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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

or

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

For the transition period from _____ to _____

Commission file number: 001-36536

CAREDX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3316839
(I.R.S. Employer
Identification Number)

3260 Bayshore Boulevard
Brisbane, California 94005
(Address of principal executive offices and zip code)

(415) 287-2300

(Registrant's telephone number, including area code)

N/A

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

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

Indicate by check mark whether the registrant has submitted electronically 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

Securities registered pursuant to Section 12(b) of the Act

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	CDNA	The Nasdaq Stock Market LLC

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

There were 42,119,913 shares of the registrant's Common Stock issued and outstanding as of May 6, 2019.

CareDx, Inc.
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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CareDx, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share data)

Assets	March 31, 2019	December 31, 2018
Current assets:		
Cash and cash equivalents	\$ 57,432	\$ 64,616
Accounts receivable	12,525	9,760
Inventory	5,177	4,943
Prepaid and other current assets	2,444	1,795
Total current assets	77,578	81,114
Property and equipment, net	3,820	4,134
Operating leases right-of-use assets	2,506	—
Intangible assets, net	31,759	33,252
Goodwill	12,005	12,005
Restricted cash	191	192
Total assets	\$ 127,859	\$ 130,697
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,859	\$ 4,711
Accrued compensation	4,860	9,156
Accrued and other liabilities	7,651	5,637
Total current liabilities	16,370	19,504
Deferred tax liability	2,571	2,968
Common stock warrant liability	10,521	10,003
Other liabilities	2,775	2,294
Total liabilities	32,237	34,769
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at March 31, 2019 and December 31, 2018; no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Common stock: \$0.001 par value; 100,000,000 shares authorized at March 31, 2019 and December 31, 2018; 41,912,469 shares and 41,384,960 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	41	41
Additional paid-in capital	419,959	412,010
Accumulated other comprehensive loss	(5,002)	(4,278)
Accumulated deficit	(319,376)	(311,845)
Total stockholders' equity	95,622	95,928
Total liabilities and stockholders' equity	\$ 127,859	\$ 130,697

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 March 31,	
	2019	2018
Revenue:		
Testing services revenue	\$ 21,518	\$ 10,604
Product revenue	4,433	3,307
License and other revenue	31	142
Total revenue	25,982	14,053
Operating expenses:		
Cost of testing services	6,838	4,112
Cost of product	2,895	2,272
Research and development	5,614	3,368
Sales and marketing	6,925	4,085
General and administrative	9,106	5,307
Change in estimated fair value of contingent consideration	—	144
Total operating expenses	31,378	19,288
Loss from operations	(5,396)	(5,235)
Other income (expense):		
Interest income (expense), net	342	(2,695)
Debt extinguishment expenses	—	(2,806)
Change in estimated fair value of common stock warrant liability and derivative liability	(3,009)	1,321
Other expense, net	(74)	(3)
Total other income (expense)	(2,741)	(4,183)
Loss before income taxes	(8,137)	(9,418)
Income tax benefit	606	424
Net loss	(7,531)	(8,994)
Net loss attributable to noncontrolling interest		(25)
Net loss attributable to CareDx, Inc.	<u>\$ (7,531)</u>	<u>\$ (8,969)</u>
Net loss per share attributable to CareDx, Inc. (Note 3):		
Basic	<u>\$ (0.18)</u>	<u>\$ (0.30)</u>
Diluted	<u>\$ (0.18)</u>	<u>\$ (0.30)</u>
Weighted-average shares used to compute net loss per share attributable to CareDx, Inc.:		
Basic	<u>41,611,399</u>	<u>29,615,441</u>
Diluted	<u>41,611,399</u>	<u>29,615,441</u>

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)

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Net loss	\$ (7,531)	\$ (8,994)
Other comprehensive loss:		
Foreign currency translation adjustments	(724)	(137)
Net comprehensive loss	(8,255)	(9,131)
Comprehensive loss attributable to noncontrolling interest, net of tax	—	(25)
Comprehensive loss attributable to CareDx, Inc.	<u>\$ (8,255)</u>	<u>\$ (9,106)</u>

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

CareDx, Inc.
Condensed Consolidated Statements of Stock and Stockholders' Equity
(Unaudited)
(In thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2018	41,384,960	\$ 41	\$ 412,010	\$ (4,278)	\$ (311,845)	\$ —	\$ 95,928
Issuance of common stock under ESPP	31,184	—	341	—	—	—	341
RSU settlements, net of shares withheld	146,159	—	(2,378)	—	—	—	(2,378)
Issuance of common stock for services	2,112	—	51	—	—	—	51
Issuance of common stock for cash upon exercise of stock options	253,347	—	1,365	—	—	—	1,365
Issuance of common stock for cash upon exercise of warrants	94,707	—	2,569	—	—	—	2,569
Employee share-based compensation expense	—	—	6,001	—	—	—	6,001
Foreign currency translation adjustment	—	—	—	(724)	—	—	(724)
Net loss	—	—	—	—	(7,531)	—	(7,531)
Balance at March 31, 2019	41,912,469	\$ 41	\$ 419,959	\$ (5,002)	\$ (319,376)	\$ —	\$ 95,622

