



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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 38,901,745 shares of the registrant's Common Stock issued and outstanding as of November 5, 2018.



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, 2018 and December 31, 2017</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2018 and 2017</u>	4
<u>Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017</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>	33
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	48
<u>Item 4. Controls and Procedures</u>	48
 <u>PART II. OTHER INFORMATION</u>	 49
<u>Item 1. Legal Proceedings</u>	49
<u>Item 1A. Risk Factors</u>	49
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
<u>Item 3. Defaults Upon Senior Securities</u>	50
<u>Item 5. Other Information</u>	51
<u>Item 6. Exhibits</u>	51
<u>Signatures</u>	53

## 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$26,202	\$16,895
Accounts receivable	9,641	2,991
Inventory	4,621	5,529
Prepaid and other assets	1,479	1,352
Total current assets	41,943	26,767
Property and equipment, net	3,022	2,075
Intangible assets, net	34,284	33,139
Goodwill	12,005	12,005
Restricted cash	192	9,579
Total assets	\$91,446	\$83,565
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$2,676	\$3,391
Accrued payroll liabilities	8,017	5,013
Accrued and other liabilities	4,718	3,735
Deferred revenue	39	39
Deferred purchase consideration	367	407
Derivative liability	—	14,600
Current debt	—	15,721
Total current liabilities	15,817	42,906
Deferred rent, net of current portion	579	913
Deferred revenue, net of current portion	701	730
Deferred tax liability	3,447	4,933
Long-term debt, net of current portion	13,384	18,338
Contingent consideration	—	1,672
Common stock warrant liability	11,612	18,712
Other liabilities	1,518	1,315
Total liabilities	47,058	89,519
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at September 30, 2018	—	—

and December 31, 2017; no shares issued and outstanding at September 30, 2018

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

and December 31, 2017

Common stock: \$0.001 par value; 100,000,000 shares authorized at September 30, 2018

and December 31, 2017; 38,784,111 shares and 28,825,019 shares issued and

outstanding at September 30, 2018 and December 31, 2017, respectively	39	29
Additional paid-in capital	356,427	264,204
Accumulated other comprehensive loss	(3,988 )	(2,345 )
Accumulated deficit	(308,090)	(268,022)
Total CareDx, Inc. stockholders' equity (deficit)	44,388	(6,134 )
Noncontrolling interest	—	180
Total stockholders' equity (deficit)	44,388	(5,954 )
Total liabilities and stockholders' equity	\$91,446	\$83,565

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		Nine Months Ended September 30,	
	30, 2018	2017	2018	2017
<b>Revenue:</b>				
Testing services revenue	\$ 16,847	\$ 8,163	\$ 41,448	\$ 24,485
Product revenue	4,223	3,872	11,080	10,916
License and other revenue	114	156	532	420
Total revenue	21,184	12,191	53,060	35,821
<b>Operating expenses:</b>				
Cost of testing services	5,752	3,156	14,432	9,224
Cost of product	3,135	2,053	8,046	6,558
Research and development	3,868	2,959	10,732	9,360
Sales and marketing	5,971	3,255	15,916	9,747
General and administrative	5,177	4,038	16,080	14,672
Goodwill impairment	—	—	—	1,958
Change in estimated fair value of contingent consideration	—	594	1,017	309
Total operating expenses	23,903	16,055	66,223	51,828
Loss from operations	(2,719 )	(3,864 )	(13,163 )	(16,007 )
Interest expense	(408 )	(1,685 )	(3,527 )	(4,166 )
Other expense, net	(40 )	(317 )	(2,891 )	(1,191 )
Change in estimated fair value of common stock warrant liability and derivative liability	(17,093 )	(8,599 )	(24,540 )	(3,404 )
Loss before income taxes	(20,260 )	(14,465 )	(44,121 )	(24,768 )
Income tax benefit	290	178	1,095	837
Net loss	(19,970 )	(14,287 )	(43,026 )	(23,931 )
Net loss attributable to noncontrolling interest	—	(19 )	(25 )	(133 )
Net loss attributable to CareDx, Inc.	\$(19,970 )	\$(14,268 )	\$(43,001 )	\$(23,798 )
Net loss per share attributable to CareDx, Inc. (Note 3):				
Basic	\$(0.54 )	\$(0.63 )	\$(1.26 )	\$(1.09 )
Diluted	\$(0.54 )	\$(0.63 )	\$(1.26 )	\$(1.09 )
Weighted average shares used to compute net loss per share attributable to CareDx, Inc.:				
Basic	37,154,293	22,526,615	34,134,138	21,765,292
Diluted	37,154,293	22,526,615	34,134,138	21,765,292

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,	
	2018	2017	2018	2017
Net loss	\$ (19,970 )	\$ (14,287 )	\$ (43,026 )	\$ (23,931 )
Other comprehensive (loss) income:				
Foreign currency translation adjustments	117	527	(1,645 )	1,461
Net comprehensive loss	(19,853 )	(13,760 )	(44,671 )	(22,470 )
Comprehensive loss attributable to noncontrolling interest, net of tax	—	(19 )	(25 )	(143 )
Comprehensive loss attributable to CareDx, Inc.	\$ (19,853 )	\$ (13,741 )	\$ (44,646 )	\$ (22,327 )

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,	
	2018	2017
<b>Operating activities:</b>		
Net loss	\$(43,026)	\$(23,931 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,039	2,740
Amortization of inventory fair market value adjustment	224	329
Loss on conversion of JGB Debt to shares of common stock	2,806	—
Amortization of debt discount and noncash interest expense	2,188	2,772
Revaluation of common stock warrant liability and derivative liability to estimated fair value	24,540	3,404
Stock-based compensation	5,078	1,316
Revaluation of contingent consideration to estimated fair value	1,017	309
Goodwill impairment charge	—	1,958
Changes in operating assets and liabilities:		
Accounts receivable	(3,830 )	(316 )
Inventory	358	462
Prepaid and other assets	(174 )	(231 )
Accounts payable	(863 )	200
Accrued payroll liabilities	3,376	392
Accrued and other liabilities	459	(857 )
Change in deferred revenue	(29 )	(22 )
Change in deferred taxes	(1,168 )	(682 )
Net cash used in operating activities	(6,005 )	(12,157 )
<b>Investing activities:</b>		
Acquisition of intangible assets through Illumina Licensing Agreement	(5,202 )	—
Acquisition of Allenex AB, net of cash acquired	(692 )	(502 )
Acquisition of assets of Conexio Genomics Pty Ltd.	—	(467 )
Purchase of property and equipment	(1,075 )	(100 )
Net cash used in investing activities	(6,969 )	(1,069 )
<b>Financing activities:</b>		
Proceeds from debt, net of issuance costs	14,282	24,002
Proceeds from issuance of common stock under employee stock purchase plan	32	93
Principal payments on debt and capital lease obligations	(11,397)	(13,252 )
Acquisition of Conexio Genomics Pty Ltd.	(171 )	—
Change in short term credit facility	(677 )	581
Proceeds from exercise of warrants	10,996	35
Repurchases of common stock under employee incentive plans	(698 )	—
Proceeds from exercise of stock options	589	—

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

Net cash provided by financing activities	12,956	11,459
Effect of exchange rate changes on cash and cash equivalents	(62 )	(104 )
Net decrease in cash, cash equivalents and restricted cash	(80 )	(1,871 )
Cash, cash equivalents, and restricted cash at beginning of period	26,474	17,401
Cash, cash equivalents, and restricted cash at end of period	\$26,394	\$ 15,530
Supplemental disclosure of cash flow information:		
Deferred purchase consideration	\$—	\$ 1,064
Shares issued in lieu of cash payment	—	1,145
Accrued interest capitalized to debt principal	—	984
Contingent consideration shares issued	2,689	—
Cash, Cash Equivalents and Restricted Cash as of:		
	September	December
	30, 2018	31, 2017
Cash and cash equivalents	\$26,202	\$ 16,895
Restricted cash	192	9,579
Total cash, cash equivalents and restricted cash at the end of period	\$26,394	\$ 26,474

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 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 diagnostic testing services, the Company offers AlloMap®, which is a gene expression solution for heart transplant patients and AlloSure®, which is a donor-derived cell free DNA (“dd-cfDNA”) solution initially used for kidney transplant patients. The Company also offers 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.

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.

In October 2017, the Company commercially launched AlloSure, its proprietary next-generation sequencing-based test to measure dd-cfDNA after transplantation. The Company believes the use of AlloSure, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, the Company believes AlloSure can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

The Company also develops, manufactures, markets and sells 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 Human Leukocyte Antigen (“HLA”) alleles, based on the sequence specific primer (“SSP”) technology. Olerup SBT™ is a complete product range for sequence-based typing of HLA alleles. Olerup QTYPE® enables speed and precision in HLA typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time polymerase chain reaction, or PCR methodology. QTYPE received CE mark certification on April 10, 2018.

In May 2018, the Company entered into a License and Commercialization Agreement with Illumina, Inc. (“Illumina”), which provides the Company with worldwide distribution, development and commercialization rights to Illumina’s next generation sequencing (“NGS”) product line for use in transplantation diagnostic testing. Refer to Note 5 for additional details.

The Company changed its internal organizational structure in the third quarter of 2018 and no longer operates in two reportable segments: Post-Transplant and Pre-Transplant. The Company’s Chief Operating Decision Maker (“CODM”) did not change as a result of this reorganization and continues to be the Chief Executive Officer (“CEO”) of the Company. Effective September 30, 2018, the Company reports in a single reportable segment. Refer to Note 16 for additional details.

The Company’s headquarters are in Brisbane, California. The primary operations are in Brisbane, U.S. and Stockholm, Sweden.

#### 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 \$308.1 million at September 30, 2018. As of September 30, 2018, the Company had cash and cash equivalents of \$26.2 million, and \$13.4 million of debt outstanding, net of debt discount, under its debt obligations, of which none is current.

On April 17, 2018, the Company entered into a credit agreement with Perceptive Credit Holdings II, LP (“Perceptive”) for an initial term loan of \$15.0 million (“the Perceptive Credit Agreement”) and repaid the outstanding indebtedness of the promissory notes previously issued to FastPartner AB and Mohammed Al Amoudi and the term loan and credit facility with Danske Bank A/S

(“Danske”). A second tranche of \$10.0 million will be available at the Company’s option subject to the satisfaction of customary conditions. Refer to Note 10 for additional details.

The Company may require additional financing in the future to fund working capital and pay its obligations as they come due. Additional financing might include issuance of equity securities, debt, cash from collaboration agreements or a combination of these. However, there can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms favorable to the Company. The Company believes its existing cash balance and expected revenues will be sufficient to meet its anticipated cash requirements for at least the next 12 months.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies and estimates used in preparation of the unaudited condensed consolidated financial statements are described in the Company’s audited consolidated financial statements as of and for the year ended December 31, 2017, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K. Material changes to the significant accounting policies previously disclosed in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 are reflected below.

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”), and follow the requirements of the Securities and Exchange Commission (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, 2017 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, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated. The Company acquired CareDx International AB, formerly Allenex AB “Allenex”, on April 14, 2016. Since the acquisition of Allenex through March 15, 2018, the Company owned less than 100% of the shares of Allenex and recorded a net loss attributable to noncontrolling interest in its condensed consolidated statements of operations equal to the percentage of the economic or ownership interest retained by the respective noncontrolling parties in such entities. On March 15, 2018, the Company acquired the remaining noncontrolling interest in Allenex and has not reported any noncontrolling interest balances since this date.

### 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) variable transaction price consideration related to contracts with customers, (ii) the determination of the accruals for clinical studies, (iii) the fair value of assets and liabilities acquired in business combinations, including contingent consideration, (iv) inventory valuation, (v) the valuation of common stock warrant liability, (vi) the fair value of embedded derivatives, (vii) measurement of stock-based compensation expense, (viii) the determination of the valuation allowance and estimated tax benefit associated with deferred tax assets and net deferred tax liability, (ix) any impairment of long-lived assets, including in-process technology and goodwill, and (x) legal contingencies. Actual results could differ from those estimates.

#### Concentrations of Credit Risk and Other Risks and Uncertainties

For the nine months ended September 30, 2018 and 2017, approximately 47% and 27%, respectively, of total revenue was derived from Medicare. No other payers or customers represented more than 10% of total revenue for these periods.

At September 30, 2018 and December 31, 2017, approximately 29% and 16%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either September 30, 2018 or December 31, 2017.

## Restricted Cash

A restricted cash balance of \$9.4 million was released upon the full conversion of the debt obligation to JGB Collateral LLC and certain of its affiliates (“JGB”) (refer to Note 10) during the three months ended March 31, 2018 and is no longer classified as restricted cash.

As a condition of the lease agreements for certain facilities and an agreement with the State of Florida Medicaid, the Company must maintain letters of credit, minimum collateral requirements and a surety bond. These agreements are collateralized by cash. The cash used to support these arrangements is classified as long-term restricted cash on the accompanying condensed consolidated balance sheets.

## Common Stock Warrant Liability and Derivative Liability

### Common Stock Warrant Liability

On January 1, 2018, the Company adopted Accounting Standard Update (“ASU”) No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. The Company determined that the common stock warrants issued to JGB (the “JGB Warrants”) meet equity classification criteria under the new standard and reclassified \$6.6 million (the fair value of the JGB Warrants as of January 1, 2018) from warrant liability to equity (additional paid in capital). As of September 30, 2018, the JGB Warrants were fully exercised.

The warrant issued to Perceptive (the “Perceptive Tranche A Warrant”), on April 17, 2018, also met the equity classification as noted in Note 13. The new standard did not impact the classification of the other warrants included in the warrant liability balance as these financial instruments have other than down-round anti-dilution adjustments features.

### Derivative Liability

The convertible debt financing with JGB (the “JGB Debt”), included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The combined embedded derivative was remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations. As of March 27, 2018, the JGB Debt was fully converted to shares of the Company’s common stock. The change in the fair market value of the derivative liability through March 27, 2018 was recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations.

On April 17, 2018, the Company entered into the Perceptive Credit Agreement, which included an embedded derivative that required bifurcation related to early repayment provisions. This embedded derivative fair value of \$0.2 million was recorded as debt issuance discount. Refer to Note 10 for additional details. The derivative is remeasured at the end of each reporting period if debt remains outstanding with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations.

## Revenue

The Company recognizes revenue from testing services, products, and license and other revenue in the amount that reflects the consideration which it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step model that includes identifying the contract with a customer,



identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

#### Testing Services Revenue

AlloMap and AlloSure patient tests are ordered by healthcare providers. The Company receives a test requisition form with payer information along with a collected patient blood sample. The Company considers the patient to be its customer and the test requisition form a contract. Testing services are performed in the Company's laboratory. Testing services represent one performance obligation in a contract and are performed when results of the test are provided to the healthcare provider, at a point of time.

The healthcare providers that order the tests and on whose behalf CareDx provides testing services are generally not responsible for the payment of these services. The first and second revenue recognition criteria are satisfied when the Company receives a test requisition form with payer information from the healthcare provider. Generally, the Company bills third-party payers upon delivery of an AlloMap or AlloSure test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer. The Company has used the portfolio approach, a practical expedient under Accounting Standards Codification ("ASC") Topic 606, to identify financial classes of payers. Transaction prices are determined for each financial class

using history of reimbursements, including analysis of an average reimbursement per test and a percentage of tests reimbursed. The Company estimates revenue for non-contracted payers and self-payers using this methodology. The estimate requires significant judgment. Revenue recognized for Medicare and other contracted payers is based on the agreed current reimbursement rate per test, adjusted for historical collection trends where applicable.

