intellectual property we acquired in this acquisition may not lead to a successful product, risks associated with milestone payments due under the merger agreement and the probability of achieving them, and the risk that Stanford University could terminate our patent license relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA if we do not meet certain performance and commercialization conditions. Additionally, the timing of the recent acquisition of Allenex may cause a heightened risk of any or all of the above factors, particularly in the near-term as we attempt to fully integrate the acquired operations. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill and other intangible assets, any of which could harm our business and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

For example, on April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex. Allenex's technology and products are new to us, and accordingly we may need to make substantial investments of resources to support the integration of Allenex, which will result in increased operating expenses and may divert resources and management attention from other areas of our business. Additional unanticipated costs may be incurred in the course of integrating the respective businesses. We cannot make any assurances that these investments will be successful. As a result of any of the aforementioned challenges, as well as other challenges and factors that may be unknown to us, we may not be able to fully realize the anticipated strategic benefits of the acquisition, which includes a complementary product portfolio and significant cross-selling opportunities. If we fail to successfully integrate Allenex, we may not realize the benefits expected from the transaction and our business may be harmed.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

\*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 or professional liability claims, which could exceed our resources.

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, such as occurred in April 2016

with respect to one of Allenex's Olerup SSP products, 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 marketing, sale and use of AlloMap and our other solutions, 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. For example, a defect in one of our diagnostic solutions could lead to a false positive or false negative result, affecting the eventual diagnosis. Any

incomplete or inaccurate analysis on the part of our technicians could also affect the reliability of the test results. A product liability or professional 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 product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. 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. Additionally, any product liability lawsuit could cause injury to our reputation, result in the suspension of our testing pending an investigation into the cause of the alleged failure, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could negatively impact our results of operations.

\*We rely extensively on third party service providers. Failure of these parties to perform as expected, or interruptions in our relationship with these providers or their provision of services to us, could interfere with our ability to provide test results.

Our relationship with any of our third party service providers may impair our ability to perform our services. The failure of any of our third party service providers to adequately perform their service obligations may reduce our revenues and increase our expenses or prevent us from providing our services in a timely manner if at all. In addition, our reputation, business and financial performance could be materially harmed if we are unable to, or are perceived as unable to, perform reliable services.

We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use to perform AlloMap. These sole source suppliers include Thermo Fisher Scientific Inc., which supplies us with instruments, laboratory reagents and consumables, Becton, Dickinson and Company, which supplies us with cell preparation tubes, or CPTs, and Therapak Corporation, which supplies us with a proprietary buffer reagent. One of the reagents supplied to us by Therapak Corporation is, in turn, obtained by Therapak Corporation from Qiagen N.V. and is a proprietary formulation of Qiagen N.V. We have no relationship with or control over, Qiagen N.V. We do not have guaranteed supply agreements with Thermo Fisher Scientific Inc., Becton, Dickinson and Company, Therapak Corporation or Qiagen N.V., which exposes us to the risk that these suppliers may choose to discontinue doing business with us at any time. We periodically forecast our needs to these sole source suppliers and enter into standard purchase orders based on these forecasts.

Additionally, we rely solely on Conexio Genomics, which was recently acquired by Illumina, Inc., for supply of the SBT product line we offer for sequence based typing of HLA alleles. We recently received a notice that Conexio's SBT products will be discontinued by December 31, 2016. We are currently negotiating with Conexio for a solution that will allow us to continue to offer SBT products. However, our reliance on a sole supplier exposes us to risks, including reduced control over production costs, timely delivery and capacity. It also exposes us to the potential inability to quickly or cost-effectively acquire or replace this product line, if at all, following the notice of discontinuation that we received.

In addition, our ABI 7900 Thermocycler, a real time polymerase chain reaction, or PCR, instrument used in AlloMap, is no longer in production. Thermo Fisher Scientific Inc. has committed to provide service and support of this instrument through 2020. We believe that there are relatively few suppliers other than Thermo Fisher Scientific Inc., Becton, Dickinson and Company and Qiagen N.V. that are currently capable of supplying the instruments, reagents and other supplies necessary for AlloMap. Even if we were to identify secondary suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Thermo Fisher Scientific Inc., Becton, Dickinson and Company or Therapak Corporation, or Therapak Corporation encounters delays or difficulties in securing from

Qiagen N.V., the quality and quantity of reagents, supplies or instruments that we require for AlloMap or other solutions we develop, we may need to reconfigure our test processes, which would result in delays in commercialization or an interruption in sales. Clinicians who order AlloMap rely on the continued availability of our test and have an expectation that results will be reported within two to three business days. If we are unable to provide results within a timely manner, clinicians may elect not to use our test in the future and our business and operating results could be harmed.

\*Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

We store sensitive intellectual property and other proprietary business information, including that of our customers, payers and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. We work with a third-party billing agent to collect and store sensitive data, including legally-protected health information, credit card information and personally identifiable information about our customers, payers, recipients and collaboration partners. A data breach or loss of data could have a material adverse effect on our operations, including the potential for material fines and business interruption.

We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party billing agent, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

\*International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States, some of which may be enhanced by our acquisition of Allenex.