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interests	Total Stockholders' Equity (Deficit)
	Shares	Amount					
Balance at December 31, 2017	28,825,019	\$ 29	\$ 264,204	\$ (2,345)	\$ (268,022)	\$ 180	\$ (5,954)
Adoption of ASC 606	—	—	—	—	2,933	—	2,933
Reclassification of warrants from liability to equity	—	—	6,550	—	—	—	6,550
Conversion of convertible debt	6,161,331	6	38,848	—	—	—	38,854
Issuance of common stock under ESPP	34,176	—	32	—	—	—	32
RSU settlements, net of shares withheld	49,330	—	(128)	—	—	—	(128)
Issuance of common stock for services	5,772	—	62	—	—	—	62
Issuance of common stock for cash upon exercise of stock options	142,554	—	80	—	—	—	80
Issuance of common stock for cash upon exercise of warrants	22,600	—	153	—	—	—	153
Employee share-based compensation expense	—	—	573	—	—	—	573
Non-employee share-based compensation expense	—	—	61	—	—	—	61
Noncontrolling interests upon acquisition	—	—	(537)	—	—	(155)	(692)
Foreign currency translation adjustment	—	—	—	(137)	—	—	(137)
Net loss	—	—	—	—	(8,969)	(25)	(8,994)
Balance at March 31, 2018	35,240,782	\$ 35	\$ 309,898	\$ (2,482)	\$ (274,058)	\$ —	\$ 33,393

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)

	Three Months Ended March 31,	
	2019	2018
Operating activities:		
Net loss	\$ (7,531)	\$ (8,994)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,161	1,039
Amortization of inventory fair market value adjustment	—	164
Loss on conversion of JGB Debt to shares of common stock	—	2,806
Amortization of debt discount and noncash interest expense	—	2,084
Revaluation of common stock warrant liability and derivative liability to estimated fair value	3,009	(1,321)
Stock-based compensation	6,053	706
Revaluation of contingent consideration to estimated fair value	—	144
Non-cash lease expense	372	—
Changes in operating assets and liabilities:		
Accounts receivable	(2,782)	(606)
Inventory	(372)	196
Prepaid and other assets	(541)	(510)
Operating leases liabilities	(475)	—
Accounts payable	(449)	835
Accrued compensation	(4,249)	(1,358)
Accrued and other liabilities	202	644
Change in deferred taxes	(265)	(347)
Net cash used in operating activities	(5,867)	(4,518)
Investing activities:		
Acquisition of Allenex AB and noncontrolling interests, net of cash acquired	—	(692)
Purchase of property and equipment	(543)	(62)
Net cash used in investing activities	(543)	(754)
Financing activities:		
Perceptive term loan issuance costs	—	(584)
Proceeds from issuance of common stock under employee stock purchase plan	341	32
Taxes paid related to net share settlement of restricted stock units	(2,378)	—
Principal payments on debt and finance lease obligations	(42)	(1,633)
Contingent payments related to the acquisition of Conexio Genomics Pty Ltd.	(52)	(13)
Change in short term credit facility	—	(225)
Proceeds from exercise of warrants	78	25
Proceeds from exercise of stock options	1,365	80
Net cash used in financing activities	(688)	(2,318)
Effect of exchange rate changes on cash and cash equivalents	(87)	17
Net decrease in cash, cash equivalents and restricted cash	(7,185)	(7,573)
Cash, cash equivalents, and restricted cash at beginning of period	64,808	26,474
Cash, cash equivalents, and restricted cash at end of period	\$ 57,623	\$ 18,901
Supplemental disclosure of cash flow information:		
Operating leases right-of-use assets	\$ 2,506	\$ —
Cash, Cash Equivalents and Restricted Cash as of:		
	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 57,432	\$ 64,616
Restricted cash	191	192
Total cash, cash equivalents and restricted cash at the end of period	\$ 57,623	\$ 64,808

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

The Company focuses on discovery, development and commercialization of clinically differentiated, high-value diagnostic 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.

Testing Services

AlloMap is a covered service for Medicare beneficiaries since January 1, 2006. In 2018, the Medicare reimbursement rate for AlloMap was set at \$3,240, which remains applicable for 2019. AlloMap has also received positive coverage decisions from many of the largest U.S. private payers.

In October 2017, the Company commercially launched AlloSure, its proprietary next generation sequencing-based test that measures dd-cfDNA in kidney transplant recipients. The Medicare reimbursement rate for AlloSure is currently \$2,841. AlloSure has also received payments from private payers on a case-by-case basis. However, no positive coverage decisions have yet been made for AlloSure. In September 2018, the Company 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. AlloSure-Heart has not yet received positive coverage decisions from Medicare or other private payers. The Company has not yet made any applications to payers for reimbursement coverage of AlloSure-Heart.

In February 2019, AlloSure-Lung® became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. The Company has not yet made any applications to payers for reimbursement coverage of AlloSure-Lung.

Products

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. 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. The Company received CE mark certification for QTYPE in April 2018.

In May 2018, the Company entered into a License and Commercialization Agreement (the “License 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. Pursuant to the License Agreement, the Company is the exclusive worldwide distributor of Illumina’s TruSight® HLA v1 and v2 product line. TruSight HLA is a NGS-based high resolution typing solution that provides NGS-level resolution to HLA typing. The Company’s suite of AlloSeq products are development-stage NGS-based kitted solutions that the Company acquired as a result of its License Agreement. These products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, a surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq BMT, a solution for chimerism testing for stem cell transplant recipients.

Business Combination

On April 25, 2019, the Company announced that it agreed to acquire OTTR Complete Transplant Management (“OTTR”). See Note 16 for further details.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of \$319.4 million at March 31, 2019. As of March 31, 2019, the Company had cash and cash equivalents of \$57.4 million.

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, 2018, 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, 2018 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 and other financial information that are normally required by U.S. GAAP can be condensed or omitted. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated 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, 2018 has been derived from audited consolidated financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated.

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year presentation, including separate presentation of debt extinguishment expenses from other expense, net. These reclassifications had no effect on the reported results of operations.

