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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2020

or

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

For the transition period from to
Commission file number: 001-36536

CAREDX, INC.
(Exact name of registrant as specified in its charter)

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

1 Tower Place
South San Francisco, California 94080
(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)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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

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

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

There were 49,257,216 shares of the registrant's Common Stock issued and outstanding as of October 27, 2020.

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)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 213,798	$ 38,223
Accounts receivable	30,610	24,057
Inventory	9,906	6,014
Prepaid and other current assets	4,345	3,628
Total current assets	258,659	71,922
Property and equipment, net	10,144	4,430
Operating leases right-of-use assets	15,802	4,730
Intangible assets, net	43,830	45,541
Goodwill	23,857	23,857
Restricted cash	260	256
Other assets	1,000	1,000
Total assets	$ 353,552	$ 151,736
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,519	$ 5,506
Accrued compensation	13,791	12,484
Accrued and other liabilities	18,617	16,838
Deferred revenue - CMS advance payment (Note 1)	20,496	—
Total current liabilities	62,423	34,828
Deferred tax liability	1,187	1,973
Common stock warrant liability	532	6,607
Deferred payments for intangible assets	3,480	5,207
Operating lease liability, less current portion	16,539	2,370
Other liabilities	747	1,751
Total liabilities	84,908	52,736
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at September 30, 2020 and December 31, 2019; no shares issued and outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at September 30, 2020 and December 31, 2019; 49,132,348 shares and 42,498,430 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	47	42
Additional paid-in capital	621,961	437,976
Accumulated other comprehensive loss	(4,352)	(5,205)
Accumulated deficit	(349,012)	(333,813)
Total stockholders' equity	268,644	99,000
Total liabilities and stockholders' equity	$ 353,552	$ 151,736

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

CareDx, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Testing services revenue	$ 45,529	$ 28,226	$ 113,264	$ 75,421
Product revenue	5,383	4,200	13,369	13,226
Digital and other revenue	2,457	1,385	6,917	2,600
Total revenue	53,369	33,811	133,550	91,247
Operating expenses:				
Cost of testing services	11,900	7,421	30,631	21,928
Cost of product	3,705	2,986	9,635	9,161
Cost of digital and other	1,210	1,087	3,966	1,650
Research and development	12,474	8,521	35,616	21,765
Sales and marketing	13,870	11,058	37,727	28,627
General and administrative	13,117	9,485	35,436	27,103
Total operating expenses	56,276	40,558	153,011	110,234
Loss from operations	(2,907)	(6,747)	(19,461)	(18,987)
Other income (expense):				
Interest income, net	29	37	146	679
Change in estimated fair value of common stock warrant liability	79	4,346	(990)	(14)
CARES Act Provider Relief Fund	—	—	4,813	—
Other expense, net	(254)	(398)	(572)	(644)
Total other (expense) income	(146)	3,985	3,397	21
Loss before income taxes	(3,053)	(2,762)	(16,064)	(18,966)
Income tax benefit	235	949	865	1,775
Net loss	$ (2,818)	$ (1,813)	(15,199)	(17,191)
Net loss per share (Note 3):				
Basic	$ (0.06)	$ (0.04)	$ (0.33)	$ (0.41)
Diluted	$ (0.06)	$ (0.04)	$ (0.33)	$ (0.41)
Weighted-average shares used to compute net loss per share:				
Basic	49,010,680	42,393,550	45,526,810	42,048,647
Diluted	49,010,680	42,393,550	45,526,810	42,048,647

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

CareDx, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (2,818)	$ (1,813)	$ (15,199)	$ (17,191)
Other comprehensive loss:				
Foreign currency translation adjustments, net of tax	962	(863)	853	(1,656)
Net comprehensive loss	$ (1,856)	$ (2,676)	$ (14,346)	$ (18,847)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	42,498,430	$ 42	$ 437,976	$ (5,205)	$ (333,813)	$ 99,000
Issuance of common stock under ESPP	38,147	—	699	—	—	699
RSU settlements, net of shares withheld	139,552	—	(1,507)	—	—	(1,507)
Issuance of common stock for services	3,091	—	66	—	—	66
Issuance of common stock for cash upon exercise of stock options	44,861	—	155	—	—	155
Issuance of common stock for cash upon exercise of warrants	295,466	—	6,299	—	—	6,299
Employee stock-based compensation expense	—	—	4,200	—	—	4,200
Foreign currency translation adjustment	—	—	—	(1,705)	—	(1,705)
Net loss	—	—	—	—	(5,823)	(5,823)
Balance at March 31, 2020	43,019,547	$ 42	$ 447,888	$ (6,910)	$ (339,636)	$ 101,384
Issuance of common shares through public equity offering, net of commissions and offering costs of $9,166	4,492,187	4	134,580	—	—	134,584
Issuance of common shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $785	1,000,000	1	23,450	—	—	23,451
RSU settlements, net of shares withheld	143,101	—	(2,030)	—	—	(2,030)
Issuance of common stock for services	2,992	—	58	—	—	58
Issuance of common stock for cash upon exercise of stock options	204,469	—	1,962	—	—	1,962
Employee stock-based compensation expense	—	—	6,320	—	—	6,320
Foreign currency translation adjustment	—	—	—	1,596	—	1,596
Net loss	—	—	—	—	(6,558)	(6,558)
Balance at June 30, 2020	48,862,296	$ 47	$ 612,228	$ (5,314)	$ (346,194)	$ 260,767
Issuance of common stock under ESPP	38,576	—	694	—	—	694
RSU settlements, net of shares withheld	34,602	—	(466)	—	—	(466)
Issuance of common stock for services	2,731	—	96	—	—	96
Issuance of common stock for cash upon exercise of stock options	159,576	—	1,647	—	—	1,647
Issuance of common stock for cash upon exercise of warrants	34,567	—	1,109	—	—	1,109
Employee stock-based compensation expense	—	—	6,653	—		6,653
Foreign currency translation adjustment	—	—	—	962	—	962
Net loss	—	—	—	—	(2,818)	(2,818)
Balance at September 30, 2020	49,132,348	$ 47	$ 621,961	$ (4,352)	$ (349,012)	$ 268,644

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	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 stock-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
Change in estimated offering costs	—	—	50	—	—	50
RSU settlements, net of shares withheld	112,760	—	(1,597)	—	—	(1,597)
Issuance of common stock for services	1,663	—	52	—	—	52
Issuance of common stock for cash upon exercise of stock options	240,734	1	1,404	—	—	1,405
Issuance of common stock for cash upon exercise of warrants	38,806	—	612	—	—	612
Employee stock-based compensation expense	—	—	4,938	—	—	4,938
Foreign currency translation adjustment	—	—	—	(69)	—	(69)
Net loss	—	—	—	—	(7,847)	(7,847)
Balance at June 30, 2019	42,306,432	$ 42	$ 425,418	$ (5,071)	$ (327,223)	$ 93,166
Contingent consideration classified as equity	—	—	222	—	—	222
Issuance of common stock under ESPP	20,528	—	418	—	—	418
RSU settlements, net of shares withheld	2,140	—	(29)	—	—	(29)
Issuance of common stock for services	1,514	—	54	—	—	54
Issuance of common stock for cash upon exercise of stock options	81,473	—	476	—	—	476
Issuance of common stock upon exercise of warrants	9,028	—	—	—	—	—
Employee stock-based compensation expense	—	—	5,912	—	—	5,912
Foreign currency translation adjustment	—	—	—	(863)	—	(863)
Net loss	—	—	—	—	(1,813)	(1,813)
Balance at September 30, 2019	42,421,115	$ 42	$ 432,471	$ (5,934)	$ (329,036)	$ 97,543

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

CareDx, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net loss	$ (15,199)	$ (17,191)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	17,424	17,010
Revaluation of common stock warrant liability to estimated fair value	990	14
Depreciation and amortization	5,052	3,840
Loss on the write-off of fixed assets	—	160
Amortization of right-of-use assets	1,896	1,129
Revaluation of contingent consideration to estimated fair value	301	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,359)	(7,816)
Inventory	(3,608)	(1,327)
Prepaid and other assets	(681)	566
Operating leases liabilities, net	(1,096)	(1,436)
Accounts payable	3,831	1,003
Accrued compensation	1,501	1,038
Accrued and other liabilities	1,581	2,478
Deferred revenue - CMS advance payment	20,496	—
Change in deferred taxes	(879)	(1,154)
Net cash provided by (used in) operating activities	26,250	(1,686)
Investing activities:		
Acquisition of business	—	(18,119)
Acquisition of intangible assets	(3,250)	(1,148)
Investment in equity securities	—	(1,000)
Additions of capital expenditures, net	(6,670)	(970)
Net cash used in investing activities	(9,920)	(21,237)
Financing activities:		
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	134,684	—
Proceeds from issuance of common shares in "at-the-market" equity offering, net of issuance costs paid	23,451	—
Proceeds from issuance of common stock under employee stock purchase plan	1,082	760
Taxes paid related to net share settlement of restricted stock units	(4,003)	(4,004)
Proceeds from exercise of warrants	343	105
Proceeds from exercise of stock options	3,764	3,245
Principal payments on debt and finance lease obligations	(136)	(128)
Contingent payments related to the acquisition of Conexio Genomics Pty Ltd.	—	(192)
Net cash provided by (used in) financing activities	159,185	(214)
Effect of exchange rate changes on cash and cash equivalents	64	(493)
Net increase (decrease) in cash, cash equivalents and restricted cash	175,579	(23,630)
Cash, cash equivalents, and restricted cash at beginning of period	38,479	64,808
Cash, cash equivalents, and restricted cash at end of period	$ 214,058	$ 41,178

	September 30, 2020	December 31, 2019
Cash, Cash Equivalents and Restricted Cash as of:		
Cash and cash equivalents	$ 213,798	$ 38,223
Restricted cash	260	256
Total cash, cash equivalents and restricted cash at the end of period	$ 214,058	$ 38,479

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 leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. The Company's headquarters are in South San Francisco, California. The primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia and Stockholm, Sweden.