As part of our longer-term growth strategy, we intend to target select international markets to grow our presence outside of the U.S. We currently have a commercial agreement for the promotion of AlloMap in Europe with Diaxonhit and are distributing AlloMap tests directly in Canada. Allenex currently distributes its products in Germany, Austria, Slovenia, Benelux, Canada, China and India. Allenex also sells, via sub-distributors, to certain countries in Central and South America. To promote the growth of our business internationally, we will need to attract additional partners to expand into new markets. Relying on partners for our sales and marketing subjects us to various risks, including:

- our partners may fail to commit the necessary resources to develop a market for our products, may spend the majority of their time selling products unrelated to ours, or may be unsuccessful in marketing our products for other reasons;
- under certain agreements, our partners' obligations, including their required level of promotional activities, may be conditioned upon our ability to achieve or maintain a specified level of reimbursement coverage;
- agreements with our partners may terminate prematurely due to disagreements or may result in disputes or litigation with our partners;
- we may not be able to renew existing partner agreements, or enter into new agreements, on acceptable terms;
- our existing relationships with partners may preclude us from entering into additional future arrangements;
- our partners may violate local laws or regulations, potentially causing reputational or monetary damage to our business;



our partners may engage in sales practices that are locally acceptable but do not comply with standards required under U.S. laws that apply to us; and  
our partners in Europe may be negatively affected by the financial instability of, and austerity measures implemented by, several countries in Europe.

If our present or future partners do not perform adequately, or we are unable to enter into agreements in new markets, we may be unable to achieve revenue growth or market acceptance in jurisdictions in which we depend on partners.

In addition, conducting international operations subjects us to new risks that, generally, we have not faced in the U.S., including:

- uncertain or changing regulatory registration and approval processes associated with AlloMap and other potential diagnostic solutions;
- failure by us to obtain regulatory approvals or adequate reimbursement for the use of our current and future solutions in various countries;
- competition from companies located in the countries in which we offer our products may put us at a competitive disadvantage;
- financial risks, such as longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- logistics and regulations associated with shipping recipient samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process solutions locally;
- difficulties in managing and staffing international operations and assuring compliance with foreign corrupt practices laws;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities;
- multiple, conflicting and changing laws and regulations such as healthcare regulatory requirements and other governmental approvals, permits and licenses;
- the imposition of trade barriers such as tariffs, quotas, preferential bidding or import or export licensing requirements;
- political and economic instability, including wars, terrorism, and political unrest, general security concerns, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- fluctuations in currency exchange rates;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, its books and records provisions or its anti-bribery provisions, as well as risks associated with other anti-bribery and anti-corruption laws; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of the above could harm our business and, consequently, our revenues and results of operations. Our expanding international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our current and future solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. Additionally, operating internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenue or profitability.

In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

Our success expanding internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

\*Our operating results may be adversely affected by unfavorable economic and market conditions.

Many of the countries in which we operate, including the U.S. and several of the members of the European Union, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. For example, on June 23, 2016, the United Kingdom, or the UK, held a referendum pursuant to which voters elected to leave the European Union, commonly referred to as Brexit. As a result of UK voters' election to leave the European Union, the British government is expected to begin negotiating the terms of the UK's future relationship with the European Union. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the European Union markets, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. In addition, Brexit may also increase the possibility that other countries may decide to leave the European Union in the future.

Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, automobile, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

We may use third party collaborators to help us develop, validate or commercialize any new diagnostic solutions, and our ability to commercialize such solutions could be impaired or delayed if these collaborations are unsuccessful.

We may in the future selectively pursue strategic collaborations for the development, validation and commercialization of any new diagnostic solutions we may develop. In any future third party collaboration, we may be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with

them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our potential solutions may be delayed if collaborators fail to fulfill their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. AlloMap testing in Europe is being conducted through an exclusive distribution agreement with a sole collaborator. Any issues arising from these arrangements will affect our ability to serve the entire region, and our reputation may suffer even if we subsequently locate new partners, which may permanently affect our business. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting changes or require us to change our compensation policies.

Accounting methods and policies for diagnostic companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock-based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our financial statements, including those contained in this Quarterly Report on Form 10-Q.

#### Risks Related to the Allenex Acquisition

\*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 U.S. and Europe. Allenex's products are used to evaluate organ transplant patients prior to their transplant procedure with 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, a 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 candidate QTYPE, which was commercially launched at the end of September 2016. The development and commercialization of QTYPE may fail for many reasons, including:

- insufficient 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.

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.

\*Each of our and Allenex's business relationships may be subject to disruption due to uncertainty associated with the acquisition.

During the post-acquisition transition period, and until the Allenex business is fully integrated, customers, vendors, licensors, suppliers and other third parties with whom we and Allenex do business or otherwise have relationships may experience uncertainty on whether the integration will be successful, and this uncertainty could materially affect their decisions with respect to existing or future business relationships. These third parties may also attempt to negotiate changes to existing business agreements, which could result in additional obligations imposed on us. For example, though we assumed a distribution agreement between Allenex and Conexio Genomics which runs through April 2018, the acquisition of Allenex by us and the acquisition of Conexio Genomics by Illumina, Inc. has created uncertainty regarding our ability to continue to distribute SBT Resolver. We recently received a notice that Conexio's SBT products will be discontinued by December 31, 2016. If we are unable to successfully replace, acquire or continue distribution of SBT Resolver, we may lose significant revenue from distribution sales for a product that cannot be readily replaced. Another possibility is that we may be required to accept less favorable terms for distribution than the current agreement provides. These types of disruptions could have a material adverse effect on our business, financial condition and results of operations.