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 transaction price estimates used for testing services revenue; accrued expenses for clinical studies; inventory valuation; the fair value of issued common stock warrants and embedded derivatives; the fair value of assets and liabilities acquired in a business combination or an assets acquisition (including identifiable intangible assets acquired); the fair value of contingent consideration recorded in connection with a business combination; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended March 31, 2019 and 2018, approximately 55% and 42%, respectively, of total revenue was derived from Medicare. No other payers or customers represented more than 10% of total revenue for these periods.

As of March 31, 2019 and December 31, 2018, approximately 34% and 27%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either March 31, 2019 or December 31, 2018.

Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, *Leases* (“ASC 842”). The Company determines if an arrangement is or contains a lease at contract inception. The Company leases office space and equipment primarily through operating leases with a limited number of finance leases. A right-of-use (“ROU”) asset, representing the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the condensed consolidated balance sheet at lease commencement based on the present value of the payment obligation. For operating leases, expense is recognized on a straight-line basis over the lease term. For finance leases, interest expense on the lease liability is recognized using the effective interest method and amortization of the ROU asset is recognized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet.

The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

The Company's leases have remaining terms of less than 1 year to 2.33 years, some of which include options to extend the lease term. The Company's lease terms may include renewal options that are reasonably certain to be exercised and termination options that are reasonably certain not to be exercised. Certain finance leases also include bargain purchase options of the leased equipment.

Recent Accounting Pronouncements

Effective January 1, 2019, the Company adopted ASC 842 using the optional transition method and applied the standard only to leases that existed at that date. Under the optional transition method, the Company does not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2019 in accordance with ASC Topic 840. The Company has also chosen to apply the package of practical expedients for existing leases, which provides relief from reassessing: (i) whether a contract is or contains a lease, (ii) lease classification, and (iii) whether initial direct costs (IDCs) can be capitalized. The Company has also made some accounting policy elections to: (i) allow the Company not to separate nonlease components from lease components, and instead to account for those as a single lease component, and (ii) elect not to recognize a ROU asset and a lease liability for leases with a term of 12 months or less (“short-term leases”).

Upon adoption of ASC 842 on January 1, 2019, the Company recorded a ROU asset of approximately \$3.0 million and a lease liability of approximately \$3.8 million. The lease liability was determined based on the present value of the remaining minimum lease payments. The ROU asset was determined based on the value of the lease liability, adjusted for the deferred rent balances of approximately \$0.8 million, which were previously included in accrued and other liabilities as well as deferred rent, net of current portion. See Note 8 for further details.

The standard did not have a material impact on the condensed consolidated statement of cash flows or the condensed consolidated statement of operations.

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”). 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. The adoption of the new standard did not have a material impact on the Company's unaudited condensed consolidated financial statements.

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 adopted ASU 2018-07 on January 1, 2019 applying a modified retrospective approach. On transition, the Company only had nonemployee equity-classified awards with an established measurement date. Accordingly, the Company did not record a cumulative-effect adjustment to retained earnings.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal – Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (“ASU 2018-15”). ASU 2018-15 is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption of ASU 2018-15 is permitted including adoption in any interim period. The Company plans to adopt the standard during 2019. The Company expects the new standard will impact its prospective unaudited condensed consolidated financial statements after adoption related to implementation costs in a cloud computing arrangement if and when entered by the Company.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*, which modifies, removes and adds certain disclosure requirements on fair value measurements based on the FASB Concepts Statement, Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements. The ASU is effective for the Company’s interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting period thereafter. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of ASU 2018-13. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is in the process of assessing the impact that the ASU will have in its unaudited condensed consolidated financial statements and disclosures. The Company does not believe adoption of the guidance will have a significant impact on its condensed consolidated financial statements.

3. NET LOSS PER SHARE

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

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

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Numerator:		
Net loss attributable to CareDx, Inc. used to compute basic and diluted net loss per share	\$ (7,531)	\$ (8,969)
Denominator:		
Weighted-average shares used to compute basic and diluted net loss per share attributable to CareDx, Inc.	41,611,399	29,615,441
Net loss per share attributable to CareDx, Inc.:		
Basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.30)</u>

The following potentially dilutive securities have been excluded from diluted net loss per share as at March 31, 2019 because their effect would be antidilutive:

	<u>March 31,</u>	
	<u>2019</u>	<u>2018</u>
Shares of common stock subject to outstanding options	2,536,412	1,940,010
Shares of common stock subject to outstanding common stock warrants	530,627	3,633,565
Restricted stock units	1,034,484	441,804
Shares of common stock subject to contingent consideration	—	227,848
Total common stock equivalents	<u>4,101,523</u>	<u>6,243,227</u>

4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value. 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 March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019			
	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
Assets				
Money market funds	\$ 20,543	\$ —	\$ —	\$ 20,543
Liabilities				
Common stock warrant liability	\$ —	\$ —	\$ 10,521	\$ 10,521

	December 31, 2018			
	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
Assets				
Money market funds	\$ 59,471	\$ —	\$ —	\$ 59,471
Liabilities				
Common stock warrant liability	\$ —	\$ —	\$ 10,003	\$ 10,003

The following table presents the issuances, exercises, 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) Common Stock Warrant Liability
Balance as of December 31, 2018	\$ 10,003
Exercise of warrants	(2,491)
Change in estimated fair value	3,009
Balance as of March 31, 2019	\$ 10,521

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

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

- *Money market funds* - Investments in money market funds are classified within Level 1. At March 31, 2019 and December 31, 2018, money market funds were included on the balance sheets in cash and cash equivalents.

- *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 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.