The Company's commercially available testing services consist of AlloSure® Kidney, which is a donor-derived cell-free DNA ("dd-cfDNA") solution for kidney transplant patients, and AlloMap® Heart, which is a gene expression solution for heart transplant patients. The Company has initiated several clinical studies to generate data on its existing and planned future testing services. In April 2020, the Company announced its first biopharma research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. 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. In 2019, the Company began providing digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management ("OttrCare") and XynManagement, Inc. ("XynManagement").

Testing Services

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017. The Medicare reimbursement rate for AlloSure Kidney is currently $2,841. AlloSure Kidney has received positive coverage decisions from Blue Cross Blue Shield ("BCBS") of South Carolina, BCBS of Kansas City and Capital Health, and is reimbursed by other private payers on a case-by-case basis.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers, including Aetna, Cigna, Health Care Services Corporation, Humana, Kaiser Foundation Health Plan, Inc. and UnitedHealthcare.

In October 2020, AlloSure Heart received a final positive Medicare coverage decision which provides coverage when used in conjunction with AlloMap Heart, with an effective date of November 2020.

AlloCell will initially be commercialized through collaborative research agreements with biopharma companies developing cell therapies.

Clinical Studies

In January 2018, the Company initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study ("K-OAR"), to develop additional data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients. K-OAR is a multicenter, non-blinded, prospective observational cohort study which has enrolled more than 1,600 renal transplant patients who will receive AlloSure Kidney long-term surveillance.

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 Heart with the dd-cfDNA analysis of AlloSure® Heart in one surveillance solution. In October 2020, AlloSure Heart received a final Medicare coverage decision. The Company has not yet made any applications to private payers for reimbursement coverage for 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. In June 2020, the Company submitted an AlloSure Lung application to the Palmetto MolDx Technical Assessment program seeking coverage and reimbursement for Medicare beneficiaries.

In September 2019, the Company announced the commencement of the Outcomes of KidneyCare on Renal Allografts ("OKRA") study, which is an extension of K-OAR. OKRA is a prospective, multi-center, observational, registry of patients receiving KidneyCare for surveillance. KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of KidneyCare iBox developing a multimodality surveillance solution. The Company has not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

Products

The Company's suite of AlloSeq products are commercial next generation sequencing ("NGS")-based kitted solutions that the Company has developed as a result of its license agreement with Illumina, Inc. ("Illumina"). These products include: AlloSeq™ Tx, a high-resolution Human Leukocyte Antigen ("HLA") typing solution, AlloSeq™ cfDNA, a surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq™ HCT, a solution for chimerism testing for stem cell transplant recipients.

The Company's other HLA typing products include: TruSight HLA, a NGS-based high resolution typing solution; Olerup SSP®, based on the sequence specific primer ("SSP") technology; and QTYPE®, which uses real-time polymerase chain reaction ("PCR") methodology, to perform HLA typing at a low to intermediate resolution for samples that require a fast turnaround time.

Digital and Other

Following the acquisitions of both OttrCare and XynManagement, the Company is a leading provider of transplant patient tracking software ("Ottr software"), as well as of transplant quality tracking and waitlist management solutions. Ottr software provides comprehensive solutions for transplant patient management and enables integration with electronic medical record ("EMR") systems providing patient surveillance management tools and outcomes data to transplant centers. XynManagement provides two unique solutions, XynQAPI software ("XynQAPI") and Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients ("SRTR") reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

In September 2020 we launched AlloCare, a mobile app that provides a patient-centric resource for transplant recipients to manage medication adherence, coordinate with Patient Care Managers for AlloSure scheduling and measure health metrics.

COVID-19 Pandemic

On January 30, 2020, the World Health Organization (the "WHO") announced a global health emergency because of a new strain of coronavirus ("COVID-19") originating in Wuhan, China and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. The full impact of the COVID-19 pandemic, including the impact associated with preventative and precautionary measures that the Company, other businesses and governments are taking, continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company, but the pandemic may materially affect the Company's financial condition, liquidity and future results of operations.

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, the Company experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020 the Company launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests. To date, more than 150 transplant centers can offer RemoTraC to their patients and over 5,000 kidney, heart, and lung transplant patients have enrolled. Based on existing and new relationships with partners, the Company has established a nationwide network of more than 10,000 mobile phlebotomists. Following the introduction of RemoTraC and with the easing of stay-at-home restrictions and the opening up of many hospitals to non-COVID-19 patients, the Company's testing services volumes returned to levels consistent with those experienced immediately prior to the COVID-19 pandemic, and volumes continued to be at or above those levels from May 2020 through to the end of the third quarter of 2020. The Company's product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as it was unable to undertake onsite discussions and demonstrations of its recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark approval in May 2020.

The Company is maintaining its testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among employees. In areas where COVID-19 impacts healthcare operations, the Company's field-based sales and clinical support teams are supporting providers through telephone and online platforms. In August 2020, the state of California released revised criteria for loosening and tightening restrictions on certain activities on generally a county-by-county basis. Under the updated executive orders, San Mateo County, where our laboratory and headquarters are located, continues to be subject to certain restrictions. These orders and others may be further modified, amended and adopted depending upon the COVID-19 transmission rates in our county and state, as well as other factors. In addition, the Company has created a COVID-19 task force that is responsible for crisis decision making, employee communications, enforcing pre-arrival temperature checking, daily health check-ins and enhanced safety training/protocols in its offices for employees that do not work from home.

Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $349.0 million at September 30, 2020. As of September 30, 2020, the Company had cash and cash equivalents of $213.8 million.

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020 the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act ("the CARES Act"). Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services ("CMS") expanded its current Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submits a request to the appropriate Medicare Administrative Contractor and meets the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million, and recorded the payment as Deferred revenue - CMS advance payment on the Company's condensed consolidated balance sheet. Refer to Note 7, Balance Sheet Components, for further explanation.

At-the-Market Equity Offering

On August 31, 2018, the Company entered into a sales agreement (the "Sales Agreement"), with Jefferies, LLC, as sales agent ("Jefferies"), pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to $50.0 million in shares of its common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During April 2020, the Company issued and sold 1,000,000 shares of its common stock under the Sales Agreement. The shares were sold at an average price of $24.24 per share for aggregate net proceeds to the Company of approximately $23.5 million, after deducting sales commissions and offering costs payable by the Company.

CARES Act Provider Relief Fund for Medicare Providers

Pursuant to the CARES Act, the U.S. Department of Health & Human Services ("HHS") distributed an initial tranche of $30.0 billion in funds to healthcare providers that received Medicare fee-for-service ("FFS") reimbursements in 2019. These payments to healthcare providers are not loans and will not be required to be repaid. As a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. Due to the recent enactment of legislation and absence of definitive guidance, there is a high degree of uncertainty around the CARES Act's implementation and the Company continues to assess the impact on its business. Furthermore, HHS has indicated that it, along with the Office of Inspector General, will be closely monitoring and auditing providers to ensure that recipients comply with the terms and conditions of relief programs and to prevent fraud and abuse. All providers will be subject to civil and criminal penalties for any deliberate omissions, misrepresentations or falsifications of any information given to HHS. Providers will be distributed a portion of the initial $30.0 billion of funds based on their share of total Medicare FFS reimbursements made by the U.S. in 2019. During April 2020, the Company received a payment of approximately $4.8 million representing its portion of the initial tranche of funds, recorded in other income (expense), net on the condensed consolidated statement of operations.

Underwritten Public Equity Offering

In June 2020, the Company sold 4,492,187 shares of common stock (which includes shares sold pursuant to the underwriters' full exercise of an overallotment option granted to the underwriters in connection with the offering) through an underwritten public offering at a price of $32.00 per share for aggregate net proceeds of approximately $134.6 million.

The Company may require additional financing in the future to fund working capital and the Company's future product developments. Additional financing might include issuance of equity securities and debt. 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 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, 2019, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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, 2019 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 notes 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, 2019 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 and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020.

Changes in Presentation

The presentation of certain prior period amounts within the previously disclosed cost of revenue have been changed, including separate line items for presentation of cost of testing services, cost of product and cost of digital and other. These changes in presentation 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; standalone fair value of digital revenue performance obligations; 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 September 30, 2020 and 2019, approximately 58% and 54%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2020 and 2019, approximately 56% and 39%, 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 September 30, 2020 and December 31, 2019, approximately 28% and 36%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either September 30, 2020 or December 31, 2019.

Leases

Effective January 1, 2019, the Company adopted Accounting Standard Codification ("ASC") Topic 842, *Leases* using the optional transition method and applied the standard only to leases that existed at that date. The Company determines if an arrangement is or contains a lease at contract inception. 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 Company's leases have remaining terms of 0.25 years to 8.42 years, some of which include options to extend the lease term.

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2018-15, *Intangibles – Goodwill and Other – Internal – Use Software (ASC 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 became 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 adopted the standard on January 1, 2020. The adoption of the new standard did not have a significant impact on the Company's condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (ASC Topic 820)* ("ASU 2018-13"), 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. ASU 2018-13 is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting periods 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 adopted the standard on January 1, 2020. The adoption of the new standard did not have a significant impact on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments (ASC Topic 326)* ("ASU 2016-13"), which amends the FASB's guidance on the impairment of financial instruments. The ASU adds to U.S. GAAP an impairment model known as the current expected credit loss ("CECL") model, which is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as an allowance its estimate of lifetime expected credit losses, which the FASB believes will result in more timely recognition of such losses. The new CECL standard is effective for public companies for annual reporting periods beginning after December 15, 2019, and interim periods therein. ASU 2016-13 has a greater impact on banks. However, nonbank entities that have financial instruments or other assets such as trade receivables, contract assets, lease receivables, financial guarantees, loans and loan commitments, and held-to-maturity debt securities are subject to the CECL model. The Company adopted the standard on January 1, 2020. The adoption of the new standard did not have an impact on the Company's condensed consolidated financial statements.

