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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 March 31, 2021

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 52,053,956 shares of the registrant's Common Stock issued and outstanding as of May 3, 2021.

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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 309,324	$ 134,669
Marketable securities	64,963	90,034
Accounts receivable	43,361	34,624
Inventory	13,721	10,012
Prepaid and other current assets	7,332	3,758
Total current assets	438,701	273,097
Property and equipment, net	11,398	10,704
Operating leases right-of-use assets	18,289	15,228
Intangible assets, net	45,457	44,355
Goodwill	26,109	23,857
Restricted cash	269	270
Other assets	1,000	1,000
Total assets	$ 541,223	$ 368,511
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,597	$ 9,653
Accrued compensation	10,495	18,466
Accrued and other liabilities	23,638	20,602
Refund liability - CMS advance payment (Note 1)	—	20,496
Total current liabilities	45,730	69,217
Deferred tax liability	945	1,299
Common stock warrant liability	420	447
Deferred payments for intangible assets	3,640	3,560
Operating lease liability, less current portion	18,462	16,069
Other liabilities	480	240
Total liabilities	69,677	90,832
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at March 31, 2021 and December 31, 2020; 51,939,121 shares and 49,441,166 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	51	49
Additional paid-in capital	828,308	632,253
Accumulated other comprehensive loss	(3,599)	(2,096)
Accumulated deficit	(353,214)	(352,527)
Total stockholders' equity	471,546	277,679
Total liabilities and stockholders' equity	$ 541,223	$ 368,511

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

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

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Testing services revenue	$ 59,281	$ 31,442
Product revenue	5,778	4,695
Digital and other revenue	2,341	2,243
Total revenue	67,400	38,380
Operating expenses:		
Cost of testing services	16,483	7,928
Cost of product	3,647	3,199
Cost of digital and other	1,449	1,265
Research and development	16,004	10,013
Sales and marketing	15,452	11,723
General and administrative	15,223	10,003
Total operating expenses	68,258	44,131
Loss from operations	(858)	(5,751)
Other income (expense):		
Interest income, net	126	96
Change in estimated fair value of common stock warrant liability	27	(405)
Other expense, net	(245)	(63)
Total other expense	(92)	(372)
Loss before income taxes	(950)	(6,123)
Income tax benefit	263	300
Net loss	$ (687)	$ (5,823)
Net loss per share (Note 3):		
Basic	$ (0.01)	$ (0.14)
Diluted	$ (0.01)	$ (0.14)
Weighted-average shares used to compute net loss per share:		
Basic	51,181,160	42,823,427
Diluted	51,181,160	42,823,427

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 March 31,	
	2021	2020
Net loss	$ (687)	$ (5,823)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	(1,503)	(1,705)
Net comprehensive loss	$ (2,190)	$ (7,528)

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, 2020	49,441,166	$ 49	$ 632,253	$ (2,096)	$ (352,527)	$ 277,679
Issuance of common shares through public equity offering, net of commissions and offering costs of $12,495	2,211,538	2	188,753	—	—	188,755
Issuance of common stock under ESPP	24,052	—	838	—	—	838
RSU settlements, net of shares withheld	121,447	—	(2,313)	—	—	(2,313)
Issuance of common stock for services	1,339	—	96	—	—	96
Issuance of common stock for cash upon exercise of stock options	139,579	—	2,193	—	—	2,193
Employee stock-based compensation expense	—	—	6,488	—	—	6,488
Foreign currency translation adjustment	—	—	—	(1,503)	—	(1,503)
Net loss	—	—	—	—	(687)	(687)
Balance at March 31, 2021	51,939,121	$ 51	$ 828,308	$ (3,599)	$ (353,214)	$ 471,546