Common Stock Warrant Liability Valuation Assumptions

	March 31, 2019	December 31, 2018
Private Placement Common Stock Warrant Liability		
Stock Price	\$ 31.52	\$ 25.14
Exercise Price	\$ 1.12	\$ 1.12
Remaining term (in years)	4.04	4.29
Volatility	81.00 %	79.00 %
Risk-free interest rate	2.20 %	2.46 %
Placement Agent Common Stock Warrant Liability		
Stock Price	\$ 31.52	\$ 25.14
Exercise Price	\$ 1.12	\$ 1.12
Remaining term (in years)	2.04	2.29
Volatility	85.00 %	86.00 %
Risk-free interest rate	2.24 %	2.44 %

5. BUSINESS COMBINATIONS AND ASSET ACQUISITIONS

Asset Acquisition

Illumina License and Commercialization Agreement

On May 4, 2018, the Company entered into 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 Tx 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 to occur 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 Tx	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—
Total	<u>\$ 5,202</u>	

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 March 31, 2019 and December 31, 2018.

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. There were no indicators of impairment in the three months ended March 31, 2019.

Intangible Assets

The following tables present details of the Company's intangible assets as of March 31, 2019 (in thousands):

	March 31, 2019				Weighted Average Remaining Useful Life (In Years)
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	
Intangible assets with finite lives:					
Customer relationships: Allenex	\$ 12,650	\$ (2,388)	\$ (1,454)	\$ 8,808	11.8
Customer relationships: Conexio	28	(9)	(1)	18	1.8
Customer relationships: TruSight HLA	380	(123)	—	257	1.8
Developed technology: Olerup SSP	11,650	(3,330)	(1,256)	7,064	6.8
Acquired technology: QTYPE	4,510	(741)	(524)	3,245	11.8
Acquired technology: Olerup SBT	127	(40)	(5)	82	1.8
Acquired technology: dd-cfDNA	6,650	(762)	—	5,888	11.6
Trademarks	2,260	(488)	(197)	1,575	11.8
Total intangible assets with finite lives	<u>\$ 38,255</u>	<u>\$ (7,881)</u>	<u>\$ (3,437)</u>	<u>\$ 26,937</u>	
Acquired in-process technology: AlloSeq Tx	2,719	—	—	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—	—	2,103	—
Total intangible assets	<u>\$ 43,077</u>	<u>\$ (7,881)</u>	<u>\$ (3,437)</u>	<u>\$ 31,759</u>	

The following tables present details of the Company's intangible assets as of December 31, 2018 (in thousands):

	December 31, 2018				Weighted Average Remaining Useful Life (In Years)
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	
Intangible assets with finite lives:					
Customer relationships: Allenex	\$ 12,650	\$ (2,198)	\$ (1,129)	\$ 9,323	12.0
Customer relationships: Conexio	28	(6)	(2)	20	2.0
Customer relationships: TruSight HLA	380	(86)	—	294	2.0
Developed technology: Olerup SSP	11,650	(3,065)	(998)	7,587	7.0
Acquired technology: QTYPE	4,510	(671)	(407)	3,432	12.0
Acquired technology: Olerup SBT	127	(28)	(6)	93	2.0
Acquired technology: dd-cfDNA	6,650	(635)	—	6,015	11.8
Trademarks	2,260	(454)	(140)	1,666	12.0
Total intangible assets with finite lives	\$ 38,255	\$ (7,143)	\$ (2,682)	\$ 28,430	
Acquired in-process technology: AlloSeq Tx	2,719	—	—	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—	—	2,103	—
Total intangible assets	\$ 43,077	\$ (7,143)	\$ (2,682)	\$ 33,252	

Amortization expense was \$0.6 million for each of the three months ended March 31, 2019 and 2018, respectively. For the three months ended March 31, 2019, 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 March 31, 2018, expenses of \$0.4 million and \$0.2 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 March 31, 2019 (in thousands):

Years Ending December 31,	Cost of Product	Sales and Marketing	Total
Remainder of 2019	\$ 1,408	\$ 781	\$ 2,189
2020	1,878	1,042	2,920
2021	1,831	884	2,715
2022	1,831	884	2,715
2023	1,831	884	2,715
Thereafter	7,499	6,184	13,683
Total future amortization expense	\$ 16,278	\$ 10,659	\$ 26,937

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 acquired in-process technology assets are less than their carrying amounts. An impairment loss would be recorded when the fair value of an acquired in-process technology assets is less than its carrying value. If and when development is complete, which generally occurs when the products are made commercially available, the associated acquired in-process technology 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):

	March 31, 2019	December 31, 2018
Finished goods	\$ 2,412	\$ 2,506
Work in progress	811	651
Raw materials	1,954	1,786
Total inventory	<u>\$ 5,177</u>	<u>\$ 4,943</u>

Accrued and other liabilities

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

	March 31, 2019	December 31, 2018
Short-term lease liability	\$ 1,866	\$ —
Clinical studies	1,791	1,815
Professional fees	926	822
Test sample processing fees	780	657
Accrued royalty	395	285
Finance leases – current portion	174	172
Customer overpayments and refunds	173	184
Deferred purchase consideration	143	190
Software implementation costs	75	58
Uninvoiced receipts	65	—
Deferred revenue	47	39
Deferred rent – current portion	—	432
Other accrued expenses	1,216	983
Total accrued and other liabilities	<u>\$ 7,651</u>	<u>\$ 5,637</u>

8. COMMITMENTS

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.