3. NET LOSS PER SHARE

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss used to compute basic and diluted net loss per share	$ (2,818)	$ (1,813)	$ (15,199)	$ (17,191)
Denominator:				
Weighted-average shares used to compute basic and diluted net loss per share	49,010,680	42,393,550	45,526,810	42,048,647
Net loss per share:				
Basic and diluted	$ (0.06)	$ (0.04)	$ (0.33)	$ (0.41)

The following potentially dilutive securities have been excluded from diluted net loss per share as at September 30, 2020 and 2019 because their effect would be antidilutive:

	Three and Nine Months Ended September 30,	
	2020	2019
Shares of common stock subject to outstanding options	3,082,273	2,668,388
Shares of common stock subject to outstanding common stock warrants	14,445	355,240
Restricted stock units	1,912,397	1,552,466
Total common stock equivalents	5,009,115	4,576,094

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

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis, as of September 30, 2020 and December 31, 2019 (in thousands):

	September 30, 2020			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 197,187	$ —	$ —	$ 197,187
Liabilities				
Common stock warrant liability	$ —	$ —	$ 532	$ 532

	December 31, 2019			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 29,177	$ —	$ —	$ 29,177
Liabilities				
Common stock warrant liability	$ —	$ —	$ 6,607	$ 6,607

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, 2019	$ 6,607
Exercise of warrants	(7,065)
Change in estimated fair value	990
Balance as of September 30, 2020	$ 532

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. Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. At September 30, 2020 and December 31, 2019, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *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:

	September 30, 2020	December 31, 2019
Private Placement Common Stock Warrant Liability		
Stock Price	$ 37.94	$ 21.57
Exercise Price	$ 1.12	$ 1.12
Remaining term (in years)	2.54	3.29
Volatility	73.00 %	81.00 %
Risk-free interest rate	0.15 %	1.62 %

5. BUSINESS COMBINATIONS

OttrCare

On May 7, 2019, the Company acquired 100% of the outstanding common stock of OttrCare for total consideration of $16.1 million. OttrCare was formed in 1993 and is a leading provider of organ transplant patient tracking software. The Ottr software provides comprehensive solutions for transplant patient management and enables integration with EMR systems providing patient surveillance management tools and outcomes data to transplant centers.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Results of operations of OttrCare have been included with the Company's results since the date of the acquisition. Acquisition-related costs of $0.6 million associated with the acquisition were expensed as incurred, and classified as part of general and administrative expenses in the condensed consolidated statement of operations.

Goodwill of $10.2 million arising from the acquisition primarily consists of synergies from integrating the Ottr software with transplant center EMR systems and the current testing solutions offered by the Company. Goodwill synergies also arise from acquired workforce know-how of transplant centers workflow. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been assigned to the Company's existing operating segment.

The following table summarizes the consideration paid for OttrCare and the provisional amounts of the assets acquired and liabilities assumed recognized at their estimated fair value at the acquisition date (in thousands):

	Total
Consideration	
Cash	$ 16,037
Accrued purchase consideration	111
Total consideration	$ 16,148
Recognized amounts of identifiable assets acquired and liabilities assumed	
Current assets	$ 1,525
Fixed assets	35
Identifiable intangible assets	6,600
Current liabilities	(2,210)
Total identifiable net assets acquired	5,950
Goodwill	10,198
Total consideration	$ 16,148

The allocation of the purchase price to assets acquired and liabilities assumed was based on the Company's best estimate of the fair value of such assets and liabilities as of the acquisition date.

The fair value of the acquired current liabilities as of June 30, 2019 included a preliminary deferred revenue balance of $2.3 million. During the three months ended September 30, 2019, the Company recorded an adjustment of $0.5 million to the initial valuation amount of deferred revenue, decreasing its balance to $1.8 million as of the acquisition date. This change is a result of updated assumptions and methodologies for acquired software maintenance contracts. As part of this adjustment, goodwill decreased by approximately $0.5 million.

At the acquisition date the Company estimated net deferred tax assets of approximately $0.2 million arising from temporary differences related to assets acquired and liabilities assumed. The Company estimated that OttrCare had net operating losses ("NOLs") carryforward of approximately $6.9 million, $4.3 million of which will begin to expire in 2033, and the remaining $2.6 million will be carried forward indefinitely. A full valuation allowance of $0.2 million was recognized as of the acquisition date resulting in no impact from deferred taxes to OttrCare's opening balance. An Internal Revenue Code Section 382 study for NOLs was finalized during the third quarter of 2019 and deferred taxes acquired are finalized as of December 31, 2019.

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

	Estimated Fair Value	Estimated Useful Lives (Years)
Customer relationships	$ 4,200	15
Developed technology	2,300	10
Trademark	100	2
Total	$ 6,600	

Customer relationships acquired by the Company represent the fair value of future projected revenue that is expected to be derived from sales of OttrCare's products to existing customers. The customer relationships' fair value has been estimated utilizing a multi-period excess earnings method under the 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 distribution of the present value of the cash flows attributable to the intangible asset.

The acquired developed technology represents the fair value of OttrCare's proprietary software. The trademark acquired consists primarily of the OttrCare brand and markings. The fair value of both the developed technology and the trademark were determined using the relief-from-royalty method under the income approach. This method considers the value of the asset to be the value of the royalty payments from which the Company is relieved of due to its ownership of the asset. The royalty rates of 15.0% and 1.0% were used to estimate the fair value of the developed technology and the trademark, respectively.

The Company utilized a discount rate of 14.5% in estimating the fair value of these three intangible assets. Unaudited supplemental pro forma information is not disclosed because it is considered immaterial.

XynManagement

On August 26, 2019, the Company acquired 100% of the outstanding common stock of XynManagement for total cash consideration of $2.0 million. As a result of the acquisition, the Company recognized contingent consideration of $1.4 million, including liability and equity components, goodwill of $1.7 million and intangible assets of $2.1 million. Goodwill synergies arise from acquired workforce know-how of transplant centers workflow. The goodwill for this acquisition is not deductible for income tax purposes. The contingent consideration relates to potential future cash payments upon reaching specified revenue and non-financial targets.

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.

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 and nine months ended September 30, 2020. The balance of the Company's goodwill as of September 30, 2020 was $23.9 million.

Intangible Assets

The following tables present details of the Company's intangible assets as of September 30, 2020 ($ in thousands):

	September 30, 2020				
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
Intangible assets with finite lives:					
Acquired and developed technology	$ 31,209	$ (8,323)	$ (1,573)	$ 21,313	9.4
Customer relationships	18,168	(4,349)	(1,239)	12,580	11.1
Commercialization rights	8,079	(837)	—	7,242	8.9
Trademarks and tradenames	2,360	(755)	(160)	1,445	10.1
Total intangible assets with finite lives	$ 59,816	$ (14,264)	$ (2,972)	$ 42,580	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	$ 61,066	$ (14,264)	$ (2,972)	$ 43,830	

The following table presents details of the Company's intangible assets as of December 31, 2019 ($ in thousands):

	December 31, 2019				
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
Intangible assets with finite lives:					
Acquired and developed technology	$ 29,106	$ (6,473)	$ (1,852)	$ 20,781	8.2
Customer relationships	18,168	(3,397)	(1,498)	13,273	10.1
Commercialization rights	8,079	(231)	—	7,848	9.7
Trademarks and tradenames	2,360	(618)	(206)	1,536	9.1
Total intangible assets with finite lives	$ 57,713	$ (10,719)	$ (3,556)	$ 43,438	
Acquired in-process technology	2,103	—	—	2,103	
Total intangible assets	$ 59,816	$ (10,719)	$ (3,556)	$ 45,541	

Acquisition of intangible assets

In June 2020, the Company commercially launched AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients. This technology can provide better sensitivity and data analysis compared to current solutions on the market.

AlloSeq HCT, previously included in Acquired in-process technology as of December 31, 2019, is included in Acquired and developed technology as of September 30, 2020.

Cibiltech License and Commercialization Agreement

Effective April 30, 2019, the Company entered into a license and commercialization agreement (the "Cibiltech Agreement") with Cibiltech SAS ("Cibiltech"). Cibiltech is a French company engaged in the development and support of predictive medicine and artificial intelligence software, services and technology, with an emphasis on personalized patient care and clinical research, including its proprietary software and service offering known in the U.S. as KidneyCare iBox for the predictive analysis of post-transplantation kidney allograft loss. The Cibiltech Agreement provides the Company with an irrevocable, non-transferable right to commercialize Cibiltech's proprietary software in the field of transplantation in the U.S. for a period of ten years. The Company estimated the fair value of the acquired commercialization rights intangible asset based on expected contractual payments discounted to present value using a discount rate of 6%. In September 2019, the Company initiated the OKRA clinical study, which incorporates KidneyCare iBox. On such date, the Company commenced amortization of the acquired commercialization intangible asset.

On July 26, 2019, pursuant to the Cibiltech Agreement, the Company purchased $1.0 million of convertible preferred shares of Cibiltech, which is recorded in other assets. The Company does not have a significant influence on Cibiltech's operations. The net carrying amount of intangible assets and the related amortization expense of intangible assets may change due to the effects of foreign currency fluctuations as a result of acquiring an entity with a functional currency other than the U.S. dollar.