The Company monitors revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. As of September 30, 2018, the Company had received payments of \$0.3 million more than estimated as of December 31, 2017, related to tests performed in prior periods. This change in estimate was included in testing services revenue in the three months ended September 30, 2018, when cash was collected. Changes in transaction price estimates are updated quarterly based on actual cash collected or changes made to contracted rates.

#### Product Revenue

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. The Company generally has a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of delivery consistent with the terms of the contract or purchase order.

#### License and Other Revenue

The Company generates revenue from license agreements. License agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. The Company's performance obligations under the 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. The Company makes judgments to determine if performance obligations are distinct or should be combined and the transaction price allocated to each performance obligation, which affect the periods over which revenue is recognized. 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 constrains variable consideration, such as milestones, if it is probable that a significant portion of revenue would be reversed. The Company's deferred revenue relates to one performance obligation, which should be recognized over time.

The Company did not recognize any revenue connected with milestones during the three or nine months ended September 30, 2018 or 2017.

#### Cost of Testing Services

Cost of testing services reflects the aggregate costs incurred in delivering the Company's testing services. The components of cost of testing are materials and service costs, direct labor costs, stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples, and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Prior to adoption of the new revenue guidance, the Company recorded costs of testing associated with performing tests (except royalties) in the period when tests were performed without consideration of whether revenue was recognized in the same period. With the adoption of the new revenue standard on January 1, 2018, revenue and cost of testing for tests performed are recognized in the same period. Royalties for licensed

technology, calculated as a percentage of testing services revenues, are recorded as license fees in cost of testing services at the time the testing services revenues are recognized.

#### Recent Accounting Pronouncements

On January 1, 2018, the Company adopted the new revenue accounting standard Revenue from Contracts with Customers (Topic 606) ("ASC 606") using the modified retrospective method. The adoption of ASC 606 resulted in a one-time adjustment of \$2.9 million to accounts receivable and retained earnings on January 1, 2018. The adjustment reflects the estimated payments to be received for tests where the result had been delivered at December 31, 2017, but associated revenue had not been recognized by December 31, 2017, because payment had not been received. As of September 30, 2018, the Company had received payments of \$3.2 million for tests where the results had been delivered at December 31, 2017 but associated revenue had not been recognized by December 31, 2017. Payments received in excess of the \$2.9 million accounts receivable adjustment recorded on January 1, 2018 were recognized in testing services revenue in the period of collection. The new standard did not impact the Company's product revenue or license and other revenue, nor did it impact contract assets or contract liabilities.

The following table summarizes the impact of the ASC 606 adoption on accounts receivable as of September 30, 2018 (in thousands):

	Balance as Reported	Balance without the adoption of ASC 606	Impact of Adoption of ASC 606
<b>Balance Sheets</b>			
Accounts Receivable	\$ 9,641	\$ 5,734	\$ 3,907

The following table summarizes the impact to the statement of operations in accordance with the new revenue standard requirements for the three and nine months ended September 30, 2018 (in thousands):

	Three Months Ended September 30, 2018		
	Balance As Reported	Balance without the adoption of ASC 606	Revenue Impact of adoption of ASC 606
<b>Statements of Operations</b>			
Testing revenue	\$ 16,847	\$ 16,561	\$ 286
Product revenue	4,223	4,223	—
License and other revenue	114	114	—
	\$ 21,184	\$ 20,898	\$ 286

	Nine Months Ended September 30, 2018		
	Balance As Reported	Balance without the adoption of ASC 606	Revenue Impact of adoption of ASC 606
<b>Statements of Operations</b>			
Testing revenue	\$ 41,448	\$ 40,637	\$ 811
Product revenue	11,080	11,080	—
License and other revenue	532	532	—
	\$ 53,060	\$ 52,249	\$ 811

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2016-02, Leases (Topic 842) (“ASC 842”), 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, generally on a straight-line basis. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. Additionally, the FASB issued ASU, No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers a practical expedient for transitioning at the adoption date. These ASUs will be effective for the Company on January 1, 2019 and the Company has chosen to use this practical expedient and recognize a cumulative-effect adjustment to the opening balance of the accumulated deficit. The Company also plans to apply other practical expedients provided by the standard. The Company has begun an implementation plan, including the identification of its lease population, the selection of a new lease software, and the implementation of changes to existing processes that will be required to implement the new lease standard. The Company believes the most significant changes to the financial statements will relate to the recognition of right-of-use assets and offsetting lease liabilities in the condensed consolidated balance sheet for operating leases. The impact on the condensed consolidated balance sheet will be contingent upon the Company's population of operating leases at adoption, however the Company does not expect the standard to have a material impact on the condensed consolidated statement of cash flows or the condensed consolidated statement of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force) (“ASU 2016-15”), 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. The Company adopted ASU 2016-15 on January 1, 2018 on a retrospective basis. The adoption of ASU 2016-15 did not have a material impact on the Company’s condensed consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force) (“ASU 2016-18”). This guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash

equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2016-18 on January 1, 2018 on a retrospective basis and included restricted cash together with cash and cash equivalents in its condensed consolidated statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting (“ASU 2017-09”). The amendments provide guidance about how to account for changes to terms or conditions of a share-based payment award required under modification accounting. ASU 2017-09 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018 on a prospective basis and the adoption of ASU 2017-09 did not have a material impact to the condensed consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”). ASU 2017-11 is effective for all interim and annual reporting periods beginning on or after December 15, 2018 with early adoption permitted. The Company adopted ASU 2017-11 on January 1, 2018, and the adoption resulted in the JGB common stock warrant liability balance being reclassified to additional paid in capital (Refer to Note 13).

In February 2018, the FASB issued ASU No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income (“ASU 2018-02”). The amendments in ASU 2018-02 allow a reclassification from accumulated other comprehensive income to retained earnings for certain tax effects resulting from the Tax Cuts and Jobs Act (the “Tax Act”). The Company is still reviewing the Tax Act and its impact to the condensed consolidated financial statements. ASU 2018-02 will become effective for all interim and annual reporting periods beginning after December 15, 2018 and may be applied retrospectively or as of the beginning of the period of adoption.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting (“ASU 2018-07”). ASU 2018-07 is effective for all interim and annual reporting periods beginning on or after December 15, 2018. The Company will adopt ASU 2018-07 on January 1, 2019 and does not expect the adoption to have a material impact to the 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):

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>Numerator:</b>				
Net loss attributable to CareDx, Inc. used to compute basic				
and diluted net loss per share	\$(19,970 )	\$(14,268 )	\$(43,001 )	\$(23,798 )
<b>Denominator:</b>				
Weighted-average shares used to compute basic and diluted				
net loss per share attributable to CareDx, Inc.	37,154,293	22,526,615	34,134,138	21,765,292
<b>Net loss per share attributable to CareDx, Inc.:</b>				
Basic and diluted	\$(0.54 )	\$(0.63 )	\$(1.26 )	\$(1.09 )

12

The following potentially dilutive securities have been excluded from diluted net loss per share as at September 30, 2018 and as at September 30, 2017, because their effect would be antidilutive:

	Three Months Ended		Nine Months Ended	
	September 30, 2018	2017	September 30, 2018	2017
Shares of common stock subject to outstanding options	2,532,171	1,992,559	2,532,171	1,992,559
Shares of common stock subject to outstanding common				
stock warrants	798,553	4,506,478	798,553	4,506,478
Shares of common stock subject to convertible notes	—	6,313,636	—	6,313,636
Shares of common stock subject to contingent consideration	—	227,845	—	227,845
Restricted stock units	894,304	340,650	894,304	340,650
Total common stock equivalents	4,225,028	13,381,168	4,225,028	13,381,168

On October 10, 2017, the Company completed an underwritten public offering (the “2017 Public Offering”), pursuant to which the Company issued and sold an aggregate of 4,992,840 shares. During 2017 and the three months ended March 31, 2018, 6,415,039 shares of common stock subject to convertible notes were issued due to the conversion of the JGB Debt. In the three months ended June 30, 2018, the Company achieved the milestone of performing 2,500 commercial AlloSure tests resulting in the issuance of 227,845 shares of common stock to the former owners of ImmuMetrix, Inc. (“IMX”) that was previously considered contingent consideration.

The Perceptive Credit Agreement includes a Tranche B loan of \$10.0 million available at the Company’s option at any time from April 17, 2018 to April 17, 2019 (the “Tranche B Term Loan”). If the Tranche B Term Loan is funded, the Company will issue to Perceptive an additional warrant to purchase up to 93,333 shares of common stock.

#### 4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value except for its debt, which was 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. 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, as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018 Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
<b>Assets</b>				
Money market funds	\$20,993	\$ —	\$—	\$20,993
<b>Liabilities</b>				
Common stock warrant liability	—	—	11,612	11,612
Perceptive derivative liability	—	—	215	215
Total liabilities	\$—	\$ —	\$11,827	\$11,827

	December 31, 2017 Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
<b>Assets</b>				
Money market funds	\$13,097	\$ —	\$—	\$13,097
<b>Liabilities</b>				
Contingent consideration	\$—	\$ —	\$1,672	\$1,672
Common stock warrant liability	—	—	18,712	18,712
JGB derivative liability	—	—	14,600	14,600
Total liabilities	\$—	\$ —	\$34,984	\$34,984

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		JGB		
	Consideration Liability	Common Stock Warrant Liability	Derivative Liability	Perceptive Derivative Liability	Total
Balance as of December 31, 2017	\$1,672	\$18,712	\$14,600	\$ —	\$34,984
Exercise of warrants	—	(27,654)	—	—	(27,654)
Conversion of JGB Debt to common stock (Note 10)	—	—	(12,066)	—	(12,066)
Reclassification to equity (Note 2)	—	(6,550)	—	—	(6,550)
Issuance of Perceptive derivative liability	—	—	—	245	245
Issuance of common stock	(2,689)	—	—	—	(2,689)
Change in estimated fair value	1,017	27,104	(2,534)	(30)	25,557
Balance as of September 30, 2018	\$—	\$11,612	\$—	\$215	\$11,827

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

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

• Money market funds - Investments in money market funds are classified within Level 1. At September 30, 2018 and December 31, 2017, money market funds were included on the balance sheets in cash and cash equivalents.

- Perceptive Credit Agreement - The Company has recorded its debt with Perceptive at carrying value. The fair value is consistent with its carry value of \$13.4 million as of September 30, 2018.

Contingent consideration liability - As of December 31, 2017, the Company had a contingent obligation to issue 227,845 shares of the Company's common stock to the former owners of IMX in conjunction with its acquisition of IMX in June 2014. The shares were issuable upon the Company completing 2,500 commercial tests involving the measurement of dd-cfDNA in organ transplant recipients in the United States by June 10, 2020. The fair value of the contingent consideration was estimated using the closing market price of the common stock multiplied by management's estimate of the probability of achievement of the contingency condition disclosed above, as of each period end. The probability of achievement of a contingency condition was a significant input in the Level 3 measurement and was 100% in presented periods. Increases (decreases) in the estimation of the probability percentage resulted in a directionally similar impact to the fair value of the contingent consideration liability. The Company achieved the contingent consideration milestone of 2,500 commercial tests and issued the 227,845 shares on May 22, 2018. There is no contingent consideration outstanding at September 30, 2018.

Common stock warrant liability – The Company utilizes a binomial-lattice pricing model (the “Monte Carlo Simulation Model”) that involves a market condition simulation to estimate the fair value of the warrants. The application of the Monte Carlo Simulation Model requires the use of a number of complex assumptions including the Company's stock

14

---

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. Increases (decreases) in the assumptions discussed above result in a directionally similar impact to the fair value of the common stock warrant liability.

**JGB Debt derivative liability** –The Company utilized the Monte Carlo Simulation Model to estimate the fair value of the compound derivative liability recorded in connection with the JGB Debt. The Monte Carlo Simulation Model used multiple input assumptions to simulate the likelihood that market conditions will be achieved through 100,000 random trials. These assumptions included the expected term of the embedded derivative, the volatility of the Company's stock prices and its peers' stock prices over such expected term, likelihood, timing, and amount of future equity financing rounds, the likelihood of any prepayment or default events, the likelihood of monthly redemptions by the JGB Debt holders, and the likelihood and ability of JGB to convert the debt into equity. In each iteration of the simulations these assumptions were used to simulate the Company's stock price drawing from a risk neutral distribution, the occurrence of a conversion event, the occurrence of a prepayment event, the occurrence of a default event, and any resulting payoff from such event. The average present value over all iterations of the simulation was then calculated. Increases (decreases) in the assumptions discussed above resulted in a directionally similar impact to the fair value of the derivative liability. The assumptions used in this simulation model were reviewed on a quarterly basis and adjusted, as needed. For the nine months ended September 30, 2017 and from January 1, 2018 to March 27, 2018, the Company recorded the changes in fair value of the derivative liability of \$0.9 million income and of \$2.5 million income, respectively, in the change in estimated value of common stock warrant liability and derivative liability in its condensed consolidated statements of operations. The derivative liability was re-measured and fully extinguished upon the final JGB Debt conversion on March 27, 2018 (see Note 10).

**Perceptive Credit Agreement derivative liability** – The Company used a net present value analysis to estimate the fair value of the embedded derivative liability recorded in connection with the Perceptive Credit Agreement. The assumptions used in the analysis were the discount rate, the probability of early repayment during the term of the Credit Agreement and the expected term of the derivative. An increase in the discount rate will result in a decrease in liability and an increase in the probability of early repayment will result in an increase in liability. The assumptions used in this analysis will be reviewed on a quarterly basis and adjusted, as needed. For the three and nine months ended September 30, 2018, the Company recorded the changes in fair value of the derivative liability of less than \$0.1 million income in the change in estimated value of common stock warrant liability and derivative liability in its condensed consolidated statements of operations.

## Common Stock Warrant Liability and Derivative Liability Valuation Assumptions

	September 30, 2018	December 31, 2017	
<b>Private Placement Common Stock Warrant Liability</b>			
Stock Price	\$ 28.85	\$	7.34
Exercise Price	\$ 1.12	\$	1.12
Remaining term (in years)	4.54		5.29
Volatility	75.00	%	66.00 %
Risk-free interest rate	2.88	%	2.21 %
<b>Subsequent Financing Common Stock Warrant Liability</b>			
Stock Price	—		7.34
Exercise Price	—		4.00
Remaining term (in years)	—		5.46
Volatility	—	%	65.00 %
Risk-free interest rate	—	%	2.21 %
<b>Placement Agent Common Stock Warrant Liability</b>			
Stock Price	\$ 28.85	\$	7.34
Exercise Price	\$ 1.12	\$	1.12
Remaining term (in years)	2.54		3.29
Volatility	83.00	%	82.00 %
Risk-free interest rate	2.81	%	1.99 %
<b>Perceptive Derivative Liability</b>			
Remaining term (in years)	4.54		—
Discount rate	7.50	%	— %
<b>JGB Common Stock Warrant Liability</b>			
Stock Price	—	\$	7.34
Exercise Price	—	\$	4.67
Remaining term (in years)	—		4.71
Volatility	—	%	69.00 %
Risk-free interest rate	—	%	1.89 %
<b>JGB Derivative Liability</b>			
Stock Price	—	\$	7.34
Remaining term (in years)	—		2.16
Volatility	—	%	69.00 %
Risk-free interest rate	—	%	2.14 %

## 5. BUSINESS COMBINATIONS AND ASSET ACQUISITIONS

## Business Combinations

## Allenex

On April 14, 2016, the Company acquired 98.3% of the outstanding common stock of Allenex, a transplant diagnostic company based in Stockholm, Sweden that developed, manufactured and sold products that help match donor organs with potential recipients prior to transplantation. Allenex had a presence and direct distribution channels in the United States 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 \$5.7 million (which represents SEK 50,620,000 as of the acquisition date) was deferred purchase consideration originally payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB, the former majority shareholders of Allenex (the "Former Majority Shareholders") by no later than March 31, 2017, subject to certain contingencies being met, 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 Former Majority Shareholders was deposited into an escrow account by the Company and subsequently invested in the Company by the Former Majority Shareholders through a purchase of the Company's equity securities in a private placement. Upon the completion of such private placement, certain contingencies in the Conditional Share Purchase Agreements were waived. On June 8, 2016, the Company delisted Allenex's common stock from Nasdaq Stockholm.

The date by which the deferred purchase consideration was due to the Former Majority Shareholders was subsequently extended to July 1, 2017. In addition, interest began accruing on the Company's obligations to the Former Majority Shareholders (the "Deferred Obligation") at a rate of 10.0% per year commencing on January 1, 2017. On July 1, 2017, the Deferred Obligation totaled \$6.3 million. On July 1, 2017, the Conditional Share Purchase Agreements were amended in order to, among other things: (i) convert approximately \$1.1 million of the Deferred Obligation into 1,022,544 shares of the Company's common stock at a per share price equal to \$1.12; (ii) require that the Company make an immediate cash payment of \$0.5 million thereby reducing the Deferred Obligation by \$0.5 million; (iii) extend the maturity date of a portion of the obligations, totaling approximately \$2.9 million, under the Conditional Share Purchase Agreements to March 31, 2019; and (iv) provide that approximately \$2.1 million of the Deferred Obligation would become payable on December 31, 2017 unless converted into shares of the Company's common stock prior to that date, which issuance of shares was subject to approval by the Company's stockholders. Interest began to accrue on the Deferred Obligation at a rate of 10% per annum commencing on July 1, 2017. On November 14, 2017, the Company further amended the Conditional Share Purchase Agreements with the Former Majority Shareholders, and, as a result, the Company paid the total remaining deferred purchase consideration of \$4.7 million, plus accrued interest.

The Company has accounted for the Allenex 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.

The fair value of the remaining 1.7% of noncontrolling interest in Allenex was purchased on March 15, 2018. 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 (April 14, 2016). The noncontrolling interest was presented as a component of stockholders' equity on the Company's condensed consolidated balance sheets at December 31, 2017.

#### Conexio

On January 20, 2017, the Company acquired the business assets of Conexio Genomics Pty. Ltd ("Conexio"). Prior to the acquisition, the Company was the exclusive distributor of the Conexio SBT™ product line for all countries excluding Australia. The Company purchased rights to many of the assets, such as machinery, facilities leases, know-how and the opportunity to retain key Conexio employees to continue producing and selling SBT products. The Company paid \$0.4 million in cash and will make quarterly payments of 20% of the gross revenue from the sale of SBT products up to an aggregate total of \$0.7 million. During each of the nine months ended September 30, 2018, and September 30, 2017, the Company paid \$0.2 million and less than \$0.1 million, respectively. The Company accounted for this transaction as a business combination.

#### Asset Acquisition

##### illumina License and Commercialization Agreement

On May 4, 2018, the Company entered into a License and Commercialization Agreement (the "License Agreement") with illumina, which provides the Company with certain worldwide distribution, development and commercialization rights to illumina's NGS product line for use in the field of bone marrow and solid organ transplantation diagnostic testing (the "Field"). As a result, from June 1, 2018, the Company is the exclusive worldwide distributor of illumina's TruSight HLA v1 and v2 product line. In addition, the Company was also granted the exclusive right to develop and commercialize other NGS product lines for use in the Field.

The License Agreement required the Company to make a \$5.0 million initial cash payment to Illumina and further requires the Company to pay royalties in the mid-single to low-double digits on sales of future commercialized products. Pursuant to the License Agreement, the Company is obligated to complete timely development and commercialization of other NGS product lines for use in the Field, and has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

As the License Agreement did not meet the definition of a business combination under ASC Topic 805, Business Combinations, the Company accounted for the transaction as an asset acquisition. In an asset acquisition goodwill is not recognized, but rather any excess consideration transferred over the fair value of the net assets acquired is allocated on a relative fair value basis to the identifiable assets acquired.

Costs relating to the assets acquired were \$5.2 million, comprising of the cash consideration of \$5.0 million and associated transaction costs of \$0.2 million. A deferred tax balance was not required to be established on the License Agreement date as the book and tax basis of the intangible assets was equivalent to the amount paid.

The allocation of the purchase price to identified intangible assets acquired was based on the Company's best estimate of the fair value of such assets as of the acquisition date. Significant assumptions utilized in the valuation of identified intangible assets were based on company specific information and projections, which are not observable in the market and are thus considered Level 3 measurements



as defined by U.S. GAAP. The Company determined the estimated fair values using Level 3 inputs after review and consideration of relevant information, including discounted cash flows, quoted market prices and estimates made by management.

Customer relationships represent the fair value of future projected revenue that is expected to be derived from sales of TruSight HLA products to existing customers of Illumina. The customer contracts and related relationships value has been estimated utilizing a multi-period excess earnings method under income approach, which reflects the present value of the projected cash flows that are expected to be generated by the customer relationships less charges representing the contribution of other assets to those cash flows that use projected cash flows with and without the intangible asset in place. The economic useful life was determined based on the life of the products, assuming that the existing customers will remain with the Company until the products becomes obsolete. The Company utilized a discount rate of 18% in estimating the fair value of the customer relationships.

The acquired in-process technology represents the fair value of products in development that have not reached commercial production at the date of acquisition. The fair value of the products was also determined using the multi-period excess earnings method under income approach. A rate of 30% and 40% for the AlloSeq HLA acquired in-process technology and the AlloSeq BMT acquired in-process technology, respectively, was utilized to discount the cash flows to the present value. The acquired in-process technology will not be amortized until completion of the related products, which is determined by when the products commence commercial production. Upon completion, each acquired in-process technology product will be amortized over its estimated useful life.

The following table summarizes the fair values of the intangible assets acquired as of the closing date (in thousands):

	Estimated Fair Value	Estimated Useful Lives (Years)
Customer relationships: TruSight HLA	\$ 380	2.6
Acquired in-process technology: AlloSeq HLA	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—
Total	\$ 5,202	

## 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 Company reported \$12.0 million of goodwill on the condensed consolidated balance sheet as of each of September 30, 2018 and December 31, 2017.

Goodwill is tested annually for impairment at the reporting unit level during the fourth quarter or earlier upon the occurrence of certain events or substantive changes in circumstances. As of September 30, 2018, as indicated in Note 16, the Company changed its operating segments from Post-Transplant and Pre-Transplant to one single operating segment. This operating segment represents one reporting unit for goodwill impairment analysis.

On January 1, 2017, the Company adopted ASU 2017-04, which eliminated the Step 2 requirement of the goodwill impairment test. Instead, the goodwill impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. The Company determined that the decrease in its market capitalization in the first quarter of 2017 constituted an indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. The goodwill impairment test determined that the fair value of the former Pre-Transplant reporting unit was \$3.5 million, which was lower than its carrying value. Accordingly, the Company recorded a goodwill impairment charge of \$2.0 million as of March 31, 2017, which represented the remaining goodwill balance in the former Pre-Transplant reporting unit. The significant assumptions utilized in the March 31, 2017 discounted cash flow analysis for the former Pre-Transplant reporting unit were a discount rate of 16.6%, a terminal growth rate of 3.2% and a capitalization multiple of 7.48.

As of December 30, 2017, the remaining goodwill amount of \$12.0 million was related to the former Post-Transplant reportable segment only. Management performed a goodwill impairment analysis and concluded that goodwill was not impaired.

There were no indicators of impairment in the three and nine months ended September 30, 2018.

## Intangible Assets

The following tables present details of the Company's intangible assets as of September 30, 2018 (in thousands):

	September 30, 2018				
	Gross		Foreign	Remaining	
	Carrying	Accumulated	Currency	Net Carrying	Useful Life
	Amount	Amortization	Translation	Amount	(In Years)
<b>Intangible assets with finite lives:</b>					
Customer relationships: Allenex	\$12,650	\$ (2,005 )	\$ (1,006 )	\$ 9,639	12.3
Customer relationships: Conexio	28	(5 )	(1 )	22	7.3
Customer relationships: TruSight HLA	380	(49 )	—	331	2.3
Developed technology: Olerup SSP	11,650	(2,796 )	(897 )	7,957	7.3
Acquired technology: Olerup QTYPE	4,510	(600 )	(363 )	3,547	12.3
Acquired technology: Olerup SBT	127	(25 )	—	102	7.3
Acquired technology: dd-cfDNA	6,650	(508 )	—	6,142	12.1
Trademarks	2,260	(419 )	(119 )	1,722	12.3
Total intangible assets with finite lives	\$38,255	\$ (6,407 )	\$ (2,386 )	\$ 29,462	
Acquired in-process technology: AlloSeq HLA	2,719	—	—	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—	—	2,103	—
Total intangible assets	\$43,077	\$ (6,407 )	\$ (2,386 )	\$ 34,284	

The following tables present details of the Company's intangible assets as of December 31, 2017 (in thousands):

	December 31, 2017				
	Gross		Foreign	Remaining	
	Carrying	Accumulated	Currency	Net Carrying	Useful Life
	Amount	Amortization	Translation	Amount	(In Years)
Customer relationships: Allenex	\$12,650	\$ (1,394 )	\$ (250 )	\$ 11,006	13.0
Customer relationships: Conexio	28	(3 )	1	26	8.1
Developed technology: Olerup SSP	11,650	(1,942 )	(258 )	9,450	8.0
Acquired technology: Olerup QTYPE	4,510	(376 )	(84 )	4,050	13.0
Acquired technology: Olerup SBT	127	(14 )	5	118	8.1
Acquired technology: dd-cfDNA	6,650	(127 )	—	6,523	12.9
Trademarks	2,260	(310 )	16	1,966	13.0
Total intangible assets	\$37,875	\$ (4,166 )	\$ (570 )	\$ 33,139	

Amortization expense was \$0.6 million and \$0.6 million for the three months ended September 30, 2018 and 2017, respectively. For the three months ended September 30, 2018, expenses of \$0.3 million and \$0.3 million were amortized to cost of product and sales and marketing expense, respectively. For the three months ended September 30, 2017, expenses of \$0.4 million and \$0.2 million were amortized to cost of product and sales and marketing expense, respectively. Amortization expense was \$1.9 million and \$1.8 million for the nine months ended September

30, 2018 and 2017, respectively. For the nine months ended September 30, 2018, expenses of \$1.1 million and \$0.8 million were amortized to cost of product and sales and marketing, expense, respectively. For the nine months ended September 30, 2017, expenses of \$1.1 million and \$0.7 million were amortized to cost of product and sales and marketing expense, respectively.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2018 (in thousands):

Years Ending December 31,	Cost of		Sales and
	Product	Marketing	Total
Remainder of 2018	\$479	\$ 269	\$748
2019	1,909	1,078	2,987
2020	1,909	1,078	2,987
2021	1,909	930	2,839
2022	1,909	930	2,839
2023	1,909	930	2,839
Thereafter	7,725	6,498	14,223
Total future amortization expense	\$17,749	\$ 11,713	\$29,462

The Company evaluates the carrying value of the intangible assets, not subject to amortization, related to acquired in-process technology assets, which are considered to be indefinite lived until the completion or abandonment of the associated research and development efforts. Accordingly, amortization of the acquired in-process technology assets will not occur until the products reach commercialization. During the period the assets are considered indefinite lived, they are tested for impairment on an annual basis, as well as between annual tests if the Company becomes aware of any events occurring or changes in circumstances that would indicate that the fair values of the AIPT assets are less than their carrying amounts. An impairment loss would be recorded when the fair value of an AIPT asset is less than its carrying value. If and when development is complete, which generally occurs when the products are made commercially available, the associated AIPT asset will be deemed definite lived and will then be amortized based on its estimated useful life.

## 7. BALANCE SHEET COMPONENTS

### Inventory

Inventory consisted of the following (in thousands):

	September	
	30,	December 31,
	2018	2017
Finished goods	\$ 2,200	\$ 2,569
Work in progress	1,272	1,471
Raw materials	1,149	1,489
Total inventory	\$ 4,621	\$ 5,529

## Accrued and other liabilities

Accrued and other liabilities consisted of the following (in thousands):

	September 30,	December 31,
	2018	2017
Clinical studies	\$ 1,740	\$ 1,115
Test sample processing fees	652	633
Professional fees	590	475
Deferred rent – current portion	426	419
Accrued royalty	224	—
Customer overpayments and refunds due	187	270
Capital leases – current portion	169	13
Software implementation costs	—	94
Accrued interest payable	—	81
Other accrued expenses	730	635
<b>Total accrued and other liabilities</b>	<b>\$ 4,718</b>	<b>\$ 3,735</b>

## 8. COMMITMENTS AND CONTINGENCIES

## Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in Brisbane, California; West Chester, Pennsylvania; Fremantle, Australia; and Stockholm, Sweden. The lease for the Company's facility in Vienna, Austria is on a month-to-month basis. The facility 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.

Rent expense under the non-cancelable operating leases was \$0.6 million and \$0.4 million for each of the three months ended September 30, 2018 and 2017, respectively. Rent expense under the non-cancelable operating leases was \$1.5 million and \$1.3 million for each of the nine months ended September 30, 2018 and 2017, respectively. Future minimum lease commitments under these operating and capital leases on September 30, 2018, are as follows (in thousands):

	Capital	Operating
Years Ending December 31,	Leases	Leases
Remainder of 2018	\$ 48	\$ 561
2019	193	2,139
2020	193	2,053
2021	67	10
2022	—	7
Total future minimum lease payments	\$ 501	\$ 4,770

The current portion of obligations under capital leases is included in accrued and other liabilities on the balance sheets. The long-term portion is included in other liabilities on the balance sheets.

## Royalty Commitments

## Roche Molecular Systems, Inc. ("Roche")

In November 2004, the Company entered into a license agreement with Roche pursuant to which Roche granted the Company the right to use certain Roche technology relating to PCR, and quantitative real-time PCR in clinical laboratory services, including in connection with AlloMap. This is a non-exclusive license agreement in the United States covering claims in multiple Roche patents.

Under the license agreement, the Company incurred 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. Royalty expenses in connection with the Roche agreement were \$0.3 million and \$0.9 million for the three and nine months ended September 30, 2017, respectively. Effective September 30, 2017, no future royalties are payable by the Company under the Roche agreement.

## The Board of Trustees of the Leland Stanford Junior University ("Stanford")

In June 2014, the Company entered into a license agreement with Stanford, or the Stanford License, which granted the Company an exclusive license to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Under the terms of the Stanford License, the Company is required to pay an annual license maintenance fee, six milestone payment amounts and royalties in the low single digits of net sales of products incorporating the licensed technology. The license maintenance fee may be offset against earned royalty payments due on net sales in that year.

Commercial sales of AlloSure, which incorporates the licensed technology from Stanford, began in October 2017. The Company incurred royalties of \$0.2 million and \$0.4 million in the three and nine months ended September 30, 2018, respectively.

#### Conexio

On January 20, 2017, the Company acquired the business assets of Conexio, which included machinery, facilities leases, know-how and the opportunity to retain key Conexio employees to continue producing and selling the SBT line of products. The Company makes quarterly payments to Conexio of 20% of the gross revenue from the sale of the SBT products using the purchased assets up to an aggregate total of \$0.7 million. During the three months ended September 30, 2018 and 2017, the Company paid Conexio less than \$0.1 million and \$0.1 million, respectively. During the nine months ended September 30, 2018 and 2017, the Company paid \$0.2 million and \$0.1 million, respectively.



## Illumina

On May 4, 2018, the Company entered into the License Agreement with Illumina. The License Agreement requires the Company to pay royalties in the mid-single to low-double digits on sales of future commercialized products. In the three months ended September 30, 2018, the Company paid no royalties to Illumina.

## Other Commitments

Pursuant to the License Agreement with Illumina, the Company is obligated to complete timely development and commercialization of other NGS product line for use in the Field, and has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

## Litigation

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the financial statements indicates that it is probable that a liability had been incurred at the date of the financial statements and (ii) the range of loss can be reasonably estimated.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2018 and as of December 31, 2017.

## 9. LICENSE AND OTHER REVENUE

### Diaxonhit

In June 2013, the Company entered into an exclusive Distribution and Licensing Agreement with Diaxonhit, SA ("Diaxonhit") a French public company, whereby Diaxonhit 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 included an upfront cash payment of approximately €387,500 (\$408,000) that is designated to offset royalties earned by the Company. The Company is entitled to receive royalties from Diaxonhit as

a percentage of net sales, as defined in the agreement, of AlloMap tests in the mid to high teens. Upon confirmation that the CE mark was in place, the Company also received an equity payment of Diaxonhit common stock with a value of €387,500 (\$476,000). The Company sold the shares of common stock in July 2013 for total consideration of \$467,000. The CE mark is a mandatory conformity marking for certain products sold within the EEA.

Other performance obligations for which the Company may recognize revenue 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 Diaxonhit. Commercial sales of the AlloMap test began in the EEA in June 2014. Total revenues and royalties recognized from this arrangement for each of the three months ended September 30, 2018 and 2017 were \$10,000. Total revenue and royalties recognized from this arrangement for each of the nine months ended September 30, 2018 and 2017 were \$29,000.

#### CardioDx, Inc.

In 2005, the Company entered into a services agreement with what at the time was a related party, CardioDx, Inc. (“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. The royalty obligation to the Company continues until 2019. The Company recognizes royalty revenues when payments are received as it was assessed that collection was not able to be estimated. Royalty revenues for each of the three months ended September 30, 2018 and 2017 were nil and \$0.1 million, respectively. Royalty revenues for the nine months ended September 30,

2018 and 2017 were \$0.3 million and \$0.4 million, respectively. Royalty revenues are included in license revenue on the condensed consolidated statements of operations. The Company had no receivable balance from CDX as of September 30, 2018 and December 31, 2017.

## 10. DEBT

Debt consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
JGB Debt	\$ —	\$ 7,743
Danske Bank Credit Facility	—	6,763
SSP Primers Loan	—	1,215
Current portion of long-term debt	\$ —	\$ 15,721
Perceptive Credit Agreement	\$ 13,384	\$ —
JGB Debt	—	14,168
FastPartner Subordinated Promissory Notes	—	2,400
Al Amoudi Subordinated Promissory Notes	—	1,770
Long-term debt, net of current portion	\$ 13,384	\$ 18,338

Unamortized debt discount and issuance costs as of September 30, 2018 and December 31, 2017 were \$1.6 million and \$4.6 million, respectively. Total interest accrued on debt as of September 30, 2018 and December 31, 2017 was nil and \$0.3 million, respectively. The current accrued interest balance of \$0.1 million and long-term accrued interest balance of \$0.2 million as of December 31, 2017, were recorded in accrued and other liabilities and in other liabilities long-term, respectively, in the condensed consolidated balance sheets.

As of September 30, 2018, future debt maturities were as follows (in thousands):

Years Ending December 31,	Amount
2021	\$2,025
2022	2,700
2023	10,275
Total debt maturities	15,000
Less: debt discount and issuance costs	(1,616)
Long-term debt, net carrying value	\$13,384

### Perceptive Credit Agreement

On April 17, 2018, the Company entered into a credit agreement with Perceptive for an initial term loan of \$15.0 million (“Tranche A Term Loan”) with a second tranche of \$10.0 million available at the Company’s option, subject to

the satisfaction of customary conditions (the “Tranche B Term Loan” and, together with the “Tranche A Term Loan”, the “Term Loan”). Approximately \$11.1 million of the proceeds of the Tranche A Term Loan were used to fully repay the Company’s outstanding indebtedness, including accrued interest, with FastPartner AB, Mohammed Al Amoudi and Danske on April 17, 2018. The remainder of the proceeds will be used for general corporate purposes.

In connection with the Perceptive Credit Agreement, the Company entered into a Security Agreement with Perceptive, as administrative agent. The Security Agreement provides that the Term Loan is secured by substantially all of the Company’s assets and a pledge of 65% of the equity interests of CareDx International AB. The Term Loan accrues interest per annum at 9.00% (the “Applicable Margin”) plus the greater of the one-month LIBOR or 1.5%. Payments under the Perceptive Credit Agreement are interest-only until the first principal payment is due on April 30, 2021, followed by monthly payments of principal and interest through the scheduled maturity date on April 17, 2023. The Term Loan may be prepaid by the Company, in whole or in part at any time, subject to a prepayment fee.

The Company paid a fee of \$0.3 million to Perceptive in its capacity as the administrative agent under the Security Agreement. In addition, on April 17, 2018, the Company issued to Perceptive the Perceptive Tranche A Warrant to purchase up to 140,000 shares of

common stock of the Company at an initial exercise price of \$8.60. The Perceptive Tranche A Warrant will be exercisable commencing on October 17, 2018 and will terminate, if not earlier exercised, on April 17, 2025.

The Tranche B Term Loan is available at the Company's option at any time from April 17, 2018 to April 17, 2019, subject to the Company achieving certain product revenue targets and satisfying customary conditions. In the event the Company exercises its option for the Tranche B Term Loan, the Company will pay to Perceptive as the administrative agent out of the proceeds of the Tranche B Term Loan a fee in the amount equal to 1.75% of the principal amount of the Tranche B Term Loan advanced on such date. If the Tranche B Term Loan is funded, the Company will issue to Perceptive an additional warrant (the "Tranche B Warrant"), to purchase up to 93,333 shares of common stock at an initial exercise price of \$8.60 and with other terms consistent with the Tranche A Warrant.

The Perceptive Credit Agreement contains financial covenants related to minimum cash balance and trailing twelve month revenue. As of September 30, 2018, the Company was in compliance with the financial covenants.

The Perceptive Credit Agreement provides for customary events of default, including, among other things, nonpayments of principal, interest and other amounts, inaccuracies in representations and warranties, failure to comply with covenants, defaults on other material indebtedness, bankruptcy or insolvency, judgments, changes of control or impairments of Perceptive's security interests. Upon the occurrence of an event of default and following any applicable cure periods, if any, the Applicable Margin shall automatically increase 3.00% per annum (the "Default Rate"). This Default Rate may be applied to the outstanding loan balances, and the Agent may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Perceptive Credit Agreement. The Company concluded that the early repayment provisions were an embedded derivative liability requiring bifurcation. This embedded derivative liability will be re-measured at each reporting period and the change in fair value will be recognized in the consolidated statement of operations.

The following table summarizes the Company's carrying value of the Perceptive Security Agreement (in thousands) on April 17, 2018, the issuance date (in thousands):

	April 17, 2018
Debt principal	\$ 15,000
Less:	
Issuance cost	(669 )
Discount related to issued warrants	(784 )
Embedded derivative liability	(245 )
Total debt discount	(1,698 )
Carrying value	\$ 13,302

#### JGB Debt

On March 15, 2017, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with JGB pursuant to which the Company issued to JGB debentures (the "Debentures") with an aggregate principal amount of \$27.8 million and warrants to purchase shares of the Company's common stock (the "JGB Warrants") for net proceeds of \$24.0 million (the "Financing"). The Company used \$11.2 million of the net proceeds from the Financing to repay its existing indebtedness under the Loan Agreement with East West Bank and was required to maintain restricted cash of \$9.4 million.

Under the Securities Purchase Agreement, the Debentures would have matured on February 28, 2020, accrued interest at 9.5% per year and were convertible into an aggregate of approximately 6,092,105 shares of the Company's common stock at a price of \$4.56 per share (the "Conversion Price"), subject to adjustment for accrued and unpaid interest and upon the occurrence of certain transactions, at the holder's option.

Additionally, after September 1, 2017, upon the satisfaction of certain conditions, including the volume weighted average price of the Company's common stock exceeding 250% of the Conversion Price for twenty consecutive trading days, the Company could have required that the Debentures be converted into shares of the Company's common stock, subject to certain limitations. Commencing on March 1, 2018, each of the holders of the Debentures had the right, at its option, to require the Company to redeem up to \$937,500 of the outstanding principal amount of its Debenture per month. The Company was required to promptly, but in any event no more than one trading day after the holder delivers a redemption notice to the Company, pay the applicable redemption amount in cash or, at the Company's election and subject to certain conditions, in shares of the Company's common stock. If the Company elected to pay the redemption amount in shares of the Company's common stock, then the shares would have been delivered based on a price equal to the lowest of (a) 88% of the average of the three lowest volume weighted average prices of the Company's common stock over the prior 20 trading days, (b) 88% of the prior trading day's volume weighted average price, or (c) the Conversion Price.

After either a change of control transaction, as defined in the Debentures, or February 28, 2018, subject to the satisfaction of certain conditions, the Company could have redeemed all of the then outstanding principal amount of the Debentures for cash by paying the outstanding principal balance, accrued and unpaid interest, and a payment premium. The payment premium would have been calculated by multiplying the outstanding balance and the following percentage: (i) 15% if the Debentures were prepaid on or prior to March 1, 2018, (ii) 8% if the Debentures were prepaid after March 1, 2018 but prior to March 1, 2019, and (iii) 5% if the Debentures were prepaid on or after March 1, 2019.

The Company's obligations under the Debentures could have been accelerated upon the occurrence of certain events of default as specified in the agreement. In the event of default and acceleration of the Company's obligations, the Company would have been required to pay (i) 115% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debentures were accelerated prior to March 1, 2018, (ii) 108% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debentures were accelerated after March 1, 2018, but prior to March 1, 2019, and (iii) 105% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debentures were accelerated after March 1, 2019. The Company's obligations under the Debentures were secured under a Security Agreement by a senior lien on all of the Company's assets, other than its interest in CareDx International AB (formerly known as Allenex AB), which was subject to a negative pledge prohibiting the incurrence of additional or replacement debt.

The Debentures contained customary affirmative and restrictive covenants and representations and warranties, including financial reporting obligations, a restriction on the Company's ability to pay cash dividends on its common stock and limitations on indebtedness, liens, investments, distributions, transfers, corporate changes, deposit accounts and subsidiaries. The Company was also required to maintain a minimum cash amount at all times, achieve commercialization of AlloSure by a certain date and achieve certain gross profit targets for sales of its AlloMap product.

In connection with the Financing, on March 15, 2017, the Company and the Purchasers entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, the Company agreed to prepare and file one or more registration statements with the SEC for the purpose of registering for resale any shares of Common Stock that may be issued by the Company upon the conversion or redemption of the Debentures or the exercise of the JGB Warrants.

The Debentures included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The compound embedded derivatives were remeasured at each reporting period and the change in fair value was recognized in the consolidated statements of operations. See also Note 4, "Fair Value Measurements".

The following table summarizes the Company's carrying value of the JGB Debt (in thousands) on the March 15, 2017 issuance date:

	March 15, 2017
Debt principal	\$ 27,780
Less:	
Issuance cost	(998 )
Original issue discount	(2,780 )
Original warrant valuation	(900 )
Embedded Derivative Liability	(2,290 )
Total debt discount	(6,968 )

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

Carrying value \$ 20,812

As a result of the issuance of 1,022,544 shares of the Company's common stock issued at a price per share equal to \$1.12 pursuant to the amendments to the Conditional Share Purchase Agreements, the conversion price of the Debentures decreased from \$4.56 per share to \$4.40 per share, effective July 3, 2017.

As a result of the 2017 Public Offering in accordance with the anti-dilution provisions in the Debentures, effective October 5, 2017, the conversion price of the Debentures decreased from \$4.40 to \$4.34 per share. On October 5, 2017, JGB elected to convert \$1.25 million of outstanding principal under the Debentures into shares of common stock. Accordingly, the Company issued 288,022 shares of common stock to JGB at a price per share of \$4.34. As a result of the sale of the 651,240 shares of common stock pursuant to the underwriters' full exercise of their option to purchase additional shares in accordance with the anti-dilution provisions in the Debentures, effective October 10, 2017, the conversion price of the Debentures were decreased from \$4.34 per share to \$4.33 per share. As of December 31, 2017, the JGB Debt had an outstanding principal balance of \$26.5 million.



On March 1, 2018, the Company notified JGB of its intent to prepay on April 13, 2018 in full the outstanding principal and interest under the Debentures. Pursuant to the terms of the Debentures, on April 13, 2018, the Company would have been obligated to pay the full amount of the outstanding principal balance of the Debentures, plus accrued and unpaid interest thereon and a prepayment premium equal to 8% of the outstanding principal balance in cash. In February and March 31, 2018, JGB converted the remaining \$26.7 million of principal and accrued interest of the JGB Debt into an aggregate of 6,161,331 shares of the Company's common stock. In connection with these conversions in the three months ended March 31, 2018, the Company recognized \$6,000 to common stock and \$38.8 million to additional paid in capital; the unamortized debt discount of \$2.7 million was extinguished; and the compound derivative liability of \$12.1 million was also extinguished. The JGB Debt conversion resulted in a \$2.8 million loss on debt extinguishment that was included in other expense, net in the condensed consolidated statements of operations.

#### Danske Bank Term Loan and Credit Facility

On June 25, 2013, Allenex entered into a term loan facility (the "Term Loan Facility") with Danske in an aggregate principal amount of up to SEK 71,000,000 (approximately \$8.8 million). The Term Loan Facility was available for utilization in advances of a minimum of SEK 5,000,000 (approximately \$0.6 million) and if more, integral multiples of SEK 1,000,000 (approximately \$0.1 million). The interest rate applicable to each advance was 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.

On June 18, 2015, Allenex also entered into a short term credit facility ("Credit Facility") with Danske with total available credit of SEK 8,000,000 (approximately \$1.0 million). As of August 4, 2016, the available credit under the Credit Facility with Danske was increased to SEK 10,000,000 (approximately \$1.2 million).

A quarterly debt covenant in the Term Loan Facility with Danske was violated on March 31, 2017, June 30, 2017, and September 30, 2017. The Company obtained a waiver for these violations. The waiver was conditional upon, among other things, the Company making a principal repayment of SEK 6,000,000 (approximately \$0.7 million) by October 31, 2017. This amount was paid on October 31, 2017. The Company was not in compliance with certain debt covenants as of December 31, 2017 or March 31, 2018. The Company repaid the full outstanding amount of SEK 47,000,000 (approximately \$5.6 million), including accrued interest of SEK 142,000 (approximately \$17,000), under the Danske Term Loan and Credit Facility on April 17, 2018.

#### FastPartner Subordinated Promissory Notes

On June 28, 2013, Allenex issued a SEK 9,400,000 (approximately \$1.1 million) subordinated promissory note to FastPartner, which had an interest rate of 10.00%. On December 29, 2015, Allenex issued a SEK 2,000,000 (approximately \$0.2 million) subordinated promissory note to FastPartner, which had an annual interest rate of 10.00%.

On March 7, 2016, Allenex issued a SEK 4,000,000 (approximately \$0.5 million) subordinated promissory note to FastPartner, which had an annual interest rate of 10.00%. Pursuant to an 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 are secured by a pledge of Allenex shares to FastPartner. The full amount of the subordinated promissory note was due July 1, 2017.

On July 1, 2017, the Company entered into a note agreement with FastPartner (the "FastPartner Note Agreement") pursuant to which, among other things, Allenex and FastPartner agreed that all amounts owed under the above subordinated promissory notes would be governed by the FastPartner Note Agreement and to defer repayment of the principal outstanding amount of SEK 15,400,000 (approximately \$1.9 million) plus accrued interest of \$0.5 million until March 31, 2019. Interest began accruing on such amount at a rate of 10% per annum, and in the event the Company makes any cash amortization repayments to JGB of the JGB Debt, or any replacement debt, Allenex will repay in cash a portion of the amount outstanding under the FastPartner Note Agreement equal to 8% of any such cash amortization repayment. As of each of March 31, 2018 and December 31, 2017, the principal outstanding amount remained at SEK 19,757,000 (approximately \$2.4 million). The Company repaid the full amount outstanding of SEK 21,300,000 (approximately \$2.5 million), including accrued interest of SEK 1,600,000 (approximately \$0.2 million), under the FastPartner Note Agreement on April 17, 2018.

#### Mohammed Al Amoudi Subordinated Promissory Note

On June 28, 2013, Allenex issued a SEK 10,600,000 (approximately \$1.2 million) subordinated promissory note to Mohammed Al Amoudi, which provides for an annual interest rate of 10.00%. Pursuant to an intercreditor agreement, until the Term Loan Facility with Danske is repaid, Mohammed Al Amoudi may not demand or receive payment of his 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 are secured by a pledge of Allenex shares to Mohammed Al Amoudi. The full amount of the subordinated promissory note was due July 1, 2017.

On July 1, 2017, the Company entered into a note agreement with Mohammed Al Amoudi (the "Al Amoudi Note Agreement") pursuant to which, among other things, Allenex and Mohammed Al Amoudi agreed to defer repayment of the principal outstanding amount of SEK 10,600,000 (approximately \$1.3 million) plus accrued interest of \$0.5 million until March 31, 2019. Interest began accruing on such amount at a rate of 10% per annum, and in the event the Company makes any cash amortization repayments to JGB of the JGB Debt, or any replacement debt, Allenex will repay in cash a portion of the amount outstanding under the Al Amoudi Note Agreement equal to 6% of any such cash amortization repayment. As of each of March 31, 2018 and December 31, 2017, the principal outstanding amount remained at SEK 14,575,000 (approximately \$1.7 million). The Company repaid the full amount outstanding of SEK 15,700,000 (approximately \$1.9 million), including accrued interest of SEK 1,200,000 (approximately \$0.1 million) under the Al Amoudi Note Agreement on April 17, 2018.

#### Loan Agreement with SSP Primers Aktiebolag

On February 25, 2015, Allenex entered into a SEK 14,000,000 (approximately \$1.7 million) loan agreement with SSP Primers Aktiebolag, pursuant to which SEK 4,000,000 (approximately \$0.5 million) was paid on March 7, 2016. The loan amount outstanding as of December 31, 2017 was SEK 10,000,000 (approximately \$1.2 million) plus accrued interest of SEK 650,000 (approximately \$0.1 million) and was fully paid on February 26, 2018.

## 11. STOCKHOLDERS' EQUITY

#### 2017 Public Offering

On October 10, 2017, the Company sold in the 2017 Public Offering an aggregate of 4,992,840 shares of its common stock, including 651,240 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares to cover over-allotments, at a public offering price of \$4.00 per share.

Net proceeds from the 2017 Public Offering were \$18.3 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

#### JGB Debt

On October 5, 2017, JGB converted \$1.25 million of outstanding principal under the Debentures into shares of common stock. Accordingly, the Company issued 288,022 shares of common stock to JGB at a price per share of \$4.34. In the three months ended March 31, 2018, JGB converted the remaining \$26.7 million of outstanding principal and accrued interest for a total issuance of 6,161,331 shares of the Company's common stock at a price per share of

\$4.33.

#### Contingent Consideration Liability

The Company had a contingent obligation to issue 227,845 shares of the Company's common stock to the former owners of IMX, in conjunction with its acquisition of IMX in June 2014. The shares were issuable upon the Company completing 2,500 commercial tests involving the measurement of dd-cfDNA in organ transplant recipients in the United States by June 10, 2020. The Company achieved the contingent consideration milestone of 2,500 commercial tests and issued the 227,845 shares in May 2018.

#### 12. 401(K) PLAN

The Company sponsors a 401(k) defined contribution plan covering all U.S. employees under the Internal Revenue Code. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. On January 1, 2018, the Company began to make contributions to the employee plan. The Company incurred expenses related to contributions to the plan of \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2018, respectively.

## 13. WARRANTS

The Company issues common stock warrants in connection with debt or equity financings to a lender, a placement agent or an investor. Issued warrants are considered standalone financial instruments and the terms of each warrant are analyzed for equity or liability classification in accordance with US GAAP. Warrants that are classified as liabilities usually have various features that would require net-cash settlement by the Company. Warrants that are not liabilities, derivatives and/or meet exception criteria are classified as equity. Warrants liabilities are re-measured at fair value at each period end with changes in fair value recorded in the condensed statements of operations until expired or exercised. The Company utilizes the Monte Carlo Simulation Model to estimate the fair value of its warrants. Refer to Note 4 for further details. Warrants that are classified as equity are valued at fair value on the date of issuance, recorded in additional paid in capital and not re-measured.

On January 1, 2018, the Company adopted new accounting guidance (refer to Note 2) and reclassified the warrants to purchase 1,338,326 shares of common stock issued to JGB from liability to equity at the fair value of \$6.6 million.

In the three months ended September 30, 2018, warrants to purchase 2,530,000 shares of common stock were exercised for cash proceeds of \$10.5 million. In the nine months ended September 30, 2018, warrants to purchase 2,998,000 shares of common stock were exercised for a cash payment of \$11.0 million.

As of September 30, 2018, outstanding warrants to purchase common stock were:

			Exercise	Number of Shares
	Classified as	Original Term	Price	Underlying Warrants
Original issue date:				
August 2009	Equity	10 years	\$ 21.78	16,298
July 2010	Equity	9 years	\$ 21.78	23,869
August 2012	Equity	7 years	\$ 21.78	167,182
January 2015	Equity	5 years	\$ 6.96	34,483
April 2016 (a)	Liability	7 years	\$ 1.12	323,021
April 2016 (b)	Liability	5 years	\$ 1.12	93,700
April 2018 (c)	Equity	7 years	\$ 8.60	140,000
April 2018 (d)	Equity	7 years	\$ 8.60	93,333
				891,886

(a) Issued on April 14, 2016 in connection with the private placement to certain accredited investors. In accordance with the anti-dilution provisions, the exercise price of the warrants issued in connection with such private placement was adjusted from \$4.98 to \$4.00, which was the price paid by investors in the Company's underwritten public offering of common stock, which closed on September 26, 2016. As a result of the issuance of 1,022,544 shares of the Company's common stock at \$1.12 in connection with the amendments to the Conditional Share Purchase Agreement, the exercise price was adjusted from \$4.00 to \$1.12, effective July 3, 2017.

(b) Issued on April 14, 2016 in connection with the private placement to placement agents. As a result of the issuance of 1,022,544 shares of the Company's common stock at \$1.12 in connection with the amendments to the

Conditional Share Purchase Agreement, the exercise price was adjusted from \$3.99 to \$1.12, effective July 3, 2017.

(c) Issued on April 17, 2018 in connection with the Perceptive Credit Agreement.

(d) The Perceptive Credit Agreement included a Tranche B loan amount available at the Company's option at any time from April 17, 2018 to April 17, 2019. If the Tranche B Term Loan is funded, the Company will issue Perceptive a Tranche B Warrant to purchase up to 93,333 shares of common stock an exercise price of \$8.60. The Perceptive Tranche B Warrant is considered issued for accounting purposes only and will not be exercisable unless and until legally issued in connection with a funding of the Tranche B Term Loan.

## 14. STOCK INCENTIVE PLANS

## Stock Options and Restricted Stock Units (“RSU”)

The following table summarizes option and unvested RSU activity under the Company’s 2014 Equity Incentive Plan and 2016 Inducement Plan and related information:

	Shares Available for Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Number of RSU Shares	Weighted-Average Grant Date Fair Value
Balance—December 31, 2017	156,429	1,941,473	\$ 4.21	439,926	\$ 4.39
Additional options authorized	1,957,075	—	—	—	—
Restricted stock grants	(22,809 )	—	—	—	—
RSUs granted	(740,334 )	—	—	740,334	11.97
RSUs forfeited	16,150	—	—	(16,150 )	5.15
RSUs vested	—	—	—	(269,806)	8.55
Repurchases of common stock under employee incentive plans	67,656	—	—	—	—
Options granted	(901,533 )	901,533	12.06	—	—
Options exercised	—	(281,465 )	2.09	—	—
Options forfeited	27,553	(27,553 )	5.19	—	—
Options expired	1,817	(1,817 )	3.55	—	—
Balance—September 30, 2018	562,004	2,532,171	\$ 7.23	894,304	\$ 9.41

The total intrinsic value of options exercised was \$2.6 million in the nine months ended September 30, 2018.

As of September 30, 2018, the total intrinsic value of outstanding RSUs was approximately \$3.0 million and there were \$6.6 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 3.19 years.

As of September 30, 2018, the total intrinsic value of outstanding options was approximately \$51.1 million and there were \$6.4 million of unrecognized compensation costs related to options, which are expected to be recognized over a weighted-average period of 3.20 years.

Options outstanding that have vested and are expected to vest at September 30, 2018 are as follows:

Number of Shares Issued	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
-------------------------	---------------------------------	---	---------------------------

				(In Thousands)
Vested	1,024,442	\$ 4.96	6.59	\$ 24,478
Expected to vest	1,329,020	8.85	7.20	26,575
Total	2,353,462			\$ 51,053

## 2014 Employee Stock Purchase Plan

During the offering period in 2017 that ended on December 31, 2017, 34,176 shares were purchased for aggregate proceeds of \$0.1 million from the issuance of shares, which occurred on January 4, 2018. During the offering period in 2018 that ended on June 30, 2018, 42,534 shares were purchased for aggregate proceeds of \$0.3 million from the issuance of shares, which occurred on July 2, 2018.



## Valuation Assumptions

The estimated fair value 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, 2018		Nine Months Ended September 30, 2017	
<b>Employee stock options</b>				
Expected term (in years)	5.8	5.7	6.0	5.9
Expected volatility	66.00%	59.33%	68.47%	56.05%
Risk-free interest rate	2.81 %	1.88 %	2.72 %	1.97 %
Expected dividend yield	— %	— %	— %	— %
<b>Employee stock purchase plan</b>				
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	59.94%	98.58%	92.71%	77.42%
Risk-free interest rate	2.14 %	1.13 %	1.76 %	0.85 %
Expected dividend yield	— %	— %	— %	— %

**Risk-free Interest Rate:** The Company based the risk-free interest rate over the expected term of the award based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of grant.

**Volatility:** The Company used an average historical stock price volatility of its own stock and those comparable public companies that were deemed to be representative of future stock price trends.

**Expected Term:** The expected term represents the period for which the Company's stock-based compensation awards are expected to be outstanding and is based on analyzing the vesting and contractual terms of the awards and the holders' historical exercise patterns and termination behavior.

**Expected Dividends:** The Company has not paid and does not anticipate paying any dividends in the near future.

## 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, 2018 and 2017, included in the statements of operations as follows (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Cost of testing	\$123	\$38	\$375	\$157
Research and development	763	104	1,438	279

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

Sales and marketing	199	32	729	127
General and administrative	775	256	2,536	753
Total	\$1,860	\$430	\$5,078	\$1,316

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 expense were capitalized for the periods presented.

## 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, 2018, the Company recorded an income tax benefit of \$0.3 million and \$1.1 million, respectively, compared to \$0.2 million and \$0.8 million for the three and nine month ended September 30, 2017, respectively. The income tax benefit of \$0.3 million and \$1.1 million

for the three and nine months ended September 30, 2018, respectively, is primarily attributable to the recognition of deferred tax assets from foreign losses. The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets. Accordingly, the U.S. net deferred tax assets have been offset by a full valuation allowance.

In accordance with the SEC's Staff Accounting Bulletin No. 118 ("SAB 118"), the effects of the Tax Act may be adjusted within a one-year measurement period from the enactment date for items that were previously reported as provisional, or where a provisional estimate could not be made. Income tax provision for the nine months ended September 30, 2018, did not reflect any adjustment to the previously assessed Tax Act enactment effect. The Company will continue to assess forthcoming guidance and accounting interpretations on the effects of the Tax Act and expects to complete its analysis within the measurement period in accordance with the SEC guidance.

Starting in 2018, companies may be subject to global intangible low tax income ("GILTI"), which is a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations as well as the new base erosion anti-abuse tax ("BEAT") under the Tax Act. GILTI will be effectively taxed at a tax rate of 10.5%. Due to the complexity of the GILTI tax rules, companies are allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to GILTI as a current-period expense when incurred or (2) factoring such amounts into a company's measurement of its deferred taxes under SAB 118. The Company has not yet made an election with respect to GILTI and does not believe GILTI will have an impact on the Company's 2018 taxes. The Company will continue to review the GILTI and BEAT rules to determine their applicability to the Company as the rules become effective.

## 16. SEGMENT REPORTING

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the 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 CEO 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.

The Company previously operated and reported its operating results in two reportable segments: Post-Transplant and Pre-Transplant. In the third quarter of 2018, the Company completed a business reorganization to support the Company's strategy to become a global transplant care leader. The position of the head of the former Pre-Transplant segment was eliminated, and global functional leaders who report to CODM were identified to manage sales and marketing, research and development, manufacturing and quality and other global functions. These changes resulted in changes to the presentation of financial information provided to the CODM for resource allocation and management performance assessment. The CODM continues to review revenue and cost of sales by testing services and products, as reported in the condensed consolidated income statement. EBIDTA and operating results are reviewed at the consolidated level only. Effective September 30, 2018, the Company reports a single operating segment.

As of and for the three and nine-months ended September 30, 2018 and 2017, there are no changes to the segment financial information reporting, except that the Company does not report results of former Post and Pre-Transplant segments. Such information is no longer prepared and therefore has not been provided to the CODM since the Company completed its reorganization during the reporting period ending September 30, 2018.

Revenues by geographic regions are based upon the customers' ship-to address for product revenue and the region of testing for testing services revenue. The following table summarizes reportable revenues by geographic regions (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30		September 30	
	2018	2017*	2018	2017*
<b>Testing services revenue</b>				
United States	\$16,675	\$8,093	\$40,988	\$24,160
Rest of the World	172	70	460	325
	\$16,847	\$8,163	\$41,448	\$24,485
<b>Product revenue</b>				
United States	\$1,738	\$1,004	\$4,066	\$2,791
Europe	2,020	2,077	5,848	5,999
Rest of the World	465	791	1,166	2,126
	\$4,223	\$3,872	\$11,080	\$10,916
<b>License and other revenue</b>				
United States	\$69	\$132	\$446	\$358
Europe	45	24	86	62
	\$114	\$156	\$532	\$420
<b>Total United States</b>	<b>\$18,482</b>	<b>\$9,229</b>	<b>\$45,500</b>	<b>\$27,309</b>
<b>Total Europe</b>	<b>\$2,065</b>	<b>\$2,101</b>	<b>\$5,934</b>	<b>\$6,061</b>
<b>Total Rest of the World</b>	<b>\$637</b>	<b>\$861</b>	<b>\$1,626</b>	<b>\$2,451</b>
<b>Total</b>	<b>\$21,184</b>	<b>\$12,191</b>	<b>\$53,060</b>	<b>\$35,821</b>

\*2017 comparative revenue information is presented based on the new organizational structure implemented in the third quarter of 2018.

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

	September	
	30, 2018	December 31, 2017
<b>Long-lived assets:</b>		
United States	\$ 2,168	\$ 1,206
Europe	690	776
Rest of the World	164	93
<b>Total</b>	<b>\$ 3,022</b>	<b>\$ 2,075</b>



## 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, 2017, filed with the Securities and Exchange Commission, or the SEC, on March 22, 2018.

### 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, AlloSure and future testing services, if any, and our ability to increase the commercial success of these testing services;
- our ability to generate revenue from sales of Olerup SSP, Olerup SBT, Olerup QTYPE, TruSight HLA, and future products, if any, and our ability to increase the commercial success of these products;
- our ability to generate revenue from the license and commercialization agreement with Illumina, Inc.;
- our plans and ability to develop and commercialize new solutions for the surveillance of heart, kidney, and other solid organ transplant recipients; our plans and ability to continue updating our products, services and technology to maintain our leading position in the surveillance market for solid organ transplants;
- our plans and ability to continue updating our sequence specific primer products and technology to maintain our leading position in the SSP market;
- our plans and ability to develop, commercialize, and/or distribute new gene expression, qPCR, cell free DNA and Next Generation Sequencing technology applications for transplantation;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our ability to remain eligible to use Registration Statements on Form S-3 for capital-raising transactions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for AlloMap, AlloSure and other future testing services, if any;
- the outcome or success of our clinical trial collaborations and registry 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 testing services and product 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 equity financing agreements and 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;

our ability to retain key members of our management team;

33

---



- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to successfully defend against or settle any litigation brought against us or other legal matters or disputes;
- our ability to expand internationally; 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 us 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 Highlights

We are a global transplant diagnostics company with product and service 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.

## Testing Services

### AlloMap

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. In 2008, AlloMap 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.

AlloMap has received positive coverage decisions for reimbursement from Medicare. The 2018 reimbursement rate for AlloMap is \$3,240, which represents a 14% increase over the 2017 reimbursement rate. AlloMap has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation (HCSC), Humana, Kaiser Foundation Health Plan, Inc., and TRICARE.

We have also successfully completed a number of landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap on the basis of our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am J Transplantation 2006), or CARGO, study, which was published in the American Journal of Transplantation. A subsequent clinical utility trial, Invasive Monitoring

Attenuation through Gene Expression (Pham MX et al., N. Eng. J. Med., 2010), or IMAGE, published in The New England Journal of Medicine, demonstrated that clinical outcomes in recipients managed with AlloMap surveillance were equivalent (non-inferior) to outcomes in recipients managed with biopsies. The results of our clinical trials have also been presented at major medical society congresses.

During the first nine months of 2018, there were 12,059 AlloMap patient test results provided to 131 of the approximately 137 heart transplant management centers in the United States.

#### AlloSure

AlloSure, our recently launched commercial transplant surveillance solution, applies proprietary next generation sequencing technology to measure donor-derived cell free DNA, or dd-cfDNA in the blood stream emanating from the donor kidney or heart. We believe AlloSure may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted heart, kidney and other solid organs, irrespective of the type of organ transplanted. We also believe the use of AlloSure, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, we believe AlloSure can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants. Effective October 9, 2017, AlloSure became available for commercial testing with Medicare coverage and reimbursement. The Medicare reimbursement rate for AlloSure is \$2,841. AlloSure has also received payment from private payers on a case-by-case basis, but no positive coverage decisions have been made.

Prior to the commercialization of AlloSure, we generated a strong body of clinical evidence. In late 2015, we announced the completion of analytical validation of AlloSure. A report describing the analytical validation of AlloSure including clinical validation detailing the quality, reality, and consistency of analytical results information for heart transplant, appeared in the November 2016 issue of The Journal of Molecular Diagnostics. The Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial, sponsored by us, was conducted between April 2015 and January 2018. DART is a 14 center 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. By the time of completion of the first analysis, 384 patients were followed in DART for up to 24 months. The results demonstrated that increased levels of dd-cfDNA, determined by the AlloSure assay, discriminated active rejection of a kidney transplant more effectively than serum creatinine values. In collaboration with clinical investigators, we published these findings in the scientific peer-reviewed Journal of the American Society of Nephrology and the Journal Applied Laboratory Medicine in March 2017. A total of 2,109 patient visits had been accrued in DART by January 2018; we plan to analyze and report on additional findings from this dataset in 2018 and into the future.

In 2018, we initiated the Kidney Allograft Outcomes AlloSure Registry, or K-OAR study, to develop further data on the clinical utility of AlloSure for surveillance of kidney transplant recipients. As of September 30, 2018, 40 centers have been initiated as K-OAR study sites.

During the first nine months of 2018, there were 7,059 AlloSure patient test results provided. Since launch, AlloSure has been ordered by 96 kidney transplant centers in the United States.

#### HeartCare

In September, 2018, we initiated the Surveillance HeartCare® Outcomes Registry (“SHORE”). SHORE is a prospective, multi-center, observational, registry of patients receiving HeartCare for surveillance.

HeartCare combines the gene expression profiling technology of AlloMap with the dd-cfDNA analysis of AlloSure-Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap – a measure of immune activity, and (ii) AlloSure-Heart® – monitors graft injury. HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection (“ACR”) and Antibody Mediated Rejection (“AMR”).

#### Products

We 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® is used to type Human Leukocyte Antigen, or HLA alleles, based on the sequence specific primer, or SSP technology. Olerup SBT™ is a complete product range for sequence-based typing of HLA alleles. Olerup QTYPE enables speed and precision in HLA typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time polymerase chain reaction, or PCR, methodology. QTYPE received CE mark certification on April 10, 2018.

On May 4, 2018, we entered into a License and Commercialization Agreement (the “License Agreement”) with Illumina, Inc. (“Illumina”), which provides us with worldwide distribution, development and commercialization rights to Illumina’s next generation sequencing (“NGS”) product line for use in transplantation diagnostic testing.

As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina’s TruSight HLA product line. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines for use in the field of bone marrow and solid organ transplantation diagnostic testing.

## Recent Highlights

### Continued the acceleration of AlloSure penetration

- In the twelve months since launch, 96 U.S. transplant centers have provided AlloSure testing to over 4,000 patients, representing approximately 2% of all U.S. living kidney transplant patients. The number of standing order patients has increased to 2,736, cumulatively

- Continued progress in AlloSure Registry (K-OAR) enrollment, with 40 centers initiated and 480 patients enrolled as of September 30, 2018

- Achieved total revenue of \$21.2 million for the third quarter of 2018, increasing 74% year-over-year

- Testing services revenue of \$16.8 million, with 3,708 AlloSure and 4,080 AlloMap patient results provided

- Product revenue of \$4.2 million

### Broadened testing services and product offerings

- Launched the Surveillance HeartCare® Outcomes Registry (SHORE) during the 22nd Annual Scientific Meeting of the Heart Failure Society of America (HFSA)

- Profiled the new AlloSeq suite of next generation sequencing based transplant laboratory products, to be launched in 2019, at the American Society of Histocompatibility and Immunogenetics (ASHI)

## Financial Operations Overview

### Revenue

We derive our revenue from testing services, products sales and license and other revenues. On January 1, 2018, we adopted the new revenue accounting standard Revenue from Contracts with Customers (Topic 606), or ASC 606, using the modified retrospective method. The adoption of ASC 606 resulted in a one-time adjustment of \$2.9 million to accounts receivable and retained earnings. This adjustment reflects the estimated payments to be received for tests where the result had been delivered at December 31, 2017, but the associated revenue had not been recognized by December 31, 2017, because payment had not been received. Under the new accounting standard, revenue is recorded considering a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation. As of September 30, 2018, we had received payments of \$3.2 million for tests where the results had been delivered at December 31, 2017, but associated revenue had not been recognized by December 31, 2017. Payments received in excess of the \$2.9 million accounts receivable adjustment recorded on January 1, 2018 were recognized in testing services revenue in the period of collection.

### Testing Services Revenue

Our testing revenue is derived from AlloMap and AlloSure tests, which represented 80% and 78% of our total revenues for the three and nine months ended September 30, 2018, respectively, and 67% and 68% of our total revenues for the three and nine months ended September 30, 2017, respectively. We currently market AlloMap and

AlloSure in the U.S. 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. Amounts received by us vary from payer to payer based on each payer's internal coverage practices and policies. We generally bill third-party payers upon delivery of an AlloMap or AlloSure test result report to the healthcare provider. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

#### Product Revenue

Our product revenue is derived primarily from sales of Olerup and TruSight branded products. Product revenue represented 20% and 21% of total revenue for the three and nine months ended September 30, 2018, respectively, and 32% and 30% of total revenue for the

three and nine months ended September 30, 2017, respectively. Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied, which is generally upon the product shipment.

#### License and Other Revenue

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 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. We make judgments that affect the periods over which we recognize revenue. We review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated revenues.

We did not recognize any revenue connected with milestones during the three or nine months ended September 30, 2018 or 2017.

#### Cost of Testing Services

Cost of testing services reflects the aggregate costs incurred in delivering our testing services. The components of cost of testing services are materials and service costs, direct labor costs, stock-based compensation expense, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Prior to adoption of the new revenue guidance, we recorded cost of testing services associated with performing tests (except royalties) in the period when tests were performed without consideration of whether revenue was recognized in the same period. With the adoption of the new revenue standard on January 1, 2018, revenue and cost of testing services for tests performed are recognized in the same period. Royalties for licensed technology, calculated as a percentage of testing services revenues, are recorded as license fees in cost of testing at the time the testing services revenues are recognized.

#### 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, including clinical operations, represent costs incurred to develop diagnostic products and services, high quality evidence to support use of our tests, as well as continued efforts related to improving our existing product and service lines. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, clinical studies 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.

### Sales and Marketing Expenses

Sales and marketing expenses represent costs incurred to sell, promote and increase awareness of our existing products and services to transplant centers and hospital laboratories. 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 bonuses based on the achievement of predetermined sales goals or other management objectives.

### General and Administrative Expenses

General and administrative expenses include costs for our executive, finance, accounting and human resources functions. Costs consist primarily of payroll and related expenses, professional service fees related to audit and accounting, certain financing transaction expenses, and legal and other contract and administrative services. We will continue to incur expenses as a result of operating as a public company.

### Goodwill Impairment

We test goodwill and indefinite-lived intangibles for impairment at least annually and more frequently if impairment indicators are present. In the three months ended March 31, 2017, we determined that the decrease in our market capitalization constituted an



indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. We identified an impairment of \$2.0 million related to goodwill.

No goodwill impairment indicators were present in the three or nine months ended September 30, 2018 and therefore no impairment was recorded.

#### Change in Estimated Fair Value of Contingent Consideration

We revalue our contingent consideration obligation liability in connection with our acquisition of IMX in 2014 at 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. We achieved the contingent consideration obligation milestone of 2,500 commercial tests and issued 227,845 shares in the three month period ended June 30, 2018. There is no contingent consideration outstanding as of September 30, 2018.

#### Interest Expense

Interest expense is associated with borrowings under our loan agreements and also includes debt discount amortization.

#### Other Expense

Other expense includes gains and losses on foreign currency transactions, on debt extinguishment, and other miscellaneous expenses. During the nine months ended September 30, 2018, we recorded \$2.8 million loss on the conversion of the JGB Debt as the difference between the value of the shares of common stock issued on the days of conversion and the amount of principal debt converted on those days, net of the allocated debt discount and derivative liability balances.

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

Common stock warrants issued in connection with our debt and equity financings are considered freestanding financial instruments and are analyzed as to whether they meet equity or liability classification in accordance with United States generally accepted accounting principles, or US GAAP. Warrants that meet liability classification are re-measured at each period end with changes in fair value recorded in our condensed consolidated statements of operations until these warrants are exercised or expire. On January 1, 2018, we adopted Accounting Standards Update No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception and this resulted in the liability balance for our warrants issued to JGB being reclassified to equity on the date of adoption.

The JGB Debt included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The embedded derivative was remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the condensed consolidated statements of operations. As of March 27, 2018, the JGB Debt had fully converted to shares of our common stock. On April 17, 2018, we entered into a credit agreement with perceptive Credit Holdings II, LP, or Perceptive, for an initial term loan of \$15.0 million, or the Perceptive Credit Agreement, which included an embedded derivative that required bifurcation related to early repayment provision. We record changes in the fair value of the derivative liabilities in the change in estimated value of common stock warrant liability and derivative liability in our condensed consolidated statements of 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 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.

Our significant accounting policies are described in Note 2 of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. We believe that the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our

financial statements. We believe the following critical accounting policies are affected by significant judgments and estimates used in the preparation of our Condensed Consolidated Financial Statements:

- Revenue recognition – estimation of variable consideration
- Determination of the accruals for clinical studies,
- Inventory valuation
- Valuation of common stock warrant liability
- Valuation of embedded derivative liability
- Valuation and impairment of goodwill, intangible assets and other long-lived assets;
- Goodwill and acquired intangible assets
- Share-based compensation; and
- Accounting for income taxes.

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our Condensed Consolidated Financial Statements during the three and nine months ended September 30, 2018 as compared to those disclosed in Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our annual report on Form 10-K for the year ended December 31, 2017, except as discussed in Note 2, Summary of Significant Accounting Policies, to the Condensed Consolidated Financial Statements in this quarterly report.

#### Recently Issued Accounting Standards

Refer to Note 2, Summary of Significant Accounting Policies - Recent Accounting Pronouncements, of the Notes to Condensed Consolidated Financial Statements in this quarterly report for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position and cash flows.

#### Results of Operations

##### Comparison of the Three Months Ended September 30, 2018 and 2017

(In thousands)

	Three Months Ended September 30,		
	2018	2017	Change
<b>Revenue:</b>			
Testing services revenue	\$16,847	\$8,163	\$8,684
Product revenue	4,223	3,872	351
License and other revenue	114	156	(42 )
Total revenue	21,184	12,191	8,993
<b>Operating expenses:</b>			
Cost of testing services	5,752	3,156	2,596
Cost of product	3,135	2,053	1,082
Research and development	3,868	2,959	909
Sales and marketing	5,971	3,255	2,716
General and administrative	5,177	4,038	1,139

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

Change in estimated fair value of contingent consideration	-	594	(594 )
Total operating expenses	23,903	16,055	7,848
Loss from operations	(2,719 )	(3,864 )	1,145
Interest expense	(408 )	(1,685 )	1,277
Other expense, net	(40 )	(317 )	277
Change in estimated fair value of common stock warrant liability and derivative liability	(17,093)	(8,599 )	(8,494)
Income tax benefit	290	178	112
Net loss	(19,970)	(14,287)	(5,683)
Net loss attributable to noncontrolling interest	—	(19 )	19
Net loss attributable to CareDx, Inc.	\$(19,970)	\$(14,268)	\$(5,702)

39

### Testing Services Revenue

Testing services revenue increased by \$8.7 million, or 106%, for the three months ended September 30, 2018 as compared to the same period in 2017. This increase is mainly due to the 3,708 AlloSure test results provided in the three months ended September 30, 2018, following the launch of AlloSure in October 2017. Additionally, AlloMap test results increased to 4,080 in the three months ended September 30, 2018, compared to 3,864 in the same period in 2017, and the Medicare reimbursement rate for AlloMap increased from \$2,841 to \$3,240 on January 1, 2018. Furthermore, in the three months ended September 30, 2018, we recognized \$0.3 million testing services revenue related to payments received in excess of the \$2.9 million accounts receivable adjustment recorded on January 1, 2018 upon adoption of ASC 606.

As described in Note 2 of the Condensed Consolidated Financial Statements, the adoption of ASC 606 on January 1, 2018, had a \$0.3 million favorable impact on Testing Revenue for the three months ended September 30, 2018, compared to the revenue under the previous methodology prescribed by ASC Topic 605, "Revenue Recognition", for the same period.

### Product Revenue

Product revenue increased by \$0.4 million, or 9%, for the three months ended September 30, 2018, compared to the same period in 2017. The increase was due to sales of the TruSight HLA products related to the License Agreement with Illumina, which was signed in May 2018, and increased sales of Olerup QTYPE, partially offset by decreased sales of Olerup SSP and Olerup SBT products.

### License and Other Revenue

License, and other revenue decreased by less than \$0.1 million for the three months ended September 30, 2018, compared to the same period in 2017.

### Cost of Testing Services

Cost of testing services increased by approximately \$2.6 million, or 82%, for the three months ended September 30, 2018, compared to the same period in 2017, primarily due to test results provided for AlloSure, which was launched in October 2017, and the increase in AlloMap test results compared to the same period in 2017.

### Cost of Product

Cost of product increased by \$1.1 million, or 53%, for the three months ended September 30, 2018, compared to the same period in 2017, primarily due to a change in the mix of products sold. The addition of sales of TruSight HLA products, which are purchased directly from Illumina, and the reduction in sales of Olerup SBT and Olerup SSP, which are manufactured internally, led to an increase of \$0.6 million. Furthermore, in the three months ended September 30, 2018, the total cost of product manufactured internally increased by \$0.2 million due to higher personnel costs and by \$0.2 million due to an increase in the obsolescence provision.

### Research and Development

Research and development expenses increased by \$0.9 million, or 31%, for the three months ended September 30, 2018, compared to the same period in 2017, due to an increase in stock-based compensation expense of \$0.6 million and an increase in clinical trial expenses of \$0.2 million.

### Sales and Marketing

Sales and marketing expenses increased by approximately \$2.7 million, or 83%, for the three months ended September 30, 2018, compared to the same period in 2017, primarily due to higher personnel related costs of \$1.0 million, higher conference fees and travel costs associated with several key transplant industry events of \$1.0 million, increased stock-based compensation expense of \$0.2 million, and an increase in consulting fees of \$0.2 million.

### General and Administrative

General and administrative expenses increased by \$1.1 million, or 28%, for the three months ended September 30, 2018, compared to the same period in 2017. This increase was primarily due to an increase of \$0.7 million in personnel related expenses, increased stock-based compensation of \$0.5 million, partially offset by lower consulting, legal and professional fees of \$0.2 million.

### Change in Estimated Fair Value of Contingent Consideration

In accordance with the IMX acquisition agreement, we estimated the contingent consideration liability fair value at each period end based on our common stock price at the end of the period and a probability of meeting the contractual milestone related to the number

of commercial AlloSure tests performed by June 2020. The contingent consideration liability was settled in the three months ended June 30, 2018, with the achievement of the contractual milestone of 2,500 commercial AlloSure tests. Changes in the fair value of the contingent liability were nil and \$0.6 million expense for the three months ended September 30, 2018 and 2017, respectively. The \$0.6 million expense reflected an increase in our share price in the three months ended September 30, 2017 and an increase in our estimate of the probability of meeting the milestone under our business combination agreement with IMX.

#### Interest Expense

Interest expense decreased by \$1.3 million for the three months ended September 30, 2018, compared to the same period in 2017. The interest expense of \$0.4 million in the three months ended September 30, 2018, primarily consisted of interest expense and debt amortization recorded in relation to the Perceptive Credit Agreement entered into on April 17, 2018.

The interest expense of \$1.7 million in the three months ended September 30, 2017, consisted of \$1.3 million of interest expense and debt discount amortization related to the JGB Debt, \$0.1 million of interest expense recorded in relation to deferred purchase consideration owed to the former shareholders of Allenex and \$0.2 million in interest expense recorded in relation to the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan.

The JGB Debt was entered into on March 15, 2017 and during the three months ended March 31, 2018 was converted into shares of our common stock. The deferred purchase consideration was related to the acquisition of Allenex and was settled in November 2017. The SSP Primers Loan was repaid in February 2018 and the Allenex Notes and Danske Bank Term Loan were repaid in April 2018.

#### Other Expense, Net

Other expense decreased by \$0.3 million in the three months ended September 30, 2018 compared to the same period in 2017. Other expense was less than \$0.1 million in the three months ended September 30, 2018. For the three months ended September 30, 2017, other expense primarily consisted of foreign exchange losses of \$0.3 million.

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

The change in estimated fair value of common stock warrant liability and derivative liability was \$17.1 million expense in the three months ended September 30, 2018 and \$8.6 million expense in the comparative period in 2017.

The \$17.1 million expense in the three months ended September 30, 2018 consisted of changes in liabilities for warrants exercised during the period and a charge for warrants that remained outstanding at September 30, 2018. In the three months ended September 30, 2018, approximately 1.2 million warrants with an average exercise price of \$3.54 per share and a June 30, 2018 estimated fair market value of \$10.14 per share were exercised. The average price of our common stock at exercise was \$22.27 per share, resulting in a charge of \$10.2 million. The remaining 0.4 million warrants classified as common stock warrant liability at September 30, 2018 were revalued, resulting in a remeasurement charge of \$6.9 million.

The \$8.6 million expense in the three months ended September 30, 2017, consisted of a remeasurement charge of \$8.2 million related to the changes in fair value of common stock warrant liability and a \$0.4 million charge for the change in fair value of the JGB embedded derivative. The \$8.2 million expense related to our common stock warrant liability was due to (i) changes in the valuation of warrants due to the change in the share price of our common stock during the period, (ii) the adjustment in the exercise price of the warrants issued in connection with a private placement transaction completed on April 14, 2016 from \$4.00 and \$3.99 per share, respectively, to \$1.12 per share, effective

July 3, 2017, as a result of the issuance of 1,022,544 shares at a price of \$1.12 pursuant to amendments to the Conditional Share Purchase Agreements we entered into with each of Midroc Invest AB, FastPartner AB, and Xenella Holding AB, the former majority shareholders of Allenex, in connection with the acquisition of Allenex, or the Conditional Share Purchase Agreements, and (iii) adjustments to the quantity and exercise price of the common stock warrants issued in connection with the JGB Debt as a result of the issuance of 1,022,544 shares at a price of \$1.12 pursuant to the amendments to the Conditional Share Purchase Agreements.

As of January 1, 2018, we adopted the new accounting standard and reclassified the outstanding common stock warrant issued in connection with the JGB Debt to equity. This warrant was not re-measured through earnings after January 1, 2018. The common stock warrant issued in connection with the JGB Debt was exercised in August 2018. The Perceptive Tranche A Warrant, issued on April 17, 2018, by us in accordance with the Perceptive Credit Agreement, was also classified as equity and excluded from quarterly remeasurement. Warrants issued in connection with a private placement transaction completed on April 14, 2016, continue to be classified as liability and will be re-measured at the end of each reporting period until expired or exercised. Changes in the common stock fair value, estimated volatility and expected contractual term will significantly impact the fair value of the warrant liability.

#### Income Tax Benefit



For the three months ended September 30, 2018, we recorded an income tax benefit of \$0.3 million on a loss before income taxes of \$20.3 million. This benefit primarily resulted from the expectation that amortization of the various intangible assets acquired, when completed and placed in service, is not expected to be deductible for tax purposes. Accordingly, a deferred tax liability was recorded at the acquisition date for the difference between the financial reporting and tax basis of the intangibles. The effective tax rate for the nine months ended September 30, 2018 differs from the federal statutory tax rate as a result of the income tax expense and benefit related to the earnings taxed in foreign jurisdictions and the amortization of the acquired intangibles.

#### Comparison of the Nine Months Ended September 30, 2018 and 2017

(In thousands)

	Nine Months Ended September 30,		
	2018	2017	Change
<b>Revenue:</b>			
Testing services revenue	\$41,448	\$24,485	\$16,963
Product revenue	11,080	10,916	164
License and other revenue	532	420	112
<b>Total revenue</b>	<b>53,060</b>	<b>35,821</b>	<b>17,239</b>
<b>Operating expenses:</b>			
Cost of testing services	14,432	9,224	5,208
Cost of product	8,046	6,558	1,488
Research and development	10,732	9,360	1,372
Sales and marketing	15,916	9,747	6,169
General and administrative	16,080	14,672	1,408
Goodwill Impairment	—	1,958	(1,958 )
Change in estimated fair value of contingent consideration	1,017	309	708
<b>Total operating expenses</b>	<b>66,223</b>	<b>51,828</b>	<b>14,395</b>
<b>Loss from operations</b>	<b>(13,163)</b>	<b>(16,007)</b>	<b>2,844</b>
Interest expense	(3,527 )	(4,166 )	639
Other expense, net	(2,891 )	(1,191 )	(1,700 )
Change in estimated fair value of common stock warrant liability and derivative liability	(24,540)	(3,404 )	(21,136)
Income tax benefit	1,095	837	258
<b>Net loss</b>	<b>(43,026)</b>	<b>(23,931)</b>	<b>(19,095)</b>
Net loss attributable to noncontrolling interest	(25 )	(133 )	108
Net loss attributable to CareDx, Inc.	\$(43,001)	\$(23,798)	\$(19,203)
Testing Services Revenue			

Testing services revenue increased by \$17.0 million, or 69%, for the nine months ended September 30, 2018, compared to the same period in 2017. This increase is mainly due to the 7,059 AlloSure test results provided in the nine months ended September 30, 2018, following the launch of AlloSure in October 2017. Additionally, AlloMap test results increased to 12,059 in the nine months ended September 30, 2018, compared to 11,475 in the same period in 2017, and the Medicare reimbursement rate for AlloMap increased from \$2,841 to \$3,240 on January 1, 2018. Furthermore, in the nine months ended September 30, 2018, we recognized \$0.3 million testing services revenue related to payments received in excess of the \$2.9 million accounts receivable adjustment recorded on January 1, 2018 upon adoption of ASC 606.

As described in Note 2 of the Condensed Consolidated Financial Statements, the adoption of ASC 606 on January 1, 2018, had a \$0.8 million favorable impact on Testing Revenue for the nine months ended September 30, 2018, compared to the revenue under the previous methodology prescribed by ASC Topic 605, "Revenue Recognition", for the same period.

#### Product Revenue

Product revenue increased by \$0.2 million, or 2%, for the nine months ended September 30, 2018, compared to the same period in 2017. The increase was due to sales of the TruSight HLA products related to the License Agreement with Illumina, which was signed in May 2018, and increased sales of Olerup QTYPE, partially offset by a decrease in sales of Olerup SSP and Olerup SBT products.

#### License and Other Revenue

License and other revenue increased by \$0.1 million for the nine months ended September 30, 2018, which is primarily due to revenue earned from Illumina under our the License Agreement.

#### Cost of Testing

Cost of testing increased by approximately \$5.2 million, or 56%, for the nine months ended September 30, 2018, compared to the same period in 2017, primarily due to the test results provided for AlloSure, which was launched in October 2017.

#### Cost of Product

Cost of product increased by \$1.5 million, or 23%, for the nine months ended September 30, 2018, compared to the same period in 2017, primarily due to a change in the mix of products sold and increase in obsolescence provision. The addition of sales of TruSight HLA products, which are purchased directly from Illumina, and the reduction in sales of Olerup SBT and Olerup SSP, which are manufactured internally, led to an increase of \$0.6 million. Furthermore, in the nine months ended September 30, 2018, the total cost of product manufactured internally increased by \$0.2 million due to higher personnel costs and by \$0.6 million due to an increase in the obsolescence provision.

#### Research and Development

Research and development expenses increased by \$1.4 million, or 15%, for the nine months ended September 30, 2018, compared to the same period in 2017. This increase reflects an increase of \$1.1 million in stock-based compensation expense and an increase of \$0.5 million in clinical trial costs, partially offset by lower personnel costs of \$0.3 million.

#### Sales and Marketing

Sales and marketing expenses increased by approximately \$6.2 million, or 63%, for the nine months ended September 30, 2018, compared to the same period in 2017, primarily due to an increase in personnel related expenses of \$2.5 million, higher conference fees and travel costs of \$2.1 million associated with several key transplant industry events, increased stock-based compensation expenses of \$0.6 million, higher facilities and software related costs of \$0.7 million and higher consulting fees of \$0.2 million.

#### General and Administrative

General and administrative expenses increased by \$1.4 million, or 10%, for the nine months ended September 30, 2018, compared to the same period in 2017. This increase primarily reflects an increase of \$1.8 million in stock-based compensation expense and an increase of \$1.0 million in personnel related expenses, partially offset by a decrease in consulting and professional fees of \$1.4 million.

#### Goodwill Impairment

In the three months ended March 31, 2017, we determined that the decrease in our market capitalization constituted an indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. We recorded a goodwill impairment charge of \$2.0 million and wrote off the remaining goodwill in the Post-Transplant reporting unit as of March 31, 2017. No impairment was identified in the nine months ended September 30, 2018.

### Change in Estimated Fair Value of Contingent Consideration

In accordance with the IMX acquisition agreement, we estimated the contingent consideration liability fair value at each period end based on our common stock price at the end of the period and a probability of meeting the contractual milestone related to the number of commercial tests performed by June 2020. The contingent consideration liability was settled in the six months ended June 30, 2018, with the achievement of the contractual milestone of 2,500 commercial AlloSure tests. Changes in fair value of the contingent liability were \$1.0 million expense compared to \$0.3 million expense for the nine months ended September 30, 2018 and 2017 respectively. The \$1.0 million expense reflected an increase in our share price from January 1, 2018 to the date of the issuance of the 227,845 shares and the settlement of the liability. The \$0.3 million expense reflected an increase in our share price in the nine months ended September 30, 2017 and an increase in our estimate of the probability of meeting the milestone under our business combination agreement with IMX.

### Interest Expense

Interest expense decreased by \$0.6 million for the nine months ended September 30, 2018, compared to the same period in 2017.

The interest expense of \$3.5 million in the nine months ended September 30, 2018, consisted of \$2.4 million of interest expense and debt discount amortization related to the JGB Debt, \$0.9 million of interest expense and debt amortization recorded in relation to the

Perceptive Credit Agreement entered into on April 17, 2018 and \$0.2 million of interest expense recorded in relation to the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan.

The interest expense of \$4.2 million in the nine months ended September 30, 2017, consisted of \$2.8 million of interest expense and debt discount amortization related to the JGB Debt, \$0.5 million of interest expense recorded in relation to deferred purchase consideration owed to the former shareholders of Allenex, \$0.6 million in interest expense recorded on the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan and \$0.1 million of interest expense recorded on the East West Bank Debt.

The JGB Debt was entered into on March 15, 2017 and during the three months ended March 31, 2018 was converted into shares of our common stock. The deferred purchase consideration was related to the acquisition of Allenex and was settled in November 2017. The SSP Primers Loan was repaid in February 2018 and the Allenex Notes and Danske Bank Term Loan were repaid in April 2018. The outstanding indebtedness under the loan agreement with East West Bank was repaid in March 2017.

#### Other Expense, Net

Other expense increased by \$1.7 million in the nine months ended September 30, 2018 compared to the same period in 2017. In the nine months ended September 30, 2018, the other expense charge primarily consisted of a loss of \$2.8 million for the conversion of the JGB Debt in the three months ended March 31, 2018. In the nine months ended September 30, 2017, the other expense charge consisted of a foreign exchange loss of \$0.8 million, \$0.3 million loss on early extinguishment of existing indebtedness under the Loan Agreement with East West Bank and a \$0.1 million transaction settlement fee.

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

The change in estimated fair value of common stock warrant liability and derivative liability was \$24.5 million expense in the nine months ended September 30, 2018 and \$3.4 million expense in the comparative period in 2017.

The \$24.5 million expense in the nine months ended September 30, 2018, consisted of a remeasurement charge of \$27.1 million related to the changes in fair value of common stock warrant liability, partially offset by a \$2.6 million gain recorded for the changes in fair value of the JGB Debt embedded derivative between January 1, 2018 and the conversion date of March 27, 2018.

The \$27.1 million remeasurement charge in the nine months ended September 30, 2018 related to changes in the fair value of common stock warrant liability and consisted of a charge for warrants exercised during the period and for warrants that remained outstanding at September 30, 2018. In the nine months ended September 30, 2018, approximately 1.7 million warrants with an average exercise price of \$2.86 per share and a December 31, 2017 fair market value of \$5.70 per share were exercised. The average price of our common stock on the days of exercise was \$19.53 per share, resulting in a charge of \$18.2 million. The remaining 0.4 million warrants classified as common stock warrant liability at September 30, 2018 were revalued, resulting in a remeasurement charge of \$8.9 million.

In the nine months ended September 30, 2017, the \$3.4 million charge reflected \$4.3 million expense related to our common stock warrant liability and \$0.9 million income related to our derivative liability. The \$4.3 million expense was primarily caused by the effect of the increase in our stock price on the mark-to-market valuations. The JGB Debt included certain embedded derivatives that required bifurcation. The value of these derivatives declined \$0.9 million from the initial valuation on March 15, 2017 to September 30, 2017.

As of January 1, 2018, we adopted the new accounting standard and reclassified the outstanding common stock warrant issued in connection with the JGB Debt to equity. This warrant was not re-measured through earnings after January 1, 2018. This common stock warrant issued in connection with the JGB Debt was exercised in August 2018. The Perceptive Tranche A Warrant, issued on April 17, 2018, by us in accordance with the Perceptive Credit Agreement, was also classified as equity and excluded from quarterly remeasurement. Warrants issued in connection with a Private Placement transaction completed on April 14, 2016, continue to be classified as liability and will be re-measured at the end of each reporting period until expired or exercised. Changes in the common stock fair value, estimated volatility and expected contractual term will significantly impact the fair value of the warrant liability.

#### Income Tax Benefit

For the nine months ended September 30, 2018, we recorded an income tax benefit of \$1.1 million on a loss before income taxes of \$44.1 million. This benefit primarily resulted from the expectation that amortization of the various intangible assets acquired, when completed and placed in service, is not expected to be deductible for tax purposes. Accordingly, a deferred tax liability was recorded at the acquisition date for the difference between the financial reporting and tax basis of the intangibles. The effective tax rate for the nine months ended September 30, 2018 differs from the federal statutory tax rate as a result of the income tax expense and benefit related to the earnings taxed in foreign jurisdictions and the amortization of the acquired intangibles.

## Cash Flows for the Nine Months Ended September 30, 2018 and 2017

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

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(6,005 )	\$(12,157 )
Investing activities	(6,969 )	(1,069 )
Financing activities	12,956	11,459
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(62 )	(104 )
Net decrease in cash, cash equivalents and restricted cash	\$(80 )	\$(1,871 )

## Operating Activities

Net cash used in operating activities consists of net loss, adjusted for certain noncash items in the statement of operations and changes in operating assets and liabilities. Cash used in operating activities for the nine months ended September 30, 2018 was \$6.0 million. Our net loss of \$43.0 million was our primary use of cash in operating activities and included a number of noncash items. Our noncash items included a \$24.5 million loss on the revaluation of common stock warrant and derivative liabilities to estimated fair value, a \$5.1 million stock-based compensation expense, \$3.0 million of depreciation and amortization expense, \$2.8 million loss on the conversion of debt to shares of our common stock, \$2.2 million amortization expense related to the JGB Debt discount, \$1.0 million contingent consideration revaluation expense and \$0.2 million of amortization expense of inventory on fair market value adjustment. Net operating assets decreased by \$1.8 million.

Cash used in operating activities for the nine months ended September 30, 2017 was \$12.2 million. Our net loss of \$24.0 million was our primary use of cash in operating activities; which also included a number of noncash items. Our noncash items included a \$3.4 million loss on revaluation of warrants and derivative liabilities to estimated fair value, a \$2.0 million of goodwill impairment related to our purchase of Allenex, \$2.7 million of depreciation and amortization, \$2.8 million of amortization of debt discount and noncash interest expense, \$1.3 million of stock-based compensation expense, \$0.3 million contingent consideration revaluation expense and \$0.3 million of amortization expense of inventory on fair market value adjustment. Net operating assets decreased \$1.0 million.

## Investing Activities

For the nine months ended September 30, 2018, net cash used in investing activities was \$7.0 million and consisted of \$5.2 million related to the acquisition of intangible assets per the Illumina License Agreement, \$1.1 million for purchases of property and equipment and \$0.7 million for the acquisition of the Allenex minority interest.

For the nine months ended September 30, 2017, net cash used in investing activities was \$1.1 million, and consisted of \$0.5 million for the acquisition of Allenex, \$0.5 million for the acquisition of the Conexio business assets and \$0.1 million purchases of property and equipment.

#### Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2018 of \$13.0 million was primarily related to the \$14.3 million net proceeds from the Perceptive Credit Agreement, cash proceeds of \$11.0 million from the exercise of warrants, and \$0.6 million cash proceeds from the exercise of stock options, partially offset by \$11.4 million of principal payments of the promissory notes issued to FastPartner AB and Mohammed Al Amoudi, Danske Term Loan, and the SSP Primers Loan, \$0.7 million of repurchase of common stock under employee incentive plans, \$0.7 million repayment of the Danske Credit Facility, and \$0.2 million of acquisition of Conexio Genomics Pty Ltd.

Net cash provided by financing activities for the nine months ended September 30, 2017 of \$11.5 million consisted primarily of \$24.0 million in net proceeds received from the JGB Debt agreement in March 2017 and a \$0.6 million increase in the Danske Credit Facility, partially offset by \$13.3 million of principal payments on debt and capital lease obligations.



## Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$308.1 million at September 30, 2018. As of September 30, 2018, we had cash and cash equivalents of \$26.2 million, and \$13.4 million of debt, net of debt discount, outstanding under our long-term debt obligations.

We may require additional financing in the future to fund working capital and pay our obligations as they come due. Additional financing might include one or more common stock offerings, debt, cash from collaboration agreements or a combination of these. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. We believe our existing cash balance and expected revenues will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

## Perceptive Credit Agreement

On April 17, 2018, we entered into a credit agreement with Perceptive for a term loan of \$15.0 million and repaid the outstanding indebtedness under the Allenex Notes, and the Danske Term Loan and Credit Facility. A second tranche of \$10.0 million will be available at our option subject to the satisfaction of customary conditions.

## Allenex Notes, Danske Term Loan and Danske Credit Facility

All outstanding amounts under the Allenex Notes of \$4.4 million and Danske Term Loan and Credit Facility of \$6.7 million were repaid on April 17, 2018.

## JGB Debt

On March 1, 2018, we notified JGB of our intent to prepay on April 13, 2018, in full the outstanding principal and interest under the JGB Debentures. During the three months ended, March 31, 2018, JGB converted all outstanding \$26.7 million of principal and accrued interest of the JGB Debt into an aggregate of 6,161,331 shares of our common stock. Restricted cash of \$9.4 million was released from any restrictions after the conversion and included in our cash and cash equivalent balance as of March 31, 2018.

## Factors Affecting Our Performance

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

The growth of our testing services revenue is tied to the number of AlloMap and AlloSure tests we receive and report. Historically, less than two percent of AlloMap 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 test report. As a result, the number of samples received largely correlates directly to the number of test reports.

### The Number of Diagnostic Products We Sell

The growth of our product revenues is tied to the sales of the Olerup SSP, Olerup QTYPE, Olerup SBT and TruSight HLA product lines. The product sales organizations are located in Stockholm, Sweden; Vienna, Austria; Fremantle, Australia and West Chester, Pennsylvania. Products are sold directly to customers in 14 countries. We also use distributors to sell products in approximately 60 countries.

### 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 healthcare providers.

On June 10, 2016, Centers for Medicare & Medicaid Services, or CMS, announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the gapfill reimbursement rate for 2017, AlloMap reimbursement for patients covered by Medicare would have been reduced from \$2,821 to \$1,921, effective January 1, 2017. This reimbursement rate, determined by gapfill submissions from the Medicare contractors, was open to reconsideration until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the Medicare contractors and in November 2016 CMS released the final 2017 Clinical Laboratory Fee Schedule reflecting the rate of reimbursement at \$2,841 for AlloMap.

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 would begin in 2017 and the new market based rates took effect on January 1, 2018. Effective January 1, 2018, Medicare plans to reimburse us \$3,240 for AlloMap testing of Medicare beneficiaries, which represents a 14% increase over the 2017 reimbursement rate. AlloMap has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation (HCSC), Humana, Kaiser Foundation Health Plan, Inc., and TRICARE.

#### Reimbursement for AlloSure

On September 26, 2017 we received notice that the Molecular Diagnostics Services, or MolDX, Program developed by Palmetto GBA has set AlloSure reimbursement at \$2,841. Effective October 9, 2017, AlloSure was made available for commercial testing with Medicare coverage and reimbursement. We believe the use of AlloSure, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, we believe AlloSure can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

#### Development of Additional Products and Services

We rely on sales of AlloMap, AlloSure, Olerup SSP, Olerup SBT, Olerup QTYPE and TruSight HLA to generate the majority of our revenue. Our development pipeline includes other transplant diagnostic solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. We expect to invest in research and development in order to develop additional products. Our success in developing new products and services 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, as well as on-going clinical and outcome studies to further the published evidence to support our commercialized AlloMap and AlloSure tests. 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

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

#### Off-Balance Sheet Arrangements

As of September 30, 2018, we had no off-balance sheet arrangements as defined under Regulation S-K 303(a)(4) of the Exchange Act, and the instructions thereto.

#### 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, we 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 condensed consolidated balance sheets contain certain recorded assets in foreign countries, namely Stockholm, Sweden, Vienna, Austria and Fremantle, Australia. 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. We had cash and cash equivalents of \$26.2 million and \$16.9 million at September 30, 2018 and December 31, 2017, respectively, which consisted of bank deposits and money market funds. Additionally, we had debt of \$13.4 million and \$34.1 million as of September 30, 2018 and December 31, 2017, respectively. Such variable 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 fifty basis point increase or decrease in interest rates would have a less than \$0.1 million impact on our unaudited condensed consolidated financial statements.

#### Foreign Currency Exchange Risk

We have operations in Sweden, Austria, Australia and sell to other countries throughout the world. As a result, we are subject to significant foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in Swedish Krona, the Euro, the Australian dollar and 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, the Euro, and the Australian Dollar, which are 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, 2018, would have negatively impacted our financial results for the nine months ended September 30, 2018 by \$0.2 million and our product revenue by \$0.5 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 Exchange Act), 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 we are required to apply our judgment in evaluating the benefits of possible controls and procedures relative to our costs. Based on such evaluation, 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 effective at the reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the nine months ended September 30, 2018 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

Our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 22, 2018, Part I –Item 1A, Risk Factors, describes important risk factors that could cause our business, financial condition, results of operations and growth prospects to differ materially from those indicated or suggested by forward-looking statements made in this Quarterly Report on Form 10-Q or presented elsewhere by management from time to time. There have been no material changes in the risk factors that appear in Part I - Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 22, 2018 other than those listed below and that the risk factor with the heading “As a result of our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2016 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, we are currently ineligible to file new short form registration statements on Form S-3, and we are unable to access our existing Registration Statement on Form S-3 for sales of securities by us, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.” is no longer applicable to us as we regained eligibility to file new short form registration statements on Form S-3 on June 1, 2018 and we filed a universal shelf registration statement on Form S-3 (File No 333-227168) on August 31, 2018, which was declared effective by the SEC on October 11, 2018. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business.

Our credit agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our credit agreement with Perceptive contains certain restrictive covenants that limit our ability to merge with other companies or consummate certain changes of control, acquire other companies, make certain investments or acquisitions, pay dividends, transfer or dispose of assets, amend certain material agreements, incur additional indebtedness, permit additional liens 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 agreement. There is no guarantee that we will be able to generate sufficient cash flow or sales to pay the principal and interest under our debt agreement.

Refer to Note 10 of the notes to the unaudited condensed consolidated financial statements included in Part I, Item I of this Quarterly Report on Form 10-Q for details on our credit agreement with Perceptive.

Our License and Commercialization Agreement with Illumina may not result in material benefits to our business.

Pursuant to our License and Commercialization Agreement with Illumina, we acquired the worldwide distribution, development and commercialization rights to Illumina, Inc.’s next generation sequencing product line for use in the field of transplantation.

Under the License Agreement, we are obligated to complete timely development and commercialization of future products, including meeting certain commercialization milestones. The failure to meet any such milestones could result in the loss of exclusivity for the affected licensed products. Additionally, we agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023 and we are required to pay royalties in the mid-single to low-double digits on sales of future commercialized products.

We cannot make any assurances that our efforts under the License Agreement will be successful. As a result, we may not be able to fully realize the anticipated strategic benefits of the License Agreement. If we fail to successfully execute on the License Agreement, we may not realize the benefits expected from the transaction and our business may be harmed.

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, debt agreement with Perceptive prohibits us from paying dividends without the Perceptive'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 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:

- 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, AlloSure 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 new solutions ;
- 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 up to \$50.0 million of additional shares of our common stock to the public through an “at the market” offering pursuant to the Sales Agreement we entered into with Jefferies, LLC on August 31, 2018. 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

50

---

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit

Number

- 3.1(1) Amended and Restated Certificate of Incorporation.
- 3.2(2) Amended and Restated Bylaws.
- 4.1(3) Form of Registrant's common stock certificate.
- 4.2(4) 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.
- 4.3(5)# 1998 Equity Incentive Plan and forms of agreements thereunder.
- 4.4(6)# 2008 Equity Incentive Plan and forms of agreement thereunder.
- 4.5(7)# ImmuMetrix, Inc. 2013 Equity Plan
- 4.6(8)# 2014 Equity Incentive Plan, as amended.
- 4.7(9)# Form of Option Agreement under the 2014 Equity Incentive Plan for New Options.
- 4.8(10)# 2014 Employee Stock Purchase Plan and forms of agreements thereunder.
- 4.9(11)# 2016 Inducement Equity Plan.
- 4.10(12)# Form of Warrant.
- 4.11(13) Form of Common Stock Purchase Warrant issued to the Purchasers on March 15, 2017.
- 4.12(14) Common Stock Purchase Warrant issued to Perceptive Credit Holdings II, LP on April 17, 2018.
- 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.
- (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 4.1 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
- (4) Incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
- (5) Incorporated by reference to Exhibit 10.2 to the Registrant's Form S-1 filed with the SEC on June 3, 2014.
- (6) Incorporated by reference to Exhibit 10.3 to the Registrant's Form S-1 filed with the SEC on June 3, 2014.
- (7) Incorporated by reference to Exhibit 10.19 to the Registrant's Form S-1 filed with the SEC on June 3, 2014.
- (8) Incorporated by reference to Exhibit 4.4 to the Registrant's Form S-8 filed with the SEC on July 18, 2014.

- (9) Incorporated by reference to Exhibit 99(d)(3) to the Registrant's Form SC TO-I filed with the SEC on October 12, 2017.
- (10) Incorporated by reference to Exhibit 4.5 to the Registrant's Form S-8 filed with the SEC on July 18, 2014.
- (11) Incorporated by reference to Exhibit 4.1 to the Registrant's Form S-8 filed with the SEC on May 23, 2016.
- (12) Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on April 14, 2016.
- (13) Incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K filed with the SEC on March 15, 2017.
- (14) Incorporated by reference to Exhibit 4.12 to the Registrant's Form 10-Q filed with the SEC on August 9, 2018.

#Indicates management contract or compensatory plan or arrangement.

\*Filed herewith.

\*\*Furnished herewith.

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 8, 2018 By: /s/ PETER MAAG  
Peter Maag  
President and Chief Executive Officer  
(Principal Executive Officer)

By: /s/ MICHAEL BELL  
Michael Bell  
Chief Financial Officer  
(Principal Accounting and Financial Officer)