The following table summarizes the lease cost for the three months ended March 31, 2019 (in thousands):

	March 31, 2019
Operating lease cost	\$ 435
Finance lease cost	56
Total lease cost	<u>\$ 491</u>

Other information:

Weighted-average remaining lease term - Operating leases (in years)	1.74
Weighted-average remaining lease term - Finance leases (in years)	2.1
Weighted-average discount rate - Operating leases (%)	10.5 %
Weighted-average discount rate - Finance leases (%)	6.4 %

Rent expense under the non-cancelable operating leases was \$0.4 million for each of the three months ended March 31, 2019 and 2018, respectively. Future minimum lease commitments under these operating and finance leases on March 31, 2019, are as follows (in thousands):

<u>Years Ending December 31,</u>	<u>Finance Leases</u>	<u>Operating Leases</u>
Remainder of 2019	\$ 145	\$ 1,665
2020	193	2,160
2021	67	124
2022	—	55
Total future minimum lease payments	<u>\$ 405</u>	<u>\$ 4,004</u>

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

Royalty Commitments

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. Company incurred royalties of \$0.3 million in the three months ended March 31, 2019.

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 March 31, 2019, 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 lines 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 March 31, 2019 and as of December 31, 2018.

9. DEBT

The Company did not have any outstanding debt as of March 31, 2019 or December 31, 2018.

JGB Debt

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 debt extinguishment expenses in the condensed consolidated statements of operations for the three months ended March 31, 2018.

Danske Bank Term Loan and Credit Facility

The Company repaid the full outstanding amount of SEK 47,000,000 (approximately \$5.6 million) plus 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

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

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 Aktieboulag

The Company repaid the full loan amount outstanding of SEK 10,000,000 (approximately \$1.2 million), including accrued interest of SEK 650,000 (approximately \$0.1 million) on February 26, 2018.

10. STOCKHOLDERS' EQUITY

JGB Debt

In the three months ended March 31, 2018, JGB converted the remaining \$26.7 million of outstanding debt 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 ImmuMetrix, Inc. ("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 227,848 shares in May 2018.

2018 Public Offering

On November 16, 2018, the Company sold in the 2018 Public Offering an aggregate of 2,300,000 shares of its common stock, including 300,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares at a public offering price of \$24.50 per share. Total net proceeds received were \$52.9 million net of underwriter's fees and issuance costs.

11. 401(K) PLAN

The Company sponsors a 401(k) defined contribution plan covering all U.S. employees under the Internal Revenue Code of 1986, as amended. 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 \$0.2 million and \$0.1 million for the three months ended March 31, 2019 and 2018, respectively.

12. 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 U.S. 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 the exception criteria are classified as equity. Warrants liabilities are remeasured at fair value at each period end with changes in fair value recorded in the condensed consolidated 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 remeasured.

In the three months ended March 31, 2019, warrants to purchase approximately 70,000 shares of common stock were exercised for cash proceeds of less than \$0.1 million. The warrant liability was remeasured prior to the exercise and a change in fair value of \$0.5 million was recorded in the condensed consolidated statement of operations. During the three months ended March 31, 2019 approximately 56,000 warrants were exercised on cashless basis and approximately 25,000 shares were issued.

As of March 31, 2019, outstanding warrants to purchase common stock were:

	Classified as	Original Term	Exercise Price	Number of Shares Underlying Warrants
Original issue date:				
August 2009	Equity	10 years	\$ 21.78	33,473
July 2010	Equity	9 years	\$ 21.78	6,694
August 2012	Equity	7 years	\$ 21.78	111,455
January 2015	Equity	5 years	\$ 6.96	34,483
April 2016	Liability	7 years	\$ 1.12	323,021
April 2016	Liability	5 years	\$ 1.12	21,501
				<u>530,627</u>

13. 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 Equity Incentive 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, 2018	322,178	2,501,057	\$ 9.10	968,364	\$ 11.49
Additional options authorized	1,655,398	—	—	—	—
Common stock awards for services	(2,112)	—	—	—	—
RSUs granted	(367,800)	—	—	367,800	27.21
RSUs vested	—	—	—	(276,954)	13.53
Options granted	(341,900)	341,900	27.52	—	—
Options exercised	—	(251,739)	5.43	—	—
Repurchase of common stock under employee incentive plans	83,923	—	—	—	—
RSUs forfeited	24,726	—	—	(24,726)	15.24
Options forfeited	54,096	(54,096)	11.53	—	—
Options expired	710	(710)	4.37	—	—
Balance—March 31, 2019	<u>1,429,219</u>	<u>2,536,412</u>	\$ 11.89	<u>1,034,484</u>	\$ 16.41

The total intrinsic value of options exercised was \$6.0 million in the three months ended March 31, 2019.

As of March 31, 2019, the total intrinsic value of outstanding RSUs was approximately \$32.6 million and there were \$13.5 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.72 years.

Options outstanding that have vested and are expected to vest at March 31, 2019 are as follows:

	Number of Shares Issued	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In Thousands)
Vested	938,223	\$ 5.41	6.56	\$ 24,497
Expected to vest	1,491,586	15.70	9.17	23,598
Total	2,429,809			\$ 48,095

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at December 31, 2018 for stock options that were in-the-money.

The total fair value of options that vested during the three months period ended March 31, 2019 was \$0.5 million. As of March 31, 2019, there were approximately \$13.1 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 3.47 years.

2014 Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (the "ESPP"), under which employees can purchase shares of its common stock based on a percentage of their compensation, but not greater than 15% of their earnings; provided, however, an eligible employee's right to purchase shares of the Company's common stock may not accrue at a rate which exceeds \$25,000 of the fair market value of such shares for each calendar year in which such rights are outstanding. The ESPP has consecutive offering periods of approximately six months in length. The purchase price per share must be equal to the lower of 85% of the fair value of the common stock on the first day of the offering period or on the exercise date.