Amortization of Intangible Assets

Amortization expense was $1.2 million and $0.8 million for the three months ended September 30, 2020 and 2019, respectively. For the three months ended September 30, 2020, expenses of $0.3 million, $0.4 million, $0.1 million and $0.4 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively. For the three months ended September 30, 2019, expenses of $0.1 million, $0.3 million, $0.1 million and $0.3 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively. Amortization expense was $3.5 million and $2.1 million for the nine months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020, expenses of $1.0 million, $1.2 million, $0.2 million and $1.1 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively. For the nine months ended September 30, 2019, expenses of $0.1 million, $1.0 million, $0.1 million and $0.9 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2020 (in thousands):

Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Digital and Other	Sales and Marketing	Total
Remainder of 2020	$ 329	$ 439	$ 86	$ 372	$ 1,226
2021	1,316	1,710	345	1,300	4,671
2022	1,316	1,710	345	1,282	4,653
2023	1,316	1,710	345	1,282	4,653
2024	1,316	1,710	345	1,282	4,653
Thereafter	6,773	5,906	1,537	8,508	22,724
Total future amortization expense	$ 12,366	$ 13,185	$ 3,003	$ 14,026	$ 42,580

7. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Finished goods	$ 1,550	$ 1,236
Work in progress	2,520	1,189
Raw materials	5,836	3,589
Total inventory	$ 9,906	$ 6,014

Accrued and other liabilities

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

	September 30, 2020	December 31, 2019
Deferred revenue	$ 3,213	$ 3,686
Clinical studies	5,351	3,068
Deferred payments for intangible assets	2,042	2,098
Short-term lease liability	1,872	3,017
Test sample processing fees	368	835
Accrued royalty	996	547
Contingent consideration	1,730	810
Professional fees	1,502	766
Other accrued expenses	1,543	2,011
Total accrued and other liabilities	$ 18,617	$ 16,838

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020, the U.S. government enacted the CARES Act. Pursuant to the CARES Act, CMS expanded its current Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submits a request to the appropriate Medicare Administrative Contractor and meets the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on the Company's condensed consolidated balance sheet.

The Company can repay the advance in full at any time or make repayments as per the following:

- Repayment will begin one year after the date the accelerated or advance payment was issued.
- During the first eleven months after repayment begins, repayment will occur through an automatic recoupment of 25 percent of Medicare payments otherwise owed to the Company.
- During the succeeding six months, repayment will occur through an automatic recoupment of 50 percent of Medicare payments otherwise owed to the Company.
- If the Company is unable to pay the total amount of the accelerated or advance payment through recoupment within 29 months, the Company will receive a demand letter requiring repayment of any outstanding balance, subject to an interest rate of four percent.

8. COMMITMENTS AND CONTINGENCIES

Leases

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

On January 2, 2020, the Company executed the second amendment to the operating lease agreement for the building located at Brisbane, California. The building is mainly utilized for laboratory operations and research and development. The lease will be extended for a period of eight years and two months starting on January 1, 2021. The Company has determined that the amendment constitutes a lease modification effective January 1, 2020. At the inception of the lease modification, the ROU asset increased by $13.0 million.

The Company's facility leases expire at various dates through 2029. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

As of September 30, 2020, the carrying value of the ROU asset was $15.8 million. The related current and non-current liabilities as of September 30, 2020 were $1.9 million and $16.5 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the condensed consolidated balance sheets.

The following table summarizes the lease cost for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost	$ 1,120	$ 453	$ 3,353	$ 1,358
Finance lease cost	51	54	155	164
Total lease cost	$ 1,171	$ 507	$ 3,508	$ 1,522

Finance lease cost includes interest from the lease liability and amortization of the ROU asset.

Other information:	
Weighted-average remaining lease term - Operating leases (in years)	7.45
Weighted-average remaining lease term - Finance leases (in years)	0.61
Weighted-average discount rate - Operating leases (%)	10.5%
Weighted-average discount rate - Finance leases (%)	6.0%

Rent expense under non-cancelable operating leases was $1.2 million and $0.5 million for the three months ended September 30, 2020 and 2019, respectively. Rent expense under non-cancelable operating leases was $3.6 million and $1.4 million for the nine months ended September 30, 2020 and 2019, respectively. Future minimum lease commitments under these operating and finance leases as of September 30, 2020 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
Remainder of 2020	$ 52	$ 857
2021	71	3,530
2022	—	3,967
2023	—	2,811
2024	—	2,909
Thereafter	—	13,267
Total future minimum lease payments	$ 123	$ 27,341

The current portion of obligations under finance leases are included in accrued and other liabilities, and the long-term portion of finance leases are included in other liabilities within 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 (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 payments and royalties in the low single digits of net sales of products incorporating the licensed technology.

Illumina

On May 4, 2018, the Company entered into a license agreement with Illumina (the “Illumina Agreement”). The Illumina Agreement requires the Company to pay royalties in the mid-single to low-double digits on sales of products covered by the Illumina Agreement.

Cibiltech Commitments

Pursuant to the Cibiltech Agreement, the Company will share an agreed-upon percentage of revenue with Cibiltech, if and when revenues are generated from KidneyCare iBox.

Other Commitments

Pursuant to the Illumina Agreement, the Company has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

Litigation and Indemnification Obligations

In response to the Company's false advertising suit filed against Natera Inc. (“Natera”), on April 10, 2019, Natera filed a counterclaim against the Company on February 18, 2020, in the U.S. District Court for the District of Delaware (the “Court”) alleging the Company made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of Court to amend its counterclaims to include additional allegations regarding purportedly false claims the Company made with respect to AlloSure; the Court has not yet ruled on Natera’s request. In addition, in response to the Company's patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against the Company on January 13, 2020, in the U.S. District Court for the District of Delaware alleging, among other things, that AlloSure also infringes Natera’s U.S. Patent 10,526,658. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera’s U.S. Patent 10,597,724. The suit seeks a judgment that the Company has infringed Natera’s patents, an order preliminarily and permanently enjoining the Company from any further infringement of such patents and unspecified damages. The Company intends to defend both of these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for these suits.

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 condensed consolidated financial statements indicates that it is probable that a liability had been incurred at the date of the condensed consolidated financial statements and (ii) the range of loss can be reasonably estimated.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at the Company’s request in such capacities. There have been no claims to date and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of September 30, 2020 and as of December 31, 2019.

9. 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 $0.1 million for each of the three months ended September 30, 2020 and 2019, respectively. The Company incurred expenses related to contributions to the plan of $0.6 million and $0.5 million for the nine months ended September 30, 2020 and 2019, respectively.

10. WARRANTS

The Company has issued common stock warrants in connection with debt or equity financings to lenders, placement agents and investors. 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. Warrants that are classified as equity are valued at their relative fair value on the date of issuance, recorded in additional paid in capital and not remeasured.

In the three months ended September 30, 2020, warrants to purchase approximately 35,000 shares of common stock were exercised for cash proceeds of less than $0.1 million. In the nine months ended September 30, 2020, warrants to purchase approximately 307,000 shares of common stock were exercised for cash proceeds of $0.3 million. During the three months ended September 30, 2020, no warrants to purchase shares of common stock were exercised on a cashless basis. During the nine months ended September 30, 2020, a warrant to purchase approximately 34,000 shares of common stock was exercised on a cashless basis and approximately 24,000 shares were issued pursuant to the exercise.

In the three months ended September 30, 2019, there were no warrants exercised to purchase shares of common stock for cash proceeds. During the three months ended September 30, 2019, warrants to purchase approximately 111,400 shares of common stock were exercised on a cashless basis and approximately 9,000 shares were issued pursuant to the exercises. In the nine months ended September 30, 2019, warrants to purchase approximately 94,000 shares of common stock were exercised for cash proceeds of $0.1 million. During the nine months ended September 30, 2019, approximately 207,400 warrants were exercised on a cashless basis and approximately 49,000 shares were issued pursuant to the exercises.

As of September 30, 2020, outstanding warrants to purchase common stock were:

	Classified as	Original Term	Exercise Price	Number of Shares Underlying Warrants
Original issue date:				
April 2016	Liability	7 years	$ 1.12	14,445
				14,445

11. STOCK INCENTIVE PLANS

Stock Options and Restricted Stock Units ("RSU")

The following table summarizes option and RSU activity under the Company's 2014 Equity Incentive Plan, 2016 Inducement Equity Incentive Plan, and 2019 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, 2019	504,775	2,609,848	$ 16.47	1,516,285	$ 22.51
Additional options authorized	1,699,549	—	—	—	—
Common stock awards for services	(8,814)	—	—	—	—
RSUs granted	(1,108,504)	—	—	1,108,504	26.64
RSUs vested	—	—	—	(552,117)	22.07
Options granted	(1,034,939)	1,034,939	28.30	—	—
Options exercised	—	(406,406)	5.18	—	—
Repurchase of common stock under employee incentive plans	159,749	—	—	—	—
RSUs forfeited	160,275	—	—	(160,275)	25.17
Options forfeited	133,196	(133,196)	25.48	—	—
Options expired	22,912	(22,912)	16.97	—	—
Balance—September 30, 2020	528,199	3,082,273	$ 21.01	1,912,397	$ 16.37

The total intrinsic value of options exercised was $4.0 million and $8.0 million in the three and nine months ended September 30, 2020, respectively. The total intrinsic value of options exercised was $2.3 million and $14.3 million in the three and nine months ended September 30, 2019, respectively.

As of September 30, 2020, the total intrinsic value of outstanding RSUs was approximately $72.4 million and there were $37.0 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.33 years.

Options outstanding that have vested and are expected to vest at September 30, 2020 are as follows:

	Number of Shares Issued (In thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	1,137	$ 14.27	6.74	$ 26,916
Expected to vest	1,797	24.92	8.90	23,391
Total	2,934			$ 50,307

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at September 30, 2020 for stock options that were in-the-money.

The total fair value of options that vested during the three and nine month periods ended September 30, 2020 was $1.9 million and $7.4 million, respectively. As of September 30, 2020, there were approximately $27.1 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 3.02 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 respective 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 2020 that ended on June 30, 2020, 38,576 shares were purchased for aggregate proceeds of $0.7 million from the issuance of shares, which occurred on July 1, 2020. During the offering period in 2019 that ended on December 31, 2019, 38,147 shares were purchased for aggregate proceeds of $0.7 million from the issuance of shares, which occurred on January 2, 2020.