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

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

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

	Three Months Ended March 31,	
	2021	2020
Operating activities:		
Net loss	$ (687)	$ (5,823)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	6,547	4,259
Revaluation of common stock warrant liability to estimated fair value	(27)	405
Depreciation and amortization	1,950	1,619
Amortization of right-of-use assets	677	612
Revaluation of contingent consideration to estimated fair value	(44)	190
Changes in operating assets and liabilities:		
Accounts receivable	(8,755)	2,346
Inventory	(4,056)	(1,343)
Prepaid and other assets	(3,628)	(545)
Operating leases liabilities, net	(320)	(344)
Accounts payable	1,496	1,757
Accrued compensation	(7,662)	(5,914)
Accrued and other liabilities	1,661	48
Refund liability - CMS advance payment	(20,496)	—
Change in deferred taxes	(286)	(322)
Net cash used in operating activities	(33,630)	(3,055)
Investing activities:		
Acquisition of business, net of cash acquired	(3,543)	—
Acquisition of intangible assets	(1,200)	—
Maturities of marketable securities	25,072	—
Additions of capital expenditures, net	(1,250)	(1,704)
Net cash provided by (used in) investing activities	19,079	(1,704)
Financing activities:		
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	188,715	—
Proceeds from issuance of common stock under employee stock purchase plan	667	358
Taxes paid related to net share settlement of restricted stock units	(2,313)	(1,507)
Proceeds from exercise of warrants	—	304
Proceeds from exercise of stock options	2,193	155
Principal payments on finance lease obligations	(34)	(45)
Net cash provided by (used in) financing activities	189,228	(735)
Effect of exchange rate changes on cash and cash equivalents	(23)	(552)
Net increase (decrease) in cash, cash equivalents and restricted cash	174,654	(6,046)
Cash, cash equivalents, and restricted cash at beginning of period	134,939	38,479
Cash, cash equivalents, and restricted cash at end of period	$ 309,593	$ 32,433

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, AlloMap® Heart, which is a gene expression solution for heart transplant patients, and AlloSure® Heart, a dd-cfDNA test which can identify underlying cell injury leading to organ rejection. 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 ("Ottr, Inc.") and XynManagement, Inc. ("XynManagement"), as well as the acquisition of TransChart LLC ("TransChart").

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 Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, the Company's Medicare Administrative contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

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 1,700 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 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. Enrollment for OKRA was negatively affected by the COVID-19 restrictions during the year 2020, and the study had been delayed by six months; however, the collection of samples are at normal levels as a result of the introduction of RemoTraC. Following the successful implementation of RemoTraC, OKRA is planned to be fully enrolled by the end of 2021. The patients will then be followed for a period of three years with the output of the study due in 2024.

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.

In March 2021, the Company acquired BFS Molecular S.R.L. (“BFS Molecular”), a software company focused on NGS-based patient testing solutions. BFS Molecular brings extensive software and algorithm development capabilities for NGS transplant surveillance products.

Digital and Other

Following the acquisitions of both Ottr, Inc. 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 XynCare. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients reporting. XynCare 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, the Company 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.

In January 2021, the Company acquired TransChart LLC for cash. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As part of its acquisition of TransChart in January 2021, the Company acquired Tx Connect, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

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 spread 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 200 transplant centers can offer RemoTraC to their patients and over 7,000 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 through March 31, 2021, volumes continued to be at or above those levels since May 2020.

In spite of the resurgence of COVID-19 infection rates, which resulted in increased stay-at-home and renewed travel restrictions, the Company did not experience a decrease in testing services volumes. 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 authorization in May 2020. The Company's product business maintained normal sales volumes during the fourth quarter of 2020 and continued to maintain normal sales volumes through the first quarter of 2021.

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 the Company's 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 $353.2 million at March 31, 2021. As of March 31, 2021, the Company had cash, cash equivalents and marketable securities of $374.3 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 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 submitted a request to the appropriate Medicare Administrative Contractor and met 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.

During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021. The Company recorded the amount as Refund liability - CMS advance payment on the condensed consolidated balance sheet as of December 31, 2020. Refer to Note 8, Balance Sheet Components, for further explanation.

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 statements of operations.

The Company is complying with the key terms and provisions of the CARES Act Provider Relief Fund, which includes, among other things, the requirement that the Company maintain appropriate records and cost documentation. The Company has registered with HHS to submit financial data indicating the use of the funds the Company received pursuant to the CARES Act Provider Relief Fund. The Company will be notified by HHS when the Provider Relief Fund Reporting Portal is open for reporting on the use of Provider Relief Fund payments.

Underwritten Public Offering of Common Stock

On June 15, 2020, the Company sold 4,492,187 shares of common stock (which included 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.

Public Offering of Common Stock

On January 25, 2021, the Company sold 1,923,077 shares of its common stock through an underwritten public offering at a public offering price of $91.00 per share. The net proceeds to the Company from the offering were approximately $164.0 million, after deducting underwriting discounts and commissions and offering expenses.