\*The market price of our common stock may decline due to increased selling pressure as a result of the acquisition or the subsequent equity financing.

In connection with the acquisition of Allenex, we issued an aggregate of 1,375,029 shares of common stock to the holders of Allenex shares, and in connection with our equity financings completed in April and June 2016, we issued an aggregate of 8,534,261 shares of common stock. The common stock issued as consideration in the acquisition was freely tradable upon consummation of the acquisition, and the common stock issued in the equity financings are freely tradable following the effectiveness of the 2016 Form S-3 on July 12, 2016. 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 determine to sell shares of common stock, or investors may perceive that such sales may occur, either of which may adversely affect the market for, and the market price of, our shares of common stock.

\*The uncertainties associated with our combination with Allenex may result in a loss of key personnel.

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 common stock following the completion of the acquisition.

As part of the acquisition of Allenex, we paid a substantial amount of cash and assumed Allenex's debt. The assumed indebtedness subjects us to increased fixed obligations, increased interest expense, and included 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 indefinite-lived 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 evaluate finite-lived intangible assets, which are long-lived assets, for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of the intangible asset may not be recoverable. Finite-lived intangible assets are intangible assets that we are amortizing over their estimated useful lives. If recoverability is in question, we would then compare the carrying amounts of the intangible 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 intangible asset over the asset's fair value determined using discounted estimates of future cash flows.

We cannot predict whether or when there will be an impairment charge connected with intangible assets, or the amount of such charge, if any. However, if the charge is significant, it could cause the market price of our common stock to decline.



\*We may not realize the full value of the inventory acquired pursuant to our combination with Allenex.

We acquired a significant amount of inventory pursuant to the business combination with Allenex. In the event we are unable to sell all or substantially all of the inventory we acquired at reasonable prices, or at all, we may be required to write-off excess or obsolete inventory, which could have a material adverse impact on our financial condition and results of operations.

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

Although we currently hold 98.3% 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 in accordance with Swedish law.

#### Risks Related to Billing and Reimbursement

Billing complexities associated with obtaining payment or reimbursement for our current and future solutions may negatively affect our revenue, cash flows and profitability.

Billing for clinical laboratory testing services is complex. In cases where we do not have a contract in place requiring the payment of a fixed fee per test, we perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we do receive a fixed fee per test, we may still have disputes over pricing and billing. We receive payment from individual recipients and from a variety of payers, such as commercial insurance carriers and governmental programs, primarily Medicare. Each payer typically has different billing requirements. Among the factors complicating our billing of third-party payers are:

- disputes among payers regarding which party is responsible for payment;
- disparity in coverage among various payers;
- different process, information and billing requirements among payers; and
  - incorrect or missing billing information, which is required to be provided by the prescribing clinician.

Additionally, from time to time, payers change processes that may affect timely payment. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. These billing complexities, and the resulted uncertainty in obtaining payment for AlloMap and future solutions, could negatively affect our revenue, cash flows and profitability.

\*Health insurers and other third-party payers may decide to revoke coverage of our existing test, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects.

Successful commercialization of AlloMap and AlloSure depends, in large part, on the availability of coverage and adequate reimbursement from government and private payers. Favorable third-party payer coverage and reimbursement are essential to meeting our immediate objectives and long-term commercial goals. We do not recognize revenue for test results delivered without a contract for reimbursement, or an established coverage policy and a history of payment. Revenue for AlloMap is recognized on a cash basis if the conditions for recognizing revenue on an accrual basis are not met. For each of the nine months ended September 30, 2016 and the year ended December 31, 2015, approximately 35% and 32%, respectively, our AlloMap revenue was recognized on a cash basis.

For new diagnostic solutions such as AlloSure, each private and government payer decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may be likely not to order a diagnostic test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic product, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

Coverage and reimbursement by a commercial payer may depend on a number of factors, including a payer's determination that our current and future solutions are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific recipient;
- cost-saving or cost-effective; and
- supported by peer-reviewed publications.

73

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In addition, several payers and other entities conduct technology assessments of new medical tests and devices and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payers and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure. We believe we have received a negative technology assessment from at least one of these entities and could receive more.

If third-party payers decide not to cover our diagnostic solutions or if they offer inadequate payment amounts, our ability to generate revenue from AlloMap and future solutions such as AlloSure could be limited. Payment for diagnostic tests furnished to Medicare beneficiaries is typically made based on a fee schedule set by CMS. In recent years, payments under these fee schedules have decreased and may decrease further. Any third-party payer may stop or lower payment at any time, which could substantially reduce our revenue. A 32% reduction in Medicare reimbursement could occur as a result of a final Medicare rate for calendar year 2017 published by CMS on September 30, 2016. We are seeking a reconsideration of this Medicare rate reduction, but CMS may implement it or some other reduced Medicare payment rate to be effective as of January 1, 2017. See the risk factor above titled “We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance”.

Since each payer makes its own decision as to whether to establish a policy to reimburse for a test, seeking payer coverage and other approvals is a time-consuming and costly process. We cannot assure you that adequate coverage and reimbursement for AlloMap or future solutions will be provided in the future by any third-party payer.