Valuation Assumptions

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Employee stock options				
Expected term (in years)	6.0	5.9	6.0	6.0
Expected volatility	77.24%	69.90%	76.12%	70.63%
Risk-free interest rate	0.36%	1.72%	0.69%	2.35%
Expected dividend yield	—%	—%	—%	—%
Employee stock purchase plan				
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	93.17%	70.80%	75.36%	73.40%
Risk-free interest rate	0.17%	2.10%	0.98%	2.28%
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 and nine months ended September 30, 2020 and 2019, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of testing services	$ 431	$ 294	$ 1,101	$ 1,423
Cost of product	97	77	289	192
Cost of digital and other	124	54	338	90
Research and development	1,224	954	3,490	3,227
Sales and marketing	1,623	1,125	4,175	2,796
General and administrative	3,249	3,460	8,031	9,282
Total	$ 6,748	$ 5,964	$ 17,424	$ 17,010

No tax benefit was recognized related to stock-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.

12. INCOME TAXES

The Company's effective tax rate may vary from the U.S. federal statutory tax rate due to the change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income. For the three and nine months ended September 30, 2020, the Company recorded an income tax benefit of $0.2 million and $0.9 million, respectively, compared to $0.9 million and $1.8 million for the three and nine months ended September 30, 2019, respectively. The income tax benefit of $0.2 million and $0.9 million for the three and nine months ended September 30, 2020, respectively, is primarily attributable to the recognition of deferred tax assets from foreign losses and acquired deferred tax liabilities that generate a source of income for the recognition of deferred tax assets previously not recognized. 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. The Company has also placed a valuation allowance on the net deferred tax assets of its Australian operations. Accordingly, the U.S. and Australia 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. The Company has not made an election with respect to GILTI and does not believe that GILTI will have a material impact on the Company's 2020 taxes. The Company will continue to review the GILTI and BEAT rules to determine their applicability to the Company and the impact that the rules may have on the Company's results of operations and financial condition.

13. 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. In determining its reportable segments, the Company considered the markets and types of customers served and the products or services provided in those markets. The Company 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Testing services revenue				
United States	$ 45,439	$ 28,126	$ 112,976	$ 75,011
Rest of World	90	100	288	410
	$ 45,529	$ 28,226	$ 113,264	$ 75,421
Product revenue				
United States	$ 2,755	$ 1,606	$ 6,032	$ 5,606
Europe	1,950	1,963	5,448	5,812
Rest of World	678	631	1,889	1,808
	$ 5,383	$ 4,200	$ 13,369	$ 13,226
Digital and other revenue				
United States	$ 2,409	$ 1,332	$ 6,745	$ 2,462
Europe	24	31	64	90
Rest of World	24	22	108	48
	$ 2,457	$ 1,385	$ 6,917	$ 2,600
Total United States	$ 50,603	$ 31,064	$ 125,753	$ 83,079
Total Europe	$ 1,974	$ 1,994	$ 5,512	$ 5,902
Total Rest of World	$ 792	$ 753	$ 2,285	$ 2,266
Total	$ 53,369	$ 33,811	$ 133,550	$ 91,247

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

	September 30, 2020	December 31, 2019
Long-lived assets:		
United States	$ 9,274	$ 3,346
Europe	376	509
Rest of World	494	575
Total	$ 10,144	$ 4,430

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 consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2020.

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," "should," "would," "project," "plan," "target," "contemplate," "predict," "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:

- the potential impact to our business, revenue, financial condition and employees, including disruptions to our testing services, laboratories, clinical trials, supply chain and operations, due to the COVID-19 global pandemic;
- our ability to take advantage of opportunities under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and the potential impact of the CARES Act on our business, results of operations, financial condition or liquidity;
- our ability to generate revenue and increase the commercial success of our current and future testing services, products and digital solutions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for our current and other future testing services, if any;
- our plans and ability to continue updating our testing services, products and digital solutions to maintain our leading position in transplantations;
- the outcome or success of our clinical trial collaborations and registry studies, including Kidney Allograft Outcomes AlloSure Registry, or K-OAR, the Outcomes of KidneyCare™ on Renal Allografts registry study, or OKRA, and the Surveillance HeartCare Outcomes Registry, or SHORE;
- 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, 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, 2019, filed with the SEC on February 28, 2020. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-

looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC as exhibits to this Quarterly Report on Form 10-Q 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

CareDx, Inc. (collectively, the "Company", "we", "us" and "our") is a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. We offer testing services, products, and digital healthcare solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients.

Highlights for the Three Months Ended September 30, 2020 and Recent Highlights

- Achieved total revenue of $53.4 million for the three months ended September 30, 2020, increasing 58% year-over-year
- Provided over 21,800 AlloSure Kidney and AlloMap Heart patient results
- Received final positive Medicare coverage decision for AlloSure Heart
- Announced publication of pivotal AlloSure Lung data

Testing Services

Heart

AlloMap Heart 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 Heart solution through ongoing studies to substantiate the clinical utility and actionability, secure positive reimbursement decisions 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 Heart, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant, can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and may help to determine the appropriate dosage levels of immunosuppressants. In 2008, AlloMap Heart received 510(k) clearance from the U.S. Food and Drug Administration for marketing and sale as a test to aid in the identification of heart transplant recipients, who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 1, 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240. AlloMap Heart 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, or HCSC, Humana, Kaiser Foundation Health Plan, Inc., several Blue Cross Blue Shield, or BCBS, Plans and UnitedHealthcare.

We have also successfully completed several landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap Heart for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap Heart based on 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 Heart 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. AlloMap Heart is now recommended as part of the International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

HeartCare includes the gene expression profiling technology of AlloMap Heart with the donor-derived cell-free DNA, or dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap Heart – a measure of immune activation, and (ii) AlloSure Heart – a measure of graft injury.

Clinical validation data from the Donor-Derived Cell-Free DNA-Outcomes AlloMap Registry (NCT02178943), or D-OAR, was published in American Journal of Transplant, or AJT, in 2019. D-OAR was an observational, prospective, multicenter study to characterize the AlloSure-Heart dd-cfDNA in a routine, clinical surveillance setting with heart transplant recipients. The D-OAR study was designed to validate that plasma levels of AlloSure-Heart dd-cfDNA can discriminate acute rejection from no rejection, as determined by endomyocardial biopsy criteria.

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection, or ACR, and Antibody Mediated Rejection. In September 2018, we initiated the SHORE study. SHORE is a prospective, multi-center, observational, registry of patients receiving HeartCare for surveillance. Patients enrolled in SHORE will be followed for 5 years with collection of clinical data and assessment of 5-year outcomes.

In October 2020, AlloSure Heart received a final Medicare coverage decision which provides coverage when used in conjunction with AlloMap Heart, with an effective date of November 2020.

Kidney

AlloSure Kidney, our transplant surveillance solution, which was commercially launched in October 2017, is our dd-cfDNA offering built on a Next Generation Sequencing, or NGS, platform. In transplantation, 109 papers from 55 studies globally have shown the value of dd-cfDNA in the management of solid organ transplantation. AlloSure is able to discriminate dd-cfDNA from recipient-cell-free DNA, targeting polymorphisms between donor and recipient. This single-nucleotide polymorphism, or SNPs, approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable, high-quality test to differentiate dd-cfDNA.

AlloSure Kidney has received positive coverage decisions for reimbursement from Medicare. The Medicare reimbursement rate for AlloSure Kidney is $2,841. AlloSure Kidney has received positive coverage decisions from BCBS of South Carolina, BCBS of Kansas City and Capital Health, and is reimbursed by other private payers on a case-by-case basis.

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated. AlloSure provides a non-invasive test, assessing allograft injury that enables more frequent, quantitative and safer assessment of allograft rejection and injury status. Beyond allograft rejection, the assessment of molecular inflammation has shown further utility in the assessment of proteinuria, formation of De Novo donor specific antibodies, or DSAs, and as a surrogate predictive measure of estimated glomerular filtration rate, or eGFR, decline. Monitoring of graft injury through AlloSure allows clinicians to optimize allograft biopsies, identify allograft injury and guide immunosuppression management more accurately.
Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016 before the commercial launch of AlloSure Kidney, an increasing body of evidence supports the use of AlloSure dd-cfDNA in the assessment and surveillance of kidney transplants. Bloom et al evaluated 102 kidney recipients and demonstrated that dd-cfDNA levels could discriminate accurately and non-invasively distinguish rejection from other types of graft injury. In contrast, serum creatinine has area under the curve, or AUC, of 50%, showing no significant difference between patients with and without rejection. Multiple publications and abstracts have shown AlloSure's value in the management of BK viremia, as well as numerous pathologies that cause molecular inflammation and injury such as DSAs and eGFR decline. Most recently its utility in the assessment of T-cell mediated rejection (TCMR) 1A and borderline rejection has also been published in the AJT.

The prospective multicenter trial: the K-OAR study, is currently ongoing and has enrolled over 1,600 patients, with plans to survey patients with AlloSure for 3 years and provide further clinical utility of AlloSure Kidney in the surveillance of kidney transplant recipients.

KidneyCare

KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of KidneyCare iBox in one surveillance solution. We have not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

In September 2019, we announced the enrollment of the first patient in the OKRA study, which is an extension of the K-OAR study. OKRA is a prospective, multi-center, observational registry of patients receiving KidneyCare for surveillance. Combined with K-OAR, 4,000 patients will be enrolled into the study.

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. One of these studies, launched in April 2020, is the ALARM study, or AlloSure Lung Allograft Remote Monitoring, with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC

will be measured. AlloSure Lung applies proprietary NGS technology to measure dd-cfDNA from the donor lung in the recipient bloodstream to monitor graft injury. In June 2020, we submitted an application to the Palmetto MolDx Technology Assessment program seeking coverage and reimbursement for AlloSure Lung.

Cellular Therapy

In April 2020, we initiated a research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. AlloCell will initially be commercialized through collaborative research agreements with biopharma companies developing cell therapies.

Products

We develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a solid organ or stem cell donor and a recipient, and help to provide post-transplant surveillance of these recipients.

QTYPE enables 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. 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 a license agreement with Illumina, Inc., or the Illumina Agreement, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS products and technologies for use in transplantation diagnostic testing.