On February 11, 2021, the Company sold 288,461 shares of its common stock pursuant to the full exercise of the overallotment option granted to the underwriters in connection with the offering. The net proceeds to the Company from the full exercise of the underwriters' overallotment option were approximately $24.7 million.

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, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. 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, 2020 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, 2020 has been derived from audited consolidated financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

Correction to Presentation

The presentation of certain prior period amounts within the accompanying condensed consolidated statements of operations have been corrected, including creating separate line items for the presentation of cost of testing services, cost of product and cost of digital and other, which were previously reported, in aggregate, in total cost of revenue of $12.4 million for the three months ended March 31, 2020. These corrections had no effect on loss from operations, loss before taxes, or net loss. The Company evaluated these corrections, considering both qualitative and quantitative factors, and concluded they are immaterial to previously issued financial statements.

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 March 31, 2021 and 2020, approximately 60% and 53%, respectively, of total revenue was derived from Medicare.

As of March 31, 2021 and December 31, 2020, approximately 31% and 28%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either March 31, 2021 or December 31, 2020.

Marketable Securities

The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of March 31, 2021, the Company's marketable securities consisted of corporate debt securities with maturities of greater than three months but less than twelve months at the time of purchase. These marketable securities are classified as current assets on the condensed consolidated balance sheet.

The Company classifies its marketable securities as held-to-maturity at the time of purchase and reevaluates such designation at each balance sheet date. The Company has the positive intent and ability to hold these marketable securities to maturity. Marketable securities are carried at amortized cost and are adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income (expense), net on the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on marketable securities are included in interest income (expense), net. The cost of securities sold will be determined using specific identification.

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 incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

As of March 31, 2021, the Company's leases had remaining terms of 0.21 years to 7.92 years, some of which include options to extend the lease term.

Recent Accounting Pronouncements

In October 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-10, Codification Improvements, which contains amendments that improve the consistency of the ASC by including all disclosure guidance in the appropriate Disclosure Section (Section 50). The FASB provided transition guidance for all the amendments in this ASU. The *amendments* in Sections B and C (Section A has been removed) of this ASU are effective for annual periods beginning after December 15, 2020 for public business entities. Early application of the amendments in this ASU is permitted for public business entities for any annual or interim period for which financial statements have not been issued. The amendments in this ASU should be applied retrospectively. The Company adopted the standard on January 1, 2021. The adoption of the new standard did not have an impact on the Company's condensed consolidated financial statements and disclosures.

3. NET LOSS PER SHARE

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

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

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss used to compute basic and diluted net loss per share	$ (687)	$ (5,823)
Denominator:		
Weighted-average shares used to compute basic and diluted net loss per share	51,181,160	42,823,427
Net loss per share:		
Basic and diluted	$ (0.01)	$ (0.14)

The following potentially dilutive securities have been excluded from diluted net loss per share as of March 31, 2021 and 2020 because their effect would be antidilutive:

	Three Months Ended March 31,	
	2021	2020
Shares of common stock subject to outstanding options	2,592,281	2,845,862
Shares of common stock subject to outstanding common stock warrants	6,264	49,006
Restricted stock units	1,853,419	1,502,012
Total common stock equivalents	4,451,964	4,396,880

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 March 31, 2021 and December 31, 2020 (in thousands):

	March 31, 2021			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 280,099	$ —	$ —	$ 280,099
Liabilities				
Common stock warrant liability	$ —	$ —	$ 420	$ 420

	December 31, 2020			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 85,797	$ —	$ —	$ 85,797
Liabilities				
Common stock warrant liability	$ —	$ —	$ 447	$ 447

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, 2020	$ 447
Exercise of warrants	—
Change in estimated fair value	(27)
Balance as of March 31, 2021	$ 420

As of March 31, 2021, the Company had one investment in convertible preferred shares carried at cost. See Note 7, "Goodwill and Intangible Assets". In the event the Company had to calculate the fair value of this investment, it would be based on Level 3 inputs. This investment is not considered material to the Company's condensed consolidated financial statements.