During the offering period in 2018 that ended on December 31, 2018, 31,184 shares were purchased for aggregate proceeds of \$0.3 million from the issuance of shares, which occurred on January 2, 2019. 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 values of employee stock options and ESPP shares were estimated using the Black-Scholes option-pricing model based on the following weighted-average assumptions:

	Three Months Ended March 31,	
	2019	2018
Employee stock options		
Expected term (in years)	6.0	6.0
Expected volatility	70.33%	79.96%
Risk-free interest rate	2.57%	2.51%
Expected dividend yield	—%	—%
Employee stock purchase plan		
Expected term (in years)	0.5	0.5
Expected volatility	76.66%	105.32%
Risk-free interest rate	2.51%	1.61%
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-based awards for the three months ended March 31, 2019 and 2018, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of testing services	\$ 776	\$ 61
Research and development	832	213
Sales and marketing	727	64
General and administrative	3,718	368
Total	\$ 6,053	\$ 706

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.

14. 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 months ended March 31, 2019 and 2018, the Company recorded an income tax benefit of \$0.6 million and \$0.4 million, respectively. The income tax benefit of \$0.6 million, is primarily attributable to the recognition of deferred tax assets from foreign losses and recognition of previous unrecognized tax benefits. 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.

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 2019 taxes. The Company will continue to review the GILTI and BEAT rules to determine their applicability to the Company as the rules become effective.

15. SEGMENT REPORTING

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the Company's Chief Operating Decision Maker ("CODM"), or decision making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its Chief Executive Officer as the CODM. The Company operates in a single reportable segment.

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 March 31,	
	2019	2018
Testing services revenue		
United States	\$ 21,386	\$ 10,460
Rest of the World	132	144
	<u>\$ 21,518</u>	<u>\$ 10,604</u>
Product revenue		
United States	\$ 1,832	\$ 845
Europe	1,943	1,973
Rest of the World	658	489
	<u>\$ 4,433</u>	<u>\$ 3,307</u>
License and other revenue		
United States	\$ 22	\$ 142
Europe	9	—
	<u>\$ 31</u>	<u>\$ 142</u>
Total United States	<u>\$ 23,240</u>	<u>\$ 11,447</u>
Total Europe	<u>\$ 1,952</u>	<u>\$ 1,973</u>
Total Rest of the World	<u>\$ 790</u>	<u>\$ 633</u>
Total	<u><u>\$ 25,982</u></u>	<u><u>\$ 14,053</u></u>

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

	March 31, 2019	December 31, 2018
Long-lived assets:		
United States	\$ 2,985	\$ 3,235
Europe	548	625
Rest of the World	287	274
Total	<u><u>\$ 3,820</u></u>	<u><u>\$ 4,134</u></u>

16. SUBSEQUENT EVENTS

On May 7, 2019 (the "Closing Date") the Company completed the acquisition of 100% of the outstanding equity of OTTR Complete Transplant Management ("OTTR") for a cash consideration of \$16 million.

OTTR is the leading provider of organ transplant patient tracking software. OTTR provides comprehensive solutions for transplant patient management, which are currently used in over 60 leading transplant centers in the US and Canada. OTTR's solutions enable integration with electronic medical records (EMR) systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

The Company plans to account for this transaction as a business combination effective as of the Closing Date.

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, 2018, filed with the Securities and Exchange Commission, or the SEC, on March 6, 2019.

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 obtain, maintain and expand reimbursement coverage from payers for AlloMap, AlloSure and other future testing services, if any;
- our ability to generate revenue from sales of Olerup SSP, Olerup SBT, 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, or (the "License Agreement") with Illumina, Inc., or ("Illumina");
- 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 transplantations;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- 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 ability to successfully assert or defend against, or settle, any litigation brought by or against us or other legal matters or disputes; 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 and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019. 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 solutions for transplant patients. We also offer 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.

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 Medicare reimbursement rate for AlloMap was set as \$3,240 on January 1, 2018, which remains applicable for 2019. 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., TRICARE and UnitedHealthcare.

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 three months of 2019, there were 4,280 AlloMap patient test results provided to 115 of the approximately 127 heart transplant management centers in the United States.

AlloSure

AlloSure, our transplant surveillance solution which was commercially launched in October 2017, 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. We believe AlloSure may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted heart, kidney, or other solid organ, 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 to the date of this filing.

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 2019. We plan to analyze and report on additional findings from this dataset in 2019 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 March 31, 2019, 50 centers have been initiated as K-OAR study sites.

During the first three months of 2019, there were 5,710 AlloSure patient test results provided. In the first quarter of 2019, AlloSure was ordered by 101 kidney transplant centers in the United States.

HeartCare

In September 2018, we initiated the Surveillance HeartCare Outcomes Registry, or 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”). We have not yet made any applications to payers for reimbursement coverage of AlloSure-Heart.

AlloSure-Lung

In February 2019, AlloSure-Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. AlloSure-Lung applies proprietary next generation sequencing, or NGS, technology to measure dd-cfDNA in the blood stream emanating from the donor lung to monitor graft injury. AlloSure-Lung has not received positive coverage decisions from Medicare or other private payers yet. We have not yet made any applications to payers for reimbursement coverage of AlloSure-Lung.

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. We also help clinicians manage transplant patients after the transplant has occurred.

QTYPE enables speed and precision in Human Leukocyte Antigen, or 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. Olerup SSP is used to type 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.

On May 4, 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's 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. TruSight HLA is a high resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines. These products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq BMT, a NGS solution for chimerism testing for stem cell transplant recipients.