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 in the field of bone marrow and solid organ transplantation on diagnostic testing. These NGS 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 HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark approval on January 10, 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

Also in September 2019, we commercially launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than current solutions and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has simple NGS workflow, with a single tube for processing and steps to reduce errors. AlloSeq Tx 17 received CE mark approval on May 15, 2020.

In June 2020, we commercially launched AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients. This technology can provide better sensitivity and data analysis compared to current solutions on the market.

Digital

In 2019, we began providing digital solutions to transplant centers following the acquisition of Ottr Complete Transplant Management, or OttrCare, and XynManagement, Inc., or XynManagement.

On May 7, 2019, we acquired 100% of the outstanding common stock of OttrCare. OttrCare was formed in 1993 and is a leading provider of transplant patient tracking software, or the Ottr software, which provides comprehensive solutions for transplant patient management. The Ottr software enables integration with electronic medical records, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

On August 26, 2019, we acquired 100% of the outstanding common stock of XynManagement. XynManagement provides two unique solutions, XynQAPI software, or XynQAPI, and Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients, or SRTR, reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

In September 2020 we launched AlloCare, a mobile app that provides a patient-centric resource for transplant recipients to manage medication adherence, coordinate with Patient Care Managers for AlloSure scheduling and measure health metrics.

COVID-19 Impact

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, we experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020 we launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests. To date, more than 150 transplant centers can offer RemoTraC to their patients and over 5,000 kidney, heart, and lung transplant patients have enrolled. Based on existing and new relationships with partners, we have established a nationwide network of more than 10,000 mobile phlebotomists. Following the introduction of RemoTraC and with the easing of stay-at-home restrictions and the opening up of many hospitals to non-COVID-19 patients, the Company's testing services volumes returned to levels consistent with those experienced immediately prior to the COVID-19 pandemic, and volumes continued to be at or above those levels from May 2020 through to the end of the third quarter of 2020. The Company's product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as it was unable to undertake onsite discussions and demonstrations of its recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark approval in May 2020.

We are maintaining our testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among our employees. In areas where COVID-19 impacts healthcare operations, our field-based sales and clinical support teams are supporting providers through telephone and online platforms. In August 2020, the state of California released revised criteria for loosening and tightening restrictions on certain activities on generally a county-by-county basis. Under the updated executive orders, San Mateo County, where our laboratory and headquarters are located, continues to be subject to certain restrictions. These orders and others may be further modified, amended and adopted depending upon the COVID-19 transmission rates in our county and state, as well as other factors. In addition, we have created a COVID-19 task force that is responsible for crisis decision making, employee communications, enforcing pre-arrival temperature checking, daily health check-ins and enhanced safety training/protocols in our offices for employees that do not work from home.

Due to COVID-19, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, there may be disruptions in our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities.

In addition, our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

Financial Operations Overview

Revenue

We derive our revenue from testing services, products sales and digital and other revenues. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

Our testing services revenue is derived from AlloSure Kidney and AlloMap Heart tests, which represented 85% of our total revenues for each of the three and nine months ended September 30, 2020, and 83% of our total revenues for each of the three and nine months ended September 30, 2019. 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; and (v) 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.

In April 2020, we announced our first biopharma research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. AlloCell will initially be commercialized through collaborative research agreements with biopharma companies developing cell therapies.

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP, QTYPE and TruSight products. Product revenue represented 10% of total revenue for each of the three and nine months ended September 30, 2020, and 12% and 14% of total revenue for the three and nine months ended September 30, 2019, 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.

Digital and Other Revenue

Our digital and other revenue is mainly derived from sales of our Ottr software and XynQAPI licenses and services and other licensing agreements. Digital and other revenue represented 5% of total revenue for each of the three and nine months ended September 30, 2020, and 4% and 3% of total revenue for the three and nine months ended September 30, 2019, respectively.

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 unaudited condensed consolidated financial statements:

- Revenue recognition;
- Business combination;
- Acquired intangible assets;
- Impairment of goodwill, intangible assets and other long-lived assets; and
- Common stock warrant liability.

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our unaudited condensed consolidated financial statements during the three and nine months ended September 30, 2020 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, 2019, except that there is no derivative liability outstanding as of December 31, 2019 and September 30, 2020 and the determination of the estimated present value of lease payments using our incremental borrowing rate 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, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position and cash flows.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

(In thousands)

	Three Months Ended September 30,		
	2020	2019	Change
Revenue:			
Testing services revenue	$ 45,529	$ 28,226	$ 17,303
Product revenue	5,383	4,200	1,183
Digital and other revenue	2,457	1,385	1,072
Total revenue	53,369	33,811	19,558
Operating expenses:			
Cost of testing services	11,900	7,421	4,479
Cost of product	3,705	2,986	719
Cost of digital and other	1,210	1,087	123
Research and development	12,474	8,521	3,953
Sales and marketing	13,870	11,058	2,812
General and administrative	13,117	9,485	3,632
Total operating expenses	56,276	40,558	15,718
Loss from operations	(2,907)	(6,747)	3,840
Other income (expense):			
Interest income, net	29	37	(8)
Change in estimated fair value of common stock warrant liability	79	4,346	(4,267)
Other expense, net	(254)	(398)	144
Total other (expense) income	(146)	3,985	(4,131)
Loss before income taxes	(3,053)	(2,762)	(291)
Income tax benefit	235	949	(714)
Net loss	$ (2,818)	$ (1,813)	$ (1,005)

Testing Services Revenue

Testing services revenue increased by $17.3 million, or 61%, for the three months ended September 30, 2020 as compared to the same period in 2019. This increase is primarily due to an increase of more than 8,500 AlloSure Kidney and AlloMap Heart patient results provided in the three months ended September 30, 2020, compared to the same period in 2019.

Product Revenue

Product revenue increased by $1.2 million, or 28%, for the three months ended September 30, 2020, compared to the same period in 2019. The increase is primarily due to an increase in sales of NGS HLA typing products due to existing customers switching from legacy SSP HLA typing to NGS HLA typing, and new customers adopting NGS HLA typing technology.

Digital and Other Revenue

Digital and other revenue increased by $1.1 million, or 77% for the three months ended September 30, 2020 compared to the same period in 2019, primarily due to new Ottr software implementations and the acquisition of XynManagement in August 2019.

Cost of Testing Services

Cost of testing services increased by $4.5 million, or 60%, for the three months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in testing volume, the cost of providing RemoTraC and increased utilization of mobile phlebotomy.

Cost of Product

Cost of product increased by $0.7 million, or 24%, for the three months ended September 30, 2020 compared to the same period in 2019. The increase is primarily due to the increase in product sales.

Cost of Digital and Other

Cost of digital and other increased by $0.1 million, or 11%, for the three months ended September 30, 2020 compared to the same period in 2019, primarily due to increased cost from the acquisition of XynManagement in August 2019.

Research and Development

Research and development expenses increased by $4.0 million, or 46%, for the three months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in personnel-related costs of $1.3 million, an increase of $1.2 million in clinical studies, a $0.8 million increase in consumable expenditures, a $0.4 million increase in license and collaboration fees and an increase in stock-based compensation expense of $0.2 million.

Sales and Marketing

Sales and marketing expenses increased by $2.8 million, or 25%, for the three months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in personnel-related costs of $1.8 million, advertising costs of $0.8 million, consulting fees of $0.5 million, stock-based compensation of $0.5 million and sponsorships of $0.2 million. These increases were offset by a decrease of $1.1 million in lower travel costs due to COVID-19.

General and Administrative

General and administrative expenses increased by $3.6 million, or 38%, for the three months ended September 30, 2020 compared to the same period in 2019. This increase was primarily due to legal fees of $1.8 million related to litigation, an increase of $1.2 million in personnel-related costs and an increase of $0.4 million in consulting fees.

Change in Estimated Fair Value of Common Stock Warrant Liability

The change in estimated fair value of common stock warrant liability decreased from income of $4.3 million for the three months ended September 30, 2019 to income of $0.1 million for the three months ended September 30, 2020, resulting in a net change of $4.3 million, or 98%.

The $0.1 million income in the three months ended September 30, 2020 reflects a remeasurement gain of $1.2 million for the change in the fair value of our common stock warrant liability and a remeasurement charge of $1.1 million for warrants exercised during the period. In the three months ended September 30, 2020, warrants to purchase approximately 35,000 shares of common stock with an average exercise price of $1.12 per share were exercised.

The $4.3 million income in the three months ended September 30, 2019 consisted of a fair market value adjustment for outstanding warrants. This remeasurement gain reflects the decrease in the price of shares of our common stock, and the reduction of the remaining expected term of outstanding warrants during the three months ended September 30, 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019

	Nine Months Ended September 30,		
	2020	2019	Change
Revenue:			
Testing services revenue	$ 113,264	$ 75,421	$ 37,843
Product revenue	13,369	13,226	143
Digital and other revenue	6,917	2,600	4,317
Total revenue	133,550	91,247	42,303
Operating expenses:			
Cost of testing services	30,631	21,928	8,703
Cost of product	9,635	9,161	474
Cost of digital and other	3,966	1,650	2,316
Research and development	35,616	21,765	13,851
Sales and marketing	37,727	28,627	9,100
General and administrative	35,436	27,103	8,333
Total operating expenses	153,011	110,234	42,777
Loss from operations	(19,461)	(18,987)	(474)
Other income (expense):			
Interest income, net	146	679	(533)
Change in estimated fair value of common stock warrant liability	(990)	(14)	(976)
CARES Act Provider Relief Fund	4,813	—	4,813
Other expense, net	(572)	(644)	72
Total other income (expense)	3,397	21	3,376
Loss before income taxes	(16,064)	(18,966)	2,902
Income tax benefit	865	1,775	(910)
Net loss	$ (15,199)	$ (17,191)	$ 1,992

Testing Services Revenue

Testing services revenue increased by $37.8 million, or 50%, for the nine months ended September 30, 2020 as compared to the same period in 2019. This increase is primarily due to an increase of more than 18,700 AlloSure Kidney and AlloMap Heart patient results provided in the nine months ended September 30, 2020, compared to the same period in 2019.