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 March 31, 2021 and December 31, 2020, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *Marketable securities*—Investments in marketable securities are classified within Level 2. The securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.
- *Common stock warrant liability* – The Company utilizes a binomial-lattice pricing model (the "Monte Carlo Simulation Model") that involves a market condition simulation to estimate the fair value of the warrants. The application of the Monte Carlo Simulation Model requires the use of a number of complex assumptions, including the Company's stock price, expected life of the warrants, stock price volatility determined from the Company's historical stock prices and stock prices of peer companies in the diagnostics industry, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of the warrants. Increases (decreases) in the assumptions discussed above result in a directionally similar impact to the fair value of the common stock warrant liability.

Common Stock Warrant Liability Valuation Assumptions:

	March 31, 2021	December 31, 2020
Private Placement Common Stock Warrant Liability		
Stock Price	$ 68.09	$ 72.45
Exercise Price	$ 1.12	$ 1.12
Remaining term (in years)	2.04	2.28
Volatility	72.00 %	73.00 %
Risk-free interest rate	0.17 %	0.14 %

5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

A reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets to the amount reported within the condensed consolidated statements of cash flows is shown in the table below (in thousands):

	March 31, 2021	December 31, 2020	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 309,324	$ 134,669	$ 32,191	$ 38,223
Restricted cash	269	270	242	256
Total cash, cash equivalents, and restricted cash at the end of the period	$ 309,593	$ 134,939	$ 32,433	$ 38,479

Marketable Securities

All marketable securities were considered held-to-maturity at March 31, 2021 and December 31, 2020. As of March 31, 2021 and December 31, 2020, some of the Company's marketable securities were in an unrealized loss position. The Company determined that it had the positive intent and ability to hold until maturity all marketable securities that have been in a continuous loss position, thus there was no recognition of any other-than-temporary impairment as of March 31, 2021 and December 31, 2020. All marketable securities with unrealized losses as of each balance sheet date have been in a loss position for less than twelve months.

The amortized cost, gross unrealized holding losses, and fair value of the Company's marketable securities by major security type at each balance sheet date are summarized in the table below (in thousands):

	March 31, 2021		
	Amortized Cost	Unrealized Holding Losses	Fair Value
Short-term marketable securities:			
Corporate debt securities	$ 64,963	$ (66)	$ 64,897
Total short-term marketable securities	$ 64,963	$ (66)	$ 64,897

	December 31, 2020		
	Amortized Cost	Unrealized Holding Losses	Fair Value
Short-term marketable securities:			
Corporate debt securities	$ 90,034	$ (136)	$ 89,898
Total short-term marketable securities	$ 90,034	$ (136)	$ 89,898

Contractual maturities of the short-term marketable securities all mature within one year as of March 31, 2021.

6. BUSINESS COMBINATIONS

TransChart LLC

In January 2021, the Company acquired TransChart for cash. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. TransChart builds on the Company's digital offerings, which include Ottr, Inc. transplant electronic medical record software and XynQAPI transplant quality management solutions. As a result of the acquisition, the Company recognized goodwill of $2.3 million and intangible assets of $2.0 million.

The pro forma impact of the TransChart acquisition is not material, and the results of operations of the acquisition have been included in the Company's condensed consolidated statements of operations from the respective acquisition date.

7. 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 months ended March 31, 2021. The balance of the Company's goodwill as of March 31, 2021 and December 31, 2020 was $26.1 million and $23.9 million, respectively.

Intangible Assets

The following tables present details of the Company’s intangible assets as of March 31, 2021 ($ in thousands):

	March 31, 2021				
	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	$ 33,569	$ (9,692)	$ (1,262)	$ 22,615	9.0
Customer relationships	19,308	(5,015)	(953)	13,340	10.6
Commercialization rights	8,079	(1,241)	—	6,838	8.4
Trademarks and tradenames	2,380	(856)	(110)	1,414	9.6
Total intangible assets with finite lives	$ 63,336	$ (16,804)	$ (2,325)	$ 44,207	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	$ 64,586	$ (16,804)	$ (2,325)	$ 45,457	

The following table presents details of the Company’s intangible assets as of December 31, 2020 ($ in thousands):

	December 31, 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	$ (8,991)	$ (725)	$ 21,493	9.1
Customer relationships	18,168	(4,684)	(449)	13,035	10.9
Commercialization rights	8,079	(1,039)	—	7,040	8.7
Trademarks and tradenames	2,360	(804)	(19)	1,537	9.9
Total intangible assets with finite lives	$ 59,816	$ (15,518)	$ (1,193)	$ 43,105	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	$ 61,066	$ (15,518)	$ (1,193)	$ 44,355	

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 has the potential to provide better sensitivity and data analysis compared to current solutions on the market. AlloSeq HCT is included in Acquired and developed technology as of December 31, 2020 and March 31, 2021.

Amortization of Intangible Assets

Amortization expense was $1.3 million and $1.1 million for the three months ended March 31, 2021 and 2020, respectively. For the three months ended March 31, 2021, expenses of $0.3 million, $0.5 million, $0.1 million and $0.4 million were amortized to cost of testing services, cost of product, cost of digital and other and sales and marketing, respectively. For the three months ended March 31, 2020, expenses of $0.3 million, $0.4 million, $0.1 million and $0.3 million were amortized to cost of testing services, 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 March 31, 2021 (in thousands):

Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Digital and Other	Sales and Marketing	Total
Remainder of 2021	$ 987	$ 1,430	$ 323	$ 1,083	$ 3,823
2022	1,316	1,906	431	1,437	5,090
2023	1,316	1,906	431	1,427	5,080
2024	1,316	1,906	431	1,427	5,080
2025	1,316	1,906	431	1,427	5,080
Thereafter	5,457	5,020	1,622	7,955	20,054
Total future amortization expense	$ 11,708	$ 14,074	$ 3,669	$ 14,756	$ 44,207

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Finished goods	$ 2,416	$ 1,702
Work in progress	3,210	2,936
Raw materials	8,095	5,374
Total inventory	$ 13,721	$ 10,012

Accrued and Other Liabilities

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

	March 31, 2021	December 31, 2020
Deferred revenue	$ 3,522	$ 3,530
Clinical studies	7,023	6,733
Deferred payments for intangible assets	2,000	2,000
Short-term lease liability	3,126	2,033
Test sample processing fees	505	416
Accrued royalty	1,342	1,072
Contingent consideration	694	738
Professional fees	2,393	1,529
Other accrued expenses	3,033	2,551
Total accrued and other liabilities	$ 23,638	$ 20,602

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 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 submitted a request to the appropriate Medicare Administrative Contractor and met 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.

During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021. The Company recorded the amount as Refund liability - CMS advance payment on the condensed consolidated balance sheet as of December 31, 2020.

9. 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.

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 was extended for a period of eight years and two months starting on January 1, 2021. The Company had determined that the amendment constituted 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 March 31, 2021, the carrying value of the ROU asset was $18.3 million. The related current and non-current liabilities as of March 31, 2021 were $3.1 million and $18.5 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 months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Operating lease cost	$ 1,205	$ 1,119
Finance lease cost	30	53
Total lease cost	$ 1,235	$ 1,172

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)	6.78
Weighted-average remaining lease term - Finance leases (in years)	0.22
Weighted-average discount rate - Operating leases (%)	10.5%
Weighted-average discount rate - Finance leases (%)	4.8%

Maturities of operating and finance lease liabilities as of March 31, 2021 are as follows (in thousands):

Year Ending December 31,	Finance Leases	Operating Leases
Remainder of 2021	$ 34	$ 3,718
2022	—	4,971
2023	—	3,724
2024	—	3,846
2025	—	3,988
Thereafter	—	10,256
Total lease payments	34	30,503
Less imputed interest	—	8,915
Present value of future minimum lease payments	$ 34	21,588
Less operating lease liability, current portion		3,126
Operating lease liability, long-term portion		$ 18,462

The current portion of obligations under finance leases is included in accrued and other liabilities, and the long-term portion of finance leases is 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 that certain license and commercialization agreement that the Company entered into with Cibiltech SAS (“Cibiltech”) effective April 30, 2019, 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, and the Court granted Natera’s request. Trial is currently scheduled to begin on July 26, 2021.

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 Court alleging, among other things, that AlloSure 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.

10. 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. The Company incurred expenses related to contributions to the plan of $0.5 million and $0.3 million for the three months ended March 31, 2021 and 2020, respectively.

11. WARRANTS

The Company issues 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 March 31, 2021, there were no warrants exercised to purchase shares of common stock for cash proceeds.

In the three months ended March 31, 2020, warrants to purchase approximately 272,000 shares of common stock were exercised for cash payments of $0.3 million. During the three months ended March 31, 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.

As of March 31, 2021, 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	6,264
				6,264

12. 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, 2020	672,968	2,670,398	$ 21.92	1,884,866	$ 28.42
Additional shares authorized	1,977,647	—	—	—	—
Common stock awards for services	(1,339)	—	—	—	—
RSUs granted	(246,379)	—	—	246,379	82.62
RSUs vested	—	—	—	(207,881)	24.06
Options granted	(127,925)	127,925	81.06	—	—
Options exercised	—	(139,579)	13.99	—	—
Repurchase of common stock under employee incentive plans	74,434	—	—	—	—
RSUs forfeited	69,945	—	—	(69,945)	29.32
Options forfeited	66,213	(66,213)	25.70	—	—
Options expired	250	(250)	22.59	—	—
Balance—March 31, 2021	2,485,814	2,592,281	$ 25.17	1,853,419	$ 36.14

The total intrinsic value of options exercised was $9.1 million and $0.7 million for the three months ended March 31, 2021 and 2020, respectively.

As of March 31, 2021, the total intrinsic value of outstanding RSUs was approximately $126.2 million and there were $50.7 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 1.91 years.

Options outstanding that have vested and are expected to vest at March 31, 2021 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	1,045	$ 16.09	6.54	$ 54,318
Expected to vest	1,398	31.91	8.68	52,508
Total	2,443			$ 106,826

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at March 31, 2021 for stock options that were in-the-money.

The total fair value of options that vested during the three months ended March 31, 2021 was $2.7 million. As of March 31, 2021, there were approximately $25.2 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.89 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 December 31, 2020, 24,052 shares were purchased for aggregate proceeds of $0.8 million from the issuance of shares, which occurred on January 4, 2021.

Valuation Assumptions

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

	Three Months Ended March 31,	
	2021	2020
Employee stock options		
Expected term (in years)	6.0	6.0
Expected volatility	77.69%	74.00%
Risk-free interest rate	0.68%	1.35%
Expected dividend yield	—%	—%
Employee stock purchase plan		
Expected term (in years)	0.5	0.5
Expected volatility	53.10%	62.56%
Risk-free interest rate	0.09%	1.57%
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 non-employee stock-based awards for the three months ended March 31, 2021 and 2020, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Cost of testing services	$ 395	$ 247
Cost of product	76	59
Cost of digital and other	108	59
Research and development	1,358	810
Sales and marketing	1,659	971
General and administrative	2,951	2,113
Total	$ 6,547	$ 4,259

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.

13. INCOME TAXES

The Company's effective tax rate may vary from the U.S. federal statutory tax rate due to the change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income. For the three months ended March 31, 2021 and 2020, the Company recorded an income tax benefit of $0.3 million and $0.3 million, respectively. The income tax benefit of $0.3 million 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 Cuts and Jobs Act of 2017. 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 2021 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.

14. 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 March 31,	
	2021	2020
Testing services revenue		
United States	$ 59,021	$ 31,329
Rest of World	260	113
	$ 59,281	$ 31,442
Product revenue		
United States	$ 2,495	$ 2,061
Europe	2,252	2,002
Rest of World	1,031	632
	$ 5,778	$ 4,695
Digital and other revenue		
United States	$ 2,288	$ 2,183
Europe	31	30
Rest of World	22	30
	$ 2,341	$ 2,243
Total United States	$ 63,804	$ 35,573
Total Europe	$ 2,283	$ 2,032
Total Rest of World	$ 1,313	$ 775
Total	$ 67,400	$ 38,380

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

	March 31, 2021	December 31, 2020
Long-lived assets:		
United States	$ 10,700	$ 9,888
Europe	302	351
Rest of World	396	465
Total	$ 11,398	$ 10,704

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, 2020, filed with the Securities and Exchange Commission, or the SEC, on February 24, 2021.

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 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, 2020, filed with the SEC on February 24, 2021. 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., or 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 March 31, 2021 and Recent Highlights

- Achieved total revenue of $67.4 million for the three months ended March 31, 2021, increasing 76% year-over-year
- Total AlloSure and AlloMap patient results provided in the quarter were approximately 33,200, which includes approximately 5,900 AlloSure Heart patient results
- As of March 31, 2021, over 60 U.S.-based transplant centers have adopted an AlloSure Kidney testing protocol, and we now connect more than 20,000 dialysis patients seeking to be referred for transplant with over 30 centers and greater than 500 dialysis centers through Tx Connect
- Completed successful public offering raising approximately $188.7 million in net proceeds, increasing cash, cash equivalents and marketable securities to $374.3 million as of March 31, 2021

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 of AlloMap Heart, 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., or Kaiser, several Blue Cross Blue Shield, or BCBS, plans and UnitedHealthcare.

In October 2020, we received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753. AlloSure Heart has received positive coverage from Geisinger Health and is covered for use throughout Kaiser.

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) study, which was published in the American Journal of Transplant, or AJT. A subsequent clinical utility trial, Invasive Monitoring Attenuation through Gene Expression (Pham MX et al., N. Eng. J. Med., 2010), 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 ISHLT (International Society for Heart and Lung Transplantation) 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 the 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 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.

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and 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 Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA, targeting polymorphisms between donor and recipient. This single-nucleotide polymorphism approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable and 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 is covered for use within Kaiser and has received positive coverage decisions from BCBS of South Carolina, BCBS of Kansas City, Capital Health and BCBS Vermont. Additional coverage by other private payers occurs on a contractual or 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 Kidney 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, the 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 Kidney 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, there has been an increasing body of evidence supports the use of AlloSure Kidney 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 of 50%, showing no significant difference between patients with and without rejection. Multiple publications and abstracts have shown AlloSure Kidney'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, has enrolled over 1,700 patients, with plans to survey patients with AlloSure Kidney 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, Inc.'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 authorization 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 other solutions on the market 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 authorization 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 has the potential to provide better sensitivity and data analysis compared to current solutions on the market.

In March 2021, the Company acquired BFS Molecular S.R.L. (“BFS Molecular”), a software company focused on NGS-based patient testing solutions. BFS Molecular brings extensive software and algorithm development capabilities for NGS transplant surveillance products.

Digital

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

On May 7, 2019, we acquired 100% of the outstanding common stock of Ottr, Inc. Ottr, Inc. 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, or EMR, 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 XynCare. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients reporting. XynCare 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.

In January 2021, we acquired TransChart LLC, or TransChart, for cash. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Connect, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

COVID-19 Impact

In the final weeks of March 2020 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 2020 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 200 transplant centers can offer RemoTraC to their patients and over 7,000 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, our testing services volumes returned to levels consistent with those experienced immediately prior to the COVID-19 pandemic, and, through March 31, 2021, volumes continued to be at or above those levels since May 2020. In spite of the resurgence of COVID-19 infection rates, which resulted in increased stay-at-home and renewed travel restrictions, we did not experience a decrease in testing services volumes. Our product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as we were unable to undertake onsite discussions and demonstrations of our recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. Our product business maintained normal sales volumes during the fourth quarter of 2020 and continued to maintain normal sales volumes through the first quarter of 2021.

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, AlloMap Heart and AlloSure Heart tests, which represented 88% and 82% of our total revenue for the three months ended March 31, 2021 and 2020, respectively. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; 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 as well as general nephrologists managing transplant recipients . 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.

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP, QTYPE and TruSight products. Product revenue represented 9% and 12% of total revenue for the three months ended March 31, 2021 and 2020, 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, XynQAPI and TransChart licenses and services and other licensing agreements. Digital and other revenue represented 3% and 6% of total revenue for the three months ended March 31, 2021 and 2020, 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.

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

- Revenue recognition;
- Business combinations;
- 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 months ended March 31, 2021 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, 2020.

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 March 31, 2021 and 2020

(In thousands)

	Three Months Ended March 31,		
	2021	2020	Change
Revenue:			
Testing services revenue	$ 59,281	$ 31,442	$ 27,839
Product revenue	5,778	4,695	1,083
Digital and other revenue	2,341	2,243	98
Total revenue	67,400	38,380	29,020
Operating expenses:			
Cost of testing services	16,483	7,928	8,555
Cost of product	3,647	3,199	448
Cost of digital and other	1,449	1,265	184
Research and development	16,004	10,013	5,991
Sales and marketing	15,452	11,723	3,729
General and administrative	15,223	10,003	5,220
Total operating expenses	68,258	44,131	24,127
Loss from operations	(858)	(5,751)	4,893
Other income (expense):			
Interest income, net	126	96	30
Change in estimated fair value of common stock warrant liability	27	(405)	432
Other expense, net