Recent Highlights

- Accelerated leadership position in transplantation diagnostics in the first quarter of 2019
 - Performed 5,710 AlloSure tests for approximately 4,300 kidney transplant patients
 - Continued progress in AlloSure Registry (K-OAR) enrollment, with 50 centers initiated and 1,006 patients enrolled as of March 31, 2019
 - Provided 4,280 AlloMap patient results, increasing 11% year-over-year
- Achieved total revenue of \$26.0 million for the first quarter of 2019, increasing 85% year-over-year
 - Testing services revenue of \$21.5 million, growth of 103% compared to prior year period
 - Product revenue of \$4.4 million, increase of 34% year-over-year
- Generated GAAP net loss of \$7.5 million, adjusted net income of \$2.2 million and positive adjusted EBITDA of \$1.8 million
- Acquired OTTR Complete Transplant Management, enabling direct integration into transplant center EMR systems

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. Under ASC 606, 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. The adoption of ASC 606 resulted in a one-time adjustment of \$2.9 million to accounts receivable and accumulated deficit. The adoption of ASC 606 did not have any impact on product and license and other revenue recognized in prior periods.

Testing Services Revenue

Our testing services revenue is derived from AlloMap and AlloSure tests, which represented 83% and 75% of our total revenues for the three months ended March 31, 2019 and 2018, respectively. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; (v) our ability to expand into markets outside of the United States; and (vi) how quickly we can successfully commercialize new product offerings.

We currently market testing services 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 a test result

report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

During the three months ended March 31, 2019, we performed 4,280 commercial AlloMap tests and 5,710 AlloSure tests that are included in our estimated testing services revenue. All tests for both AlloMap and AlloSure were performed from our Brisbane, California laboratory.

Product Revenue

Our product revenue is derived primarily from sales of Olerup SSP, QTYPE, Olerup SBT and TruSight products. Product revenue represented 17% and 24% of total revenue for the three months ended March 31, 2019 and 2018, respectively. We recognize product revenue from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. We generally have 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. 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.

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
- Determination of incremental borrowing rate for lease liabilities
- Valuation of common stock warrant 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 months ended March 31, 2019 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, 2018, except as discussed in Note 2, Summary of Significant Accounting Policies, in the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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 March 31, 2019 and 2018

(In thousands)

	Three Months Ended March 31,		Change
	2019	2018	
Revenue:			
Testing services revenue	\$ 21,518	\$ 10,604	\$ 10,914
Product revenue	4,433	3,307	1,126
License and other revenue	31	142	(111)
Total revenue	25,982	14,053	11,929
Operating expenses:			
Cost of testing services	6,838	4,112	2,726
Cost of product	2,895	2,272	623
Research and development	5,614	3,368	2,246
Sales and marketing	6,925	4,085	2,840
General and administrative	9,106	5,307	3,799
Change in estimated fair value of contingent consideration	—	144	(144)
Total operating expenses	31,378	19,288	12,090
Loss from operations	(5,396)	(5,235)	(161)
Other income (expense):			
Interest income (expense), net	342	(2,695)	3,037
Debt extinguishment expenses	—	(2,806)	2,806
Change in estimated fair value of common stock warrant liability and derivative liability	(3,009)	1,321	(4,330)
Other expense, net	(74)	(3)	(71)
Total other income (expense)	(2,741)	(4,183)	1,442
Income tax benefit	606	424	182
Net loss	(7,531)	(8,994)	2,905
Net loss attributable to noncontrolling interest	—	(25)	25
Net loss attributable to CareDx, Inc.	<u>\$ (7,531)</u>	<u>\$ (8,969)</u>	<u>\$ 2,880</u>

Testing Services Revenue

Testing services revenue increased by \$10.9 million, or 103%, for the three months ended March 31, 2019 as compared to the same period in 2018. This increase is mainly due to the 5,710 AlloSure test results provided in the three months ended March 31, 2019, compared to 1,051 in the same period. Additionally, AlloMap test results increased to 4,280 in the three months ended March 31, 2019, compared to 3,847 in the same period in 2018.

Product Revenue

Product revenue increased by \$1.1 million, or 34%, for the three months ended March 31, 2019, compared to the same period in 2018. The increase is mainly 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 QTYPE, partially offset by decreased sales of Olerup SSP products.

Cost of Testing Services

Cost of testing services increased by approximately \$2.7 million, or 66%, for the three months ended March 31, 2019, compared to the same period in 2018, primarily due to the increase in test results provided for AlloSure and AlloMap compared to the same period in 2018.

Cost of Product

Cost of product increased by \$0.6 million, or 27%, for the three months ended March 31, 2019, compared to the same period in 2018, primarily due to the increase in Product Revenue.

Research and Development

Research and development expenses increased by \$2.2 million, or 67%, for the three months ended March 31, 2019, compared to the same period in 2018, primarily due to an increase in personnel related costs of \$1.2 million and stock-based compensation expense of \$0.6 million. The overall increase in spend is driven by our commitment to invest in NGS product lines and advancing clinical trials such as K-OAR and SHORE.

Sales and Marketing

Sales and marketing expenses increased by approximately \$2.8 million, or 70%, for the three months ended March 31, 2019, compared to the same period in 2018, primarily due to higher personnel related costs of \$1.0 million, higher costs of \$1.0 million mainly related to various tradeshows and events and increased stock-based compensation expense of \$0.7 million.

General and Administrative

General and administrative expenses increased by \$3.8 million, or 72%, for the three months ended March 31, 2019, compared to the same period in 2018. This increase was primarily due to an increase in stock-based compensation of \$3.4 million and an increase of \$1.1 million in personnel related expenses, partially offset by lower audit fees of \$0.9 million.

Interest Income (Expense), net

For the three months ended March 31, 2019, we recorded interest income of 0.3 million. This was primarily due to interest generated by our money market accounts.

The net interest expense of \$2.7 million in the three months ended March 31, 2018 primarily consisted of \$1.8 million debt discount amortization related to the JGB Debt and interest expense of \$0.9 million recorded on the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan.

Debt Extinguishment Expenses

In connection with the repayment and conversion to shares of common stock of all outstanding debt obligations during the three months ended March 31, 2018, we recorded \$2.8 million loss on the conversion of the convertible debt financing with JGB (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

The change in estimated fair value of common stock warrant liability and derivative liability was \$3.0 million expense in the three months ended March 31, 2019 and \$1.3 million income in the comparative period in 2018.

The \$3.0 million expense in the three months ended March 31, 2019 reflects changes in the fair value of our common stock warrant liability and a charge for warrants exercised in the three months period ended March 31, 2019. In the three months ended March 31, 2019, we recorded a revaluation charge of \$0.5 million on the 0.3 million common stock warrants outstanding at March 31, 2019. Approximately 70,000 warrants with an average exercise price of \$1.12 per share were exercised. The average price of our common stock at exercise was \$35.50 per share, resulting in a charge of \$2.5 million.

The \$1.3 million income in the three months ended March 31, 2018 was comprised of \$2.5 million of income related to the changes in fair value of the JGB Debt embedded derivative liability and \$1.2 million of expense related to the change in value of our common stock warrant liability.

Income Tax Benefit

For the three months ended March 31, 2019, we recorded an income tax benefit of \$0.6 million on a loss before income taxes of \$8.0 million. The effective tax rate for the three months ended March 31, 2019 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.

For the three months ended March 31, 2018, we recorded an income tax benefit of \$0.4 million on a loss before income taxes of \$9.4 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.

Cash Flows for the Three Months Ended March 31, 2019 and 2018

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

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (5,867)	\$ (4,518)
Investing activities	(543)	(754)
Financing activities	(688)	(2,318)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(87)	17
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (7,185)</u>	<u>\$ (7,573)</u>

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 three months ended March 31, 2019 was \$5.9 million. Our net loss of \$7.5 million was our primary use of cash in operating activities and included a number of noncash items. Our noncash items included a \$6.1 stock-based compensation expense, \$3.0 million loss on the revaluation of common stock warrant and derivative liabilities to estimated fair value, \$1.2 million of depreciation and amortization expense and \$0.4 million of non-cash lease expense. Net operating assets decreased by \$8.9 million.

Investing Activities

For the three months ended March 31, 2019, net cash used in investing activities was \$0.5 million related to purchases of property and equipment.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2019 of \$0.7 million was primarily related to repurchase of common stock under employee incentive plans of \$2.4 million and contingent payments related to the acquisition of Conexio Genomics Pty. Ltd of \$0.1 million, partially offset by proceeds from exercise of stock options of \$ 1.4 million, proceeds from issuance of common stock under employee stock purchase plan of \$0.3 million and proceeds from exercise of warrants of \$0.1 million.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$319.4 million at March 31, 2019. As of March 31, 2019, we had cash and cash equivalents of \$57.4 million and no debt outstanding.

Factors Affecting Our Performance

The Number of AlloMap and AlloSure Tests We Receive and Report

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

The Number of Diagnostic Products We Sell

The growth of our product revenues is tied to the sales of the Olerup SSP, 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.

The Protecting Access to Medicare Act of 2014, or PAMA, includes a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or 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 reimburses us \$3,240 for AlloMap testing of Medicare beneficiaries, an increase from the 2017 reimbursement rate of \$2,840. 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., TRICARE and UnitedHealthcare.

Reimbursement for AlloSure

On September 26, 2017 we received notice that the Molecular Diagnostics Services, or MoIDX, Program developed by Palmetto GBA had 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.

Continued Growth of Product Sales

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 HLA alleles based on SSP technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles. 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 PCR methodology. QTYPE received CE mark certification on April 10, 2018.

In May 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in transplantation diagnostic testing. As a result, from June 1, 2018, we are the exclusive worldwide distributor of Illumina's TruSight HLA v1 and v2 product line. In addition, we were also granted the exclusive right to develop and commercialize other NGS product lines for use in the Field, as defined in the agreement.

Development of Additional Products

We rely on sales of AlloMap, AlloSure, Olerup SSP, Olerup SBT, 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 research and development 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 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 March 31, 2019, 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 \$57.4 million and \$64.6 million at March 31, 2019 and December 31, 2018, respectively, which consisted of bank deposits and money market funds. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

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 Euro 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 March 31, 2019, would have negatively impacted our financial results for the three months ended March 31, 2019 by \$0.1 million and our product revenue by \$0.2 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 three months ended March 31, 2019 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, 2018, filed with the SEC on March 6, 2019, 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, 2018, filed with the SEC on March 6, 2019. 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.

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

Issuer Purchases of Equity Securities

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding obligations during the three months ended March 31, 2019:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)
January 1, 2019 - January 31, 2019	21,996	(1) \$	1.31
February 1, 2019 - February 28, 2019	24,161	(1)	5.69
March 1, 2019 - March 31, 2019	37,766	(1)	2.48
Total	83,923		—

(1) Represents shares of our common stock withheld from employees for the payment of taxes.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On May 6, 2019, Dr. James Yee, our Executive Vice President and Chief Medical Officer, informed us that he intends to retire as an employee of CareDx on June 28, 2019. Dr. Yee will begin serving as a consultant to us upon his retirement.

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 Incentive Plan.](#)
- 4.10(12)# [Form of Warrant.](#)
- 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.

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: May 8, 2019

By: /s/ PETER MAAG
Peter Maag
Chief Executive Officer
(Principal Executive Officer)

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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Peter Maag, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CareDx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

By: /s/ Peter Maag

Peter Maag
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Bell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CareDx, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2019

By: /s/ Michael Bell

Michael Bell

Chief Financial Officer

(Principal Accounting and Financial Officer)