Product Revenue

Product revenue increased by $0.1 million, or 1% for the nine months ended September 30, 2020, compared to the same period in 2019. Our product business was impacted by a reduction in forecasted sales volume throughout the second and third quarters of 2020 due to COVID-19, as there were delays in onsite discussions and demonstrations of recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark approval in May 2020.

Digital and Other Revenue

Digital and other revenue increased by $4.3 million for the nine months ended September 30, 2020 compared to the same period in 2019, primarily due to new Ottr software implementations and our acquisitions of OttrCare in May 2019 and XynManagement in August 2019.

Cost of Testing Services

Cost of testing services increased by $8.7 million, or 40%, for the nine months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in testing volume, the cost of providing RemoTraC and increased utilization of mobile phlebotomy.

Cost of Product

Cost of product increased by $0.5 million, or 5%, for the nine months ended September 30, 2020 compared to the same period in 2019. The increase is primarily due to increased sales, amortization of intangibles and freight costs.

Cost of Digital and Other

Cost of digital and other increased by $2.3 million, or 140%, for the nine months ended September 30, 2020 compared to the same period in 2019, primarily due to the acquisitions of OttrCare in May 2019 and XynManagement in August 2019.

Research and Development

Research and development expenses increased by $13.9 million, or 64%, for the nine months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in personnel-related costs of $6.4 million, an increase of $3.6 million in clinical studies, a $1.9 million increase in consulting fees, a $0.9 million increase in consumable expenditures, a $0.8 million increase in license and collaboration fees and stock-based compensation expense of $0.3 million.

Sales and Marketing

Sales and marketing expenses increased by $9.1 million, or 32%, for the nine months ended September 30, 2020, compared to the same period in 2019, primarily due to an increase in personnel-related costs of $6.3 million, advertising costs of $1.5 million, and stock-based compensation expense of $1.4 million.

General and Administrative

General and administrative expenses increased by $8.3 million, or 31%, for the nine months ended September 30, 2020, compared to the same period in 2019. This increase was primarily due to legal fees of $3.4 million related to litigation and general legal expenses, an increase of $3.0 million in personnel-related costs, an increase of $2.1 million of consulting fees, $0.4 million of software expense, $0.2 million of dues and subscriptions and a mark to market adjustment of the contingent consideration of $0.3 million. These increases were partially offset by lower stock-based compensation expense of $1.3 million.

Change in Estimated Fair Value of Common Stock Warrant Liability

The change in estimated fair value of common stock warrant liability decreased from an expense of less than $0.1 million for the nine months ended September 30, 2019 to an expense of $1.0 million for the nine months ended September 30, 2020, resulting in a net change of $1.0 million.

The $1.0 million expense in the nine months ended September 30, 2020 reflects a remeasurement gain of $6.1 million for the change in the fair value of our common stock warrant liability and a remeasurement charge of $7.1 million for warrants exercised during the period. In the nine months ended September 30, 2020, warrants to purchase approximately 307,000 shares of common stock with an average exercise price of $1.12 per share were exercised.

The expense for the change in estimated fair value of common stock warrants decreased by $24.5 million, or 100%, for the nine months ended September 30, 2019, compared to the same period in 2018. The expense in the nine months ended September 30, 2019 was $14 thousand, comprised of a $1.0 million remeasurement charge for warrants exercised during the period and a $1.0 million remeasurement gain related to the change in fair value of our common stock warrant liability.

CARES Act Provider Relief Fund

The CARES Act Provider Relief Fund increased by $4.8 million, or 100%, for the nine months ended September 30, 2020, compared to the same period in 2019, primarily due to the CARES Act payment we received in April 2020.

Cash Flows for the Nine Months Ended September 30, 2020 and 2019

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

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 26,250	$ (1,686)
Investing activities	(9,920)	(21,237)
Financing activities	159,185	(214)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	64	(493)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 175,579	$ (23,630)

Operating Activities

Net cash provided by (used in) operating activities consists of net loss, adjusted for certain noncash items in the condensed consolidated statement of operations and changes in operating assets and liabilities.

Cash provided by operating activities for the nine months ended September 30, 2020 was $26.3 million. Our net loss of $15.2 million included $4.8 million of cash provided by the CARES Act Provider Relief Fund, and our net loss was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $17.4 million in stock-based compensation expense, a $1.0 million loss on the revaluation of common stock warrant liability to estimated fair value and $5.1 million of depreciation and amortization expense. Net operating assets decreased by $4.7 million, offset by an increase in Deferred revenue - CMS advance payment of $20.5 million.

Cash used in operating activities for the nine months ended September 30, 2019 was $1.7 million. Our net loss of $17.2 million was our primary use of cash in operating activities and included a number of noncash items. Our noncash items included a $17.0 million stock-based compensation expense, and a $3.8 million of depreciation and amortization expense. Net operating assets decreased by $6.6 million.

Investing Activities

For the nine months ended September 30, 2020, net cash used in investing activities of $9.9 million consisted of $6.7 million related to additions of capital expenditures, net, $2.0 million related to payments for the license and commercialization agreement with Cibiltech and $1.3 million related to payments for acquired intangibles.

For the nine months ended September 30, 2019, net cash used in investing activities was $21.2 million and consisted of $18.1 million related to the acquisitions of Ottr and XynManagement, $1.1 million related to the acquisition of intangible assets, $1.0 million related to investment in equity securities, and investments of $1.0 million related to additions of capital expenditures.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 of $159.2 million was primarily related to $134.7 million of proceeds from the issuance of common shares in a public equity offering, net of issuance costs, $23.5 million of proceeds from the issuance of common shares in an “at-the-market” equity offering, net of issuance costs, proceeds from issuances of common stock under our employee stock purchase plan of $1.1 million, proceeds from exercises of warrants of $0.3 million and proceeds from exercises of stock options of $3.8 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $4.0 million.

For the nine months ended September 30, 2019, net cash used in financing activities of $0.2 million was primarily related to taxes paid related to net share settlement of restricted stock units of $4.0 million, partially offset by proceeds from exercise of stock options of $3.2 million and proceeds from the issuance of common stock pursuant to our employee stock purchase plan of $0.8 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 $349.0 million at September 30, 2020. As of September 30, 2020, we had cash and cash equivalents of $213.8 million and no debt outstanding.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity.

Since March 31, 2020, and in response to the outbreak of the COVID-19 pandemic, we have increased our cash and cash equivalents by undertaking the following:

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020, the U.S. government enacted the CARES Act. Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services, or CMS, expanded its current Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submits a request to the appropriate Medicare Administrative Contractor and meets the required qualifications. During April 2020, we received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on our condensed consolidated balance sheet.

We can repay the advance in full at any time or make repayments as per the following terms:

- Repayment will begin one year after the date the accelerated or advance payment was issued.
- During the first eleven months after repayment begins, repayment will occur through an automatic recoupment of 25 percent of Medicare payments otherwise owed to us.
- During the succeeding six months, repayment will occur through an automatic recoupment of 50 percent of Medicare payments otherwise owed to us.
- If we are unable to pay the total amount of the accelerated or advance payment through recoupment within 29 months, we will receive a demand letter requiring repayment of any outstanding balance, subject to an interest rate of four percent.

At-the-Market Equity Offering

On August 31, 2018, we entered into a sales agreement, or the Sales Agreement, with Jefferies, LLC, as sales agent, or Jefferies, pursuant to which we may offer and sell, from time to time, through Jefferies, up to $50.0 million in shares of our common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. During April 2020, we issued and sold 1,000,000 shares of our common stock under the Sales Agreement. The shares were sold at an average price of $24.24 per share for aggregate net proceeds to us of approximately $23.5 million, after deducting sales commissions and offering costs payable by us.

CARES Act Provider Relief Fund for Medicare Providers

Pursuant to the CARES Act, the U.S. Department of Health & Human Services, or HHS, distributed an initial tranche of $30.0 billion in funds to healthcare providers that received Medicare fee-for-service, or FFS, reimbursements in 2019. These payments to healthcare providers are not loans and will not be required to be repaid. As a condition to receiving these payments, providers must agree to certain terms and conditions and submit sufficient documentation demonstrating that the funds are being used for healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic. Due to the recent enactment of legislation and absence of definitive guidance, there is a high degree of uncertainty around the CARES Act's implementation and we continue to assess the impact on our business. Furthermore, HHS has indicated that it, along with the Office of Inspector General, will be closely monitoring and auditing providers to ensure that recipients comply with the terms and conditions of relief programs and to prevent fraud and abuse. All providers will be subject to civil and criminal penalties for any deliberate omissions, misrepresentations or falsifications of any information given to HHS. Providers will be distributed a portion of the initial $30.0 billion based on their share of total Medicare FFS reimbursements made by the U.S. in 2019. During April 2020, we received a payment of approximately $4.8 million, representing our portion of the initial tranche of funds recorded in other income (expense), net on the condensed consolidated statement of operations.

Underwritten Public Offering

In June 2020, we sold 4,492,187 shares of common stock (which includes shares sold pursuant to the underwriters' full exercise of an overallotment option granted to the underwriters in connection with the offering) through an underwritten public offering at a price of $32.00 per share for aggregate net proceeds of approximately $134.6 million.

Factors Affecting Our Performance

COVID-19 Pandemic

COVID-19 may impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities. Clinical trials, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

The Number of AlloSure Kidney and AlloMap Heart Tests We Receive and Report

The growth of our testing services business is tied to the number of AlloSure Kidney and AlloMap Heart patient samples we receive and patient results we report. 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.

Reimbursement for AlloMap Heart

AlloMap Heart test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap Heart, as the International Society of Heart and Lung, Transplantation included AlloMap in guidelines, payers adopted coverage policies and many payers no longer consider AlloMap Heart 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 and third party payer reimbursement, and to expand utilization by 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 Heart testing of Medicare beneficiaries, an increase from the 2017 reimbursement rate of $2,841. The CARES Act freezes current (2020) CMS CLFS rates through 2021. Further, the CARES Act delays the reporting cycle under PAMA to January 1 and March 31, 2022 although the data collection period remains January 1 through June 30, 2019. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, HCSC, Humana, Kaiser Foundation Health Plan, Inc., several BCBS plans and UnitedHealthcare.