Reimbursement for AlloMap comes primarily from Medicare, private third party payers such as insurance companies and managed care organizations, Medicaid and hospitals. The reimbursement process can take six months or more to complete depending on the payer. Coverage policies approving AlloMap have been adopted by many of the largest private payers, including Aetna, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc. and WellPoint, and a number of state Medicaid programs. Many of the payers with positive coverage policies have also entered into contracts with us to formalize pricing and payment terms. We continue to work with third-party payers to seek such coverage and to appeal denial decisions based on existing and ongoing studies, peer reviewed publications, support from physician and patient groups and the growing number of AlloMap tests that have been reimbursed by public and private payers. There are no assurances that the current policies will not be modified in the future. If our test is considered on a policy-wide level by major third-party payers, whether at our request or on their own initiative, and our test is determined to be ineligible for coverage and reimbursement by such payers, our collection efforts and potential for revenue growth could be adversely impacted.

Our Medicare Part B coverage for AlloMap is included in a formal local coverage decision for molecular diagnostics; however, any change in this coverage decision or other future adverse coverage decisions by the CMS, including with respect to coding, could substantially reduce our revenue.

Medicare reimbursements currently comprise a significant portion of our revenue. Our current Medicare Part B reimbursement was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the national coverage certainty afforded by a formal coverage determination by CMS. This means that Medicare contractors, including our California Medicare contractor, currently may continue to develop their own coverage and reimbursement policies with respect to our technology.

Decisions by CMS with respect to coding could also affect our revenue. For example, on September 25, 2013, CMS released the preliminary payment determinations for the Clinical Laboratory Fee Schedule, or CLFS, for 2014. CMS proposed to not recognize certain Current Procedural Terminology codes, or CPT codes, called Multianalyte Assays with Algorithmic Analyses codes, or MAAA codes, as valid for Medicare purposes under the CLFS because it determined that an algorithm is not a clinical diagnostic test. This preliminary determination would have reversed a

CMS final determination released on November 6, 2012 for 2013 that withdrew a proposal to not cover algorithmic analysis and stated that laboratories performing MAAA tests for Medicare beneficiaries should continue to bill for these tests in 2013 as they were then billed under the CLFS. When the final payment determination for 2014 was issued, CMS stated instead that it will continue to consider each test classified by the CPT as a MAAA on its own merits, and payment amounts would be determined using a gapfill methodology if the Medicare contractor determines the code is payable.

Until 2016 AlloMap was billed using an unlisted CPT code, but in 2016 a new CPT Category 1 MAAA code was added that specifically describes the test. The AlloMap test also has been assigned a second Z code<sup>TM</sup> identifier through a program for molecular diagnostics, which is included on all Medicare claims. If in the future CMS makes a determination not to pay for this code, or for any MAAA codes, this could be harmful to our business, and could have negative spillover implications that prevent or limit coverage by other third-party payers that might mirror aspects of Medicare payment criteria.

\*Our transition from an outsourced billings and collections vendor to an in-house staff has negatively affected our cash collection cycle.

During 2015, we transitioned our billing and collections functions for our AlloMap testing from an outside vendor to an in-house staff. On July 1, 2015, these functions began being performed by in-house staff recruited and hired by us directly. During this process, we also transitioned from the outside vendor's software, which was familiar and compatible with our accounting system and procedures, to a new software system designed for use by in-house departments in billing and collections of medical diagnostic tests. Since the transition and despite hiring experienced personnel, we have experienced a slowdown in collections and are working to remediate the slowdown. There is risk that billing and collections will not be smooth until the procedures are improved and become routine, including that payments may not be collected timely, communication errors with insurers regarding specifics of the insurance claims may occur, insurers' deadlines may not be met, payments may not be properly applied to outstanding receivables, and revenue may not be recorded accurately. There is a risk that the combination of a software system changeover, the hiring of new personnel with lack of experience with the specific nature of our billing procedures with insurers, payments being directed to a new lockbox, new reports with changes to our billing and cash collections data and other changes to the process will result in lost or reduced collections compared with prior periods or otherwise have an adverse effect on our operations, cash flows and revenue.

\*Healthcare reform measures could hinder or prevent the commercial success of AlloMap.

The pricing and reimbursement environment may change in the future and become more challenging as a result of any of several possible regulatory developments, including policies advanced by the U.S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to profitably sell any diagnostic products we may develop and commercialize. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our diagnostic products from governmental agencies or other third-party payers, which would adversely affect our business strategy, operations and financial results. For example, as a result of the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or the Affordable Care Act, substantial changes have been made and may continue to be made to the current system for paying for healthcare in the U.S., including changes made in order to extend medical benefits to those who currently lack insurance coverage. The Affordable Care Act also provided that payments under the Medicare Clinical Laboratory Fee Schedule were to receive a negative 1.75% annual adjustment through 2015. Although we have not been subject to such adjustment in the past, we cannot assure you that the claims administrators will not attempt to apply this adjustment in the future.

Among other things, the Affordable Care Act includes payment reductions to Medicare Advantage plans. These cuts have been mitigated in part by a CMS demonstration program that expired in 2015. We cannot be assured that future cuts would be mitigated by CMS. Any reductions in payment to Medicare Advantage plans could materially impact coverage and reimbursement for AlloMap.

In addition to the Affordable Care Act, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, Congress passed the "Middle Class Tax Relief and Job Creation Act of 2012" which in part reduced the potential future cost-based increases to the Medicare Clinical Laboratory Fee Schedule, or CLFS, by 2%. The Protecting Access to Medicare Act of 2014 introduced a multi-year phase in of a new payment system for services paid under the CLFS. Under this new system, beginning in 2017 laboratories will report to CMS the payment rates paid to the laboratories by commercial third-party payers including Medicare and Medicaid managed care plans, for each test and the volume of each test performed. CMS will use the reported data to set new payment rates under the CLFS beginning in 2018. For most tests, rates will only be adjusted every three years. For newly developed tests that are considered to be "advanced diagnostic lab tests," the Medicare payment rate will be the

actual list price offered to third-party payers for the first three quarters that the tests are offered, subject to later adjustment. CMS will establish subsequent payment rates using the commercial third-party payer data reported for those tests.

Regardless of the impact of the Affordable Care Act on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could decrease the amount of reimbursement available from governmental and other third-party payers. Additionally, annual federal budget negotiations frequently include healthcare payment reform measures impacting clinical laboratory payments. On April 1, 2013, cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including AlloMap. Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of AlloMap and our future diagnostic solutions, increase costs, divert management's attention and adversely affect our ability to generate revenue and achieve profitability.

## Risks Related to the Healthcare Regulatory Environment

\*In order to operate our laboratory, we have to comply with the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and state laws governing clinical laboratories.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens taken from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. If our laboratory is out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as a direct plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found to be out of compliance with CLIA program requirements and subjected to sanction, our business could be materially harmed.

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our laboratory under California law. We are required to maintain a license to conduct testing in California. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. Moreover, several states, including New York, require that we hold licenses to test specimens from patients residing in those states. Other states have similar requirements or may adopt similar requirements in the future. In addition to our California certifications, we currently hold licenses in Florida, Maryland, New York and Pennsylvania. The loss of any of these state certifications would impact our ability to provide services in those states, which could negatively affect our business. Finally, we may be subject to regulation in foreign jurisdictions where we offer our test. Failure to maintain certification in those states or countries where it is required could prevent us from testing samples from those states or countries, could lead to the suspension or loss of licenses, certificates or authorizations, and could have an adverse effect on our business.

We were inspected as part of the customary College of American Pathologists audit in 2016 and recertified under CLIA in February 2014 as a result of passing that inspection. We expect the next regular inspection under CLIA to occur in 2018. If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to perform AlloMap, which would limit our revenues and materially harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states, which could also have a material adverse effect on our business.

If the FDA's recently published draft guidance setting forth a comprehensive regulatory scheme for laboratory-developed tests, or LDTs, becomes final, we would incur substantial costs and delays associated with trying to obtain premarket clearance or approval for those solutions.

Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. The laws and regulations governing the marketing of diagnostic products for use as LDTs are extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws. For instance, while the FDA maintains that LDTs are subject to the FDA's authority as diagnostic medical devices under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA has in the past generally exercised enforcement discretion with respect to most LDTs performed by CLIA-certified laboratories.

The FDA has traditionally chosen not to exercise its authority to regulate LDTs because it regulates the primary components in most laboratory-developed tests and because it believes that laboratories certified as high complexity under CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as "in vitro diagnostic multivariate index assays," or IVDMIAs. According to the draft guidance, IVDMIAs do not fall within the scope of LDTs over which FDA has exercised enforcement discretion because such tests incorporate complex and unique

interpretation functions which require clinical validation. We believed that AlloMap met the definition of IVDMIA set forth in the draft guidance document. As a result, we applied for and obtained, in August 2008, 510(k) clearance for AlloMap for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

On July 31, 2014, the FDA notified Congress (as required by the Food and Drug Administration Safety and Innovation Act of 2012) of its intent to publish a proposed and comprehensive risk-based framework for the regulation of LDTs. The notice to Congress provides the anticipated details and proposed timing of the implementation of the draft guidance and regulatory framework, including the requirement for premarket review and approval for higher-risk LDTs, such as our planned cell-free DNA solutions for heart, kidney and other organs. Such guidance, if and when finalized, will significantly impact the timing, availability and reimbursement of our future products, and will require us to modify our business model in order to maintain compliance with these new laws. For our cell-free DNA test and all similar testing solutions, we will be required to conduct additional clinical trials to clinically validate our test, and submit to the FDA a pre-market approval application, or PMA, or 510(k) clearance application and obtain approval or clearance for the test. We cannot predict the ultimate timing or form of any FDA final guidance or regulation of LDTs, or when we



must obtain regulatory approval or clearance for our LDT solutions. There can be no assurance that any of our solutions or additional uses of solutions for which we will seek clearance or approval in the future will be cleared or approved on a timely basis, or at all, nor can there be any assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our current and future solutions. Moreover, any new FDA requirements could conflict with CLIA requirements and thereby complicate our compliance efforts.

While we believe that we are currently in material compliance with applicable laws and regulations relating to our LDTs, we cannot assure you that the FDA or other regulatory agencies would agree with our determination. A determination that we have violated these laws, or a public announcement that we are being investigated for possible violation of these laws, could hurt our business and our reputation.

If we were required to conduct additional clinical trials prior to marketing our solutions under development, those trials could lead to delays or a failure to obtain necessary regulatory approvals and harm our ability to be profitable.

If the FDA decides to regulate our solutions under development as medical devices, it could require extensive premarket clinical testing prior to submitting a regulatory application for commercial sales. Conducting clinical trials generally entails a long, expensive and uncertain process that is subject to delays and failure at any stage. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our development costs and delay test commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient blood or tissue samples or insufficient data regarding the associated clinical outcomes. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials and reduce our control over such activities. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, applicable regulatory requirements, or for other reasons, our clinical trials may have to be extended, delayed or terminated. Our reliance on third parties that we do not control would not relieve us of any applicable requirement to ensure compliance with various procedures required under good clinical practices. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our solutions under development. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our solutions under development and our ability to be profitable.

Any test for which we obtain regulatory clearance will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our contractors or commercial partners fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

AlloMap and our other solutions, along with the manufacturing processes, packaging, labeling, distribution, import, export, and advertising and promotional activities for such solutions or devices, are or will be subject to continual requirements of, and review by, CMS, state licensing agencies, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements relating to product labeling, advertising, promotion, recordkeeping and adverse event reporting. Regulatory clearance of a test or device may be subject to limitations by the regulatory body as to the indicated uses for which the product may be marketed or to other conditions of approval. For example, we are

exploring utilization of AlloMap in areas that could be considered outside the scope of our current labeling. Broader uses would require FDA approval as well as changes to the labeling. In addition, approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the test or device. Discovery of previously-unknown problems with our current or future solutions, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on operations of our laboratory;
- restrictions on manufacturing processes;
- restrictions on marketing of a test;
- warning or untitled letters;
- withdrawal of the test from the market;
- refusal to approve applications or supplements to approved applications that we may submit;
- fines, restitution or disgorgement of profits or revenue;

77

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- suspension, limitation or withdrawal of regulatory clearances;
- exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; and
- imposition of civil or criminal penalties.

We are subject to numerous fraud and abuse and other laws and regulations pertaining to our business, the violation of any one of which could harm our business.

The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with customers may expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products. Our employees, consultants, principal investigators and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. In addition to CLIA regulation, other federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to clinical laboratories and/or regulatory agencies enforcing those laws and regulations;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented to the government, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or making a false statement material to a false or fraudulent claim;

- the federal anti-kickback statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services, including clinical laboratory services, reimbursed by Medicare if the physician (or a member of the physician's family) has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- state laws regarding prohibitions on fee-splitting;

- the federal healthcare program exclusion statute; and

- state and foreign law equivalents of each of the above federal laws and regulations, such as anti-kickback, false claims, and self-referral laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may

be subject to private “qui tam” actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including

78

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mandatory treble damages and significant per-claim penalties. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Foreign governments may impose reimbursement standards, which may adversely affect our future profitability.

When we market AlloMap and our solutions under development in foreign jurisdictions, we are subject to rules and regulations in those jurisdictions relating to our testing. In some foreign countries, including countries in the European Union, the reimbursement of our current and future solutions is subject to governmental control. In these countries, reimbursement negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a test candidate. If reimbursement of our future solutions in any jurisdiction is unavailable or limited in scope or amount, or if reimbursement rates are set at unsatisfactory levels, we may be unable to, or decide not to, market our test in that jurisdiction.

\*Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions.

Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our current and future solutions. In March 2010, the Affordable Care Act became law. This law substantially changed the way healthcare is financed by both governmental and private insurers, and contained a number of provisions that have impacted our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse enforcement. Further, our combination with Allenex will also change how these provisions could impact our business.

The Protecting Access to Medicare Act of 2014, or PAMA, includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS would report initially and then on a subsequent three year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 indicating that data for reporting for the new PAMA process will begin in 2017 and the new market based rates will take effect January 1, 2018. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests

In addition to the Affordable Care Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payers. While in general it is difficult to predict specifically what effects the Affordable Care Act or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

#### Risks Related to Our Intellectual Property

\*Our competitive position depends on maintaining intellectual property protection.

Our ability to compete and to achieve and maintain profitability depends on our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patents, copyrights, trademarks, trade secrets, confidentiality agreements and license agreements to protect our intellectual property rights.

Our patent position for AlloMap is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and resting leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. Our strategy is to continue to broaden our intellectual property estate for AlloMap through the discovery and protection of gene expression patterns and their correlation with specific clinical states and outcomes, as well as the algorithms needed for clinical assessment.

As of September 30, 2016, we had 16 issued U.S. patents related to autoimmunity and transplant rejection. We have five issued U.S. patents covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap. The expiration dates of these patents range from 2021 to 2024. In the area of dd-cfDNA-based transplant diagnostics, we have filed a patent application to cover our research and development work in this field. In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford University to a U.S. patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This patent has an expiration date of November 5, 2030.

We have six issued U.S. patents covering a method of diagnosing or monitoring autoimmune or chronic inflammatory disease, such as lupus, by detecting specific genes. While we have clinical samples and patents covering lupus diagnostics, we do not intend to actively pursue the lupus test opportunity. As part of our April 2016 acquisition of Allenex and its subsidiaries, we obtained an additional five U.S. patents on donor matching technology and treatment for antibody mediated transplant rejection. In dd-cfDNA-based transplant diagnostics, we have submitted a patent application to cover some of our initial research and development work in this field. There is no guarantee that the U.S. Patent and Trademark Office, or PTO, will approve this provisional application. We do not know what claims, if any, will be granted in our existing and future applications. Our patents and patents that we exclusively license from others address fields that are rapidly evolving, and, particularly with respect to dd-cfDNA-based transplant diagnostics, it is possible that other patents have and will be granted to others that affect our ability to develop and commercialize our current and future solutions. If the reviewers of our patent applications at the PTO refuse our claims, we may not be able to sufficiently protect our intellectual property. Further, recent and future changes in the patent laws and regulations of the United States and other jurisdictions may require us to modify our patent strategy and could restrict our ability to obtain additional patents for our technology.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the United States Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. A recent decision in the *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (Fed. Cir. 2015) case decided that a dd-cfDNA product for fetal testing was not eligible for patent protection. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a “sufficient” additional feature for this purpose is uncertain. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. In particular, in September 2011, the United States Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a “first to invent” standard to a “first to file” standard and developing a post-grant review system. This has not yet had a material impact on the operation of our business and the protection and enforcement of our intellectual property, but it may in the future. The AIA and its implementation could still increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patent applications in the United States and many foreign jurisdictions are not published until at least eighteen months after filing, and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent is issued on the application. In addition, publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we or our licensors, as applicable, were the first to invent the technology (pre-AIA) or first to file

(post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own or exclusively license and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a United States patent application covering an invention that is similar to, or the same as, an invention that we own or license, we or our licensors may have to participate in an interference or other proceeding in the PTO or a court to determine priority of invention in the United States, for pre-AIA applications and patents. For post-AIA applications and patents, we or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in our inability to obtain or retain any United States patent rights with respect to such invention.

We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.

We may in the future receive offers to license patents or notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is unpredictable, expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we



may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our current or future solutions to exclude any infringing technologies would require us to re-validate the test, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our current or future solutions. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our current or future solutions or using technology that contains the allegedly infringing intellectual property, which could harm our business.

If we are unable to protect or enforce our intellectual property rights effectively in all major markets, our business would be harmed.

Filing, prosecuting, defending and enforcing patents on all of our technologies and solutions throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the U.S. and in select foreign jurisdictions and cannot guarantee that we will obtain the patent protection necessary to protect our competitive position in all major markets. Competitors may use our technologies or solutions in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U.S. These products may compete with our current and future products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. The legal systems of certain countries make it difficult or impossible to obtain patent protection for diagnostic solutions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technologies and solutions, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures we have followed to prevent such disclosure are, or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. may be less willing or unwilling to protect trade secrets. If any of the

technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

\*If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

AlloMap, AlloSure, Olerup SSP and CareDx are registered trademarks of our company in the United States. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims by third parties that we or our employees have wrongfully used or disclosed alleged trade secrets or misappropriated intellectual property, or claiming ownership of what we view as our own intellectual property.

As is commonplace in our industry, we employ individuals who were previously employed at other diagnostics, medical device, life sciences or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information of others in the course of their work for us and no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. We may also be forced to bring claims against third parties or defend against third-party claims in order to determine the ownership of our intellectual property. An adverse result in the prosecution or defense of any such claims could require us to pay substantial monetary damages and could result in the loss of valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against these claims, litigation could result in substantial costs and be a distraction to management.

\*Our business is dependent on licenses from third parties.

We license from third parties' technology necessary to develop and commercialize our products. One of our most significant licenses covers PCR technology used in AlloMap and may be required for future solutions we develop. We license this technology from Roche Molecular Systems, Inc. In connection with our acquisition of ImmuMetrix, Inc., we obtained another significant license. This one is an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This technology is critical to AlloSure, our newest dd-cfDNA-based solution for solid organ recipients. Our rights to use these and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses. We are obligated under these licenses to, among other things, pay certain royalties upon commercial sales of our products. These licenses generally last until the expiration of the last to expire of the patents included within the licenses that cover our use within our products, but the licenses may be terminated earlier in certain circumstances. Termination of any of these licenses could prevent us from producing or selling some or all of our products, and a failure of the licensors to abide by the terms of the licenses or to prevent infringement by third parties could harm our business and negatively impact our market position. Failure of a licensor to abide by the terms of a license or to prevent infringement by third parties could also harm our business and negatively impact our market position.

Risks Related to Our Common Stock

Our operating results may fluctuate, which could cause our stock price to decrease.

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by clinicians and recipients for our current and future solutions, if any;
- coverage and reimbursement decisions by third-party payers and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others;
- new or less expensive tests and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new solutions, and our success in commercializing these developments;
- our ability to integrate the business of new acquisitions, such as Allenex, efficiently;

82

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- the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel; and
- general market conditions.

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, national stock exchanges in general, and the market for life science companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Moreover, we may be subject to additional securities class action litigation as a result of volatility in the price of our common stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

The market price of our common stock has been and will likely continue to be volatile, and you could lose all or part of your investment.

Prior to our initial public offering in July 2014, there had been no public market for our shares of common stock. Our common stock is currently traded on the NASDAQ Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of life sciences stocks;
- changes in operating performance and stock market valuations of other life sciences companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;



any significant change in our management; and  
general economic conditions and slow or negative growth of our markets.

\*If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you.

Our executive officers, directors and holders of 5% or more of our outstanding common stock, and entities affiliated with them, beneficially own in the aggregate approximately 42% of our common stock as of September 30, 2016. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

\*Sales of substantial amounts of our common stock in the public markets, or sales of our common stock by our executive officers and directors under Rule 10b5-1 plans, could adversely affect the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such 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. We currently have an effective shelf registration statement on Form S-3, pursuant to which we may sell up to an aggregate of \$66 million of common stock or other securities, subject to certain limitations. We also currently have an effective resale shelf registration statement covering the sale of up to 8,534,261 shares of common stock by selling stockholders, including stockholders who acquired common stock in connection with private placements. In addition, our executive officers and directors may adopt written plans, known as "Rule 10b5-1 Plans," under which they will contract with a broker to sell shares of our common stock on a periodic basis to diversify their assets and investments. Sales made by our executive officers and directors pursuant to Rule 10b5-1, regardless of the amount of such sales, could adversely affect the market price of our common stock.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the U.S., which may adversely affect our operating results.

As a public company listed in the U.S., we incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Stock Market LLC may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of

directors, on committees of our board of directors or as members of senior management.

If equity research analysts do not publish research or reports about our business, or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our common stock and such a lack of research coverage may adversely affect the market price of our common stock. The price of our stock could decline if one or more equity research analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.



\*We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Furthermore, our loan agreement with East West Bank and our term loan facility with Danske prohibit us from paying dividends without the lender's prior consent, and we may in the future become subject to additional contractual restrictions on, or prohibitions against, the payment of dividends.

\*If we are unable to substantially utilize our net operating loss carryforwards, our financial results could be harmed.

Under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" may be subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Ownership changes beyond these limits, as determined by the IRS, may limit our ability to utilize our NOLs in the future. Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs.

\*We have identified material weaknesses in our internal control over financial reporting, and our financial controls and procedures may not in the future be sufficient to ensure timely and reliable reporting of financial information, which could materially harm our stock price and exchange listing.

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act and other requirements will increase our costs and require additional management resources. We upgraded our U.S. finance and accounting systems, procedures and controls at the beginning of 2016 and acquired Allenex on April 14, 2016. We need to implement new and additional finance and accounting systems, procedures and controls for Allenex and as we grow our business and organization and to satisfy internal control and reporting requirements. We previously identified a material weakness in our internal control over financial reporting related to an entity acquired in 2014, which was remedied. However, during the quarter ended June 30, 2016, we identified two material weaknesses in our internal control over financial reporting relating to: (i) certain areas of our financial statement close process, specifically with respect to an incorrect classification of the deferred consideration payable to the Majority Shareholders within our statement of cash flows following the Allenex acquisition, and (ii) a failure in the design and operating effectiveness of controls over our accounting for business combinations, specifically we did not complete internal control steps and used an incorrect period of tax benefit to estimate the fair value of certain intangible assets acquired in the Allenex acquisition. We are currently in the process of preparing a remediation plan to address the underlying causes of the material weaknesses described above and to improve and strengthen our internal control over financial reporting. We cannot assure you that the measures we have taken to date or any measures we may take in response to these material weaknesses in the future will be sufficient to remediate such material weaknesses or to avoid potential future material weaknesses. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate.

As a public company, we require greater financial resources than were required when we were a private company before our 2014 initial public offering. The effectiveness of our controls and procedures may in the future be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting, or if we fail to remediate the two material weaknesses in internal control over financial reporting or otherwise fail to maintain or implement effective controls and procedures for financial reporting, we could be unable to accurately and timely report our financial position, results of operations, and cash flows or key operating metrics, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our condensed consolidated financial statements or other corrective disclosures, a decline in our stock price, suspension or delisting of our common stock from the NASDAQ Global Market, SEC investigations, civil or criminal sanctions, an inability to access the capital and commercial lending markets, defaults under our credit and other agreements or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock.

Our certificate of incorporation and bylaws and Section 203 of the Delaware General Corporation Law contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include:

- our board of directors is authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti-takeover devices;
- advance notice is required for director nominations or for proposals that can be acted upon at stockholder meetings;
- our board of directors is classified such that not all members of our board are elected at one time, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- stockholder action by written consent is prohibited;
- special meetings of the stockholders may be called only by the chairman of our board of directors, a majority of our board of directors or by our chief executive officer or president (if at such time we have no chief executive officer);
- stockholders are not permitted to cumulate their votes for the election of directors; and
- stockholders may amend our bylaws and certain provisions of our certificate of incorporation only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the General Corporation Law of the State of Delaware. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our certificate of incorporation and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock.

We are an “emerging growth company,” and, because we are complying with certain reduced disclosure requirements applicable to emerging growth companies, our common stock could be less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012, and for as long as we continue to be an “emerging growth company,” we may continue to choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will continue to be an “emerging growth company” until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior September 30th, and (ii) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some

investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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: November 14, 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

- 3.1(1) Amended and Restated Certificate of Incorporation.
- 3.2(2) Amended and Restated Bylaws.
- 3.3(3) Certificate of Designation of the Preferences, Rights and Limitations of the Series A Mandatorily Convertible Preferred Stock, dated April 13, 2016.
- 4.1(4) Specimen Stock Certificate.
- 4.2(5) Sixth Amended and Restated Investors Rights Agreement, dated July 1, 2009, as amended on March 29, 2012, June 10, 2014, and July 14, 2014, between the Registrant and certain holders of the Registrant's capital stock named therein.
- 4.4(6) Form of Warrant.
- 10.1(7)# CareDx, Inc. Outside Director Compensation Policy, as amended.
- 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 3.1 to the Registrant's Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 28, 2014.

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- (2) Incorporated by reference to Exhibit 3.4 to the Registrant's Form 10-Q filed with the SEC on August 28, 2014.
- (3) Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on April 14, 2016.
- (4) Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
- (5) Incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
- (6) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on April 14, 2016.
- (7) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the Securities and Exchange Commission on July 19, 2016.

\* Filed herewith.

\*\* Furnished herewith.

# Indicates management contract or compensatory plan or arrangement.