Reimbursement for AlloSure Kidney

On September 26, 2017 we received notice that the Molecular Diagnostics Services Program, or MolDX, developed by Palmetto GBA had set AlloSure Kidney reimbursement at $2,841. Effective October 9, 2017, AlloSure Kidney was made available for commercial testing with Medicare coverage and reimbursement. We believe the use of AlloSure Kidney, 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 Kidney can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

Reimbursement for AlloSure Heart

On October 1, 2019, the MolDX Program released the draft Local Coverage Determination for AlloSure Cell-Free DNA Testing which added heart indication to the existing kidney indication for AlloSure coverage. In October 2020, AlloSure Heart received a final Medicare coverage decision from Palmetto GBA (MolDx), effective November 2020. AlloSure Heart will be covered for Medicare beneficiaries when it is used in conjunction with AlloMap Heart.

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 solid organs.

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. Olerup SSP is used to type HLA alleles based on the SSP technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles.

On May 4, 2018, we entered into the Illumina Agreement, 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 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 for use in the field of bone marrow and solid organ transplantation diagnostic testing. These NGS 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 HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark approval on January 20, 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

Also in September 2019, we commercially launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than current solutions and adding coverage of non-HLA genes that may impact transplant patient matching and

management. AlloSeq Tx has a simple NGS workflow that reduces complexity and can reduce errors. AlloSeq Tx 17 received CE mark approval on May 15, 2020.

In June 2020, we commercially launched AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients. This technology can provide better sensitivity and data analysis compared to current solutions on the market.

Continued Growth of Digital Sales

The growth of our digital revenues is tied to the continued successful integration of our Ottr and XynQAPI software businesses, as well as continued support and maintenance of existing OttrCare and XynManagement customers. The Ottr software and XynQAPI are currently implemented in multiple locations in the U.S. The Ottr software implementation and XynQAPI implementation and support teams are based in Omaha, Nebraska.

Development of Additional Services and Products

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 services and 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 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

As of September 30, 2020, there have not been any other material changes, outside of the ordinary course of business in our outstanding contractual obligations from our significant contractual obligations as of December 31, 2019, as disclosed in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 28, 2020.

Off-Balance Sheet Arrangements

As of September 30, 2020, we had no off-balance sheet arrangements as defined under Regulation S-K 303(a)(4) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the instructions thereto.

Foreign Operations

The accompanying unaudited 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 $213.8 million and $38.2 million at September 30, 2020 and December 31, 2019, 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. A hypothetical 50 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $0.8 million on our condensed consolidated financial statements.

Foreign Currency Exchange Risk

We have operations in Sweden, Austria, Australia and sell to other countries throughout the world. As a result, we are subject to significant foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in U.S. dollars and the Euro. Consequently, our revenue denominated in foreign currency is

subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona, the Euro, and the Australian Dollar, which are also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at September 30, 2020, would have negatively impacted our financial results for the nine months ended September 30, 2020 by less than $0.1 million and our product revenue by $0.7 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 such terms are defined in Rules 13a-15(b) and 15d-15(e) promulgated under the Exchange Act, as of September 30, 2020. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2020, 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 September 30, 2020 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

The information set forth in Note 8, *Commitments and Contingencies*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations" is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on February 28, 2020, or the Form 10-K, 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, 2019, filed with the SEC on February 28, 2020, other than those listed below. 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.

Risks Related to Our Business

Our business may be adversely affected by the effects of health epidemics, including the recent coronavirus outbreak.

On January 30, 2020, the World Health Organization, or the WHO, announced a global health emergency because of a new strain of coronavirus, or COVID-19, originating in Wuhan, China and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally. The full impact of the COVID-19 pandemic, including the impact associated with preventative and precautionary measures that we, other businesses and governments are taking, continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on us, but the pandemic may materially affect our financial condition, liquidity and future results of operations.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities.

In addition, our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Management is actively monitoring the effect of the global situation on our financial condition, liquidity, operations, suppliers, industry and workforce. Given the daily evolution of the COVID-19 pandemic and the global responses to curb its spread, we are not able to estimate the effects of the COVID-19 pandemic on our results of operations, financial condition or liquidity for fiscal year 2020.

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

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. In addition, we have included a discussion of a number of anticipated targets in the Form 10-K. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control, including the impact of the COVID-19 pandemic. We cannot be certain that we will

meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

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

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

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us in the U.S. would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including California, Florida, Maryland, New York, Rhode Island and Pennsylvania, which can take a significant amount of time and result in delays in our ability to begin operations at that facility. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform AlloSure Kidney, AlloMap Heart or future solutions following validation and other required procedures. We cannot be certain that we would be able to find another CLIA-certified facility willing or able to adopt AlloSure Kidney, AlloMap Heart or future solutions or able to comply with the required quality and regulatory standards, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

In mid-March 2020, in response to the COVID-19 pandemic, the Governor of California and the State Public Health Officer and Director of the California Department of Public Health ordered all individuals living in the State of California, where our laboratory is located, to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary and other permitted activities) to mitigate the impact of the COVID-19 pandemic. The executive order exempts certain individuals needed to maintain continuity of operations of essential critical infrastructure sectors and additional sectors as the State Public Health Officer may designate as critical to protect health and well-being of all Californians. In May 2020, the Governor of California issued an executive order that informed local health jurisdictions and industry sectors that they may gradually reopen under new modifications and guidance provided by the state of California. In August 2020, the state of California released revised criteria for loosening and tightening restrictions on certain activities on generally a county-by-county basis. Under the updated executive orders, San Mateo County, where our laboratory and headquarters are located, continues to be subject to certain restrictions. These orders and others may be further modified, amended and adopted depending upon the COVID-19 transmission rates in our county and state, as well as other factors. If the operations in our laboratory are deemed non-essential, or if sufficient numbers of our laboratory staff are infected with COVID-19 and are unable to perform their roles, we may not be able to perform our tests for the duration of any shelter-in-place order or while we have insufficient numbers of laboratory staff, either of which could negatively impact our business, operating results and financial condition.

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

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of recipient samples to our laboratory and enhanced tracking of these recipient samples. Should a carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions, such as the COVID-19 pandemic, affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis.

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

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we were to lose one or more of these key employees, including due to disease (such as COVID-19), disability or death, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. We do not currently maintain "key person" insurance on any of our employees.

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

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

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our or our third-party billing agent's reliance on internet technology and the number of our and our third-party billing agent's employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

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

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

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we

change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, the California Consumer Privacy Act, or the CCPA, took effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. The CCPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business.

Risks Related to Our Common Stock

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

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. In 2019, our closing stock price ranged from $19.24 to $40.08 per share, and during the nine months ended September 30, 2020, our closing stock price ranged from $13.94 to $37.94 per share. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by clinicians and recipients for our current and future solutions, if any;
- coverage and reimbursement decisions by third-party payers and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or the presentation at medical conferences;
- the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others;
- new or less expensive tests and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new solutions, and our success in commercializing these developments;
- our ability to efficiently integrate the business of new acquisitions;
- the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the U.S. Food and Drug Administration regarding its decisions in regulating our activities;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel;
- public health emergencies such as the COVID-19 pandemic; and
- general market conditions.

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

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

Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the risk factors discussed here and the risk factors described in this Part II, Item 1A of this Quarterly Report on Form 10-Q and under Item "1A. Risk Factors" in the Form 10-K, factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of life sciences stocks;

- changes in operating performance and stock market valuations of other life sciences companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- entering into financing or other arrangements with rights or terms senior to the interests of common stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the Securities and Exchange Commission;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- public health emergencies, including the COVID-19 pandemic; and
- general economic conditions and slow or negative growth of our markets.

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 September 30, 2020:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)
July 1, 2020 - July 31, 2020	1,309	(1)	$ 6.19
August 1, 2020 - August 31, 2020	11,429	(1)	7.10
September 1, 2020 - September 30, 2020	3,408	(1)	6.66
Total	16,146		—

(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

None.

ITEM 6. EXHIBITS

Exhibit Number	
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
3.3(3)	Certificate of Amendment of Amended and Restated Bylaws.
4.1(4)	Form of Registrant's common stock certificate.
4.2(5)#	2014 Equity Incentive Plan, as amended.
4.3(6)#	Form of Option Agreement under the 2014 Equity Incentive Plan for New Options.
4.4(7)#	2014 Employee Stock Purchase Plan and forms of agreements thereunder.
4.5(8)#	2016 Inducement Equity Incentive Plan.
4.6(9)	Form of Warrant.
4.7(10)#	CareDx, Inc. 2019 Inducement Equity Incentive Plan.
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 3.1 to the Registrant's Form 8-K filed with the SEC on June 9, 2020.
(4)	Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
(5)	Incorporated by reference to Exhibit 4.4 to the Registrant's Form S-8 filed with the SEC on July 18, 2014.
(6)	Incorporated by reference to Exhibit 99(d)(3) to the Registrant's Form SC TO-I filed with the SEC on October 12, 2017.
(7)	Incorporated by reference to Exhibit 4.5 to the Registrant's Form S-8 filed with the SEC on July 18, 2014.
(8)	Incorporated by reference to Exhibit 4.1 to the Registrant's Form S-8 filed with the SEC on May 23, 2016.
(9)	Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on April 14, 2016.
(10)	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on September 4, 2019.
#	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: October 29, 2020

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

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

Exhibit 31.1

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: October 29, 2020

By: /s/ Peter Maag

Peter Maag
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: October 29, 2020

By: /s/ Michael Bell

Michael Bell
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Peter Maag
Peter Maag
Chairman and Chief Executive Officer
(Principal Executive Officer)
Date: October 29, 2020

By: /s/ Michael Bell
Michael Bell
Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: October 29, 2020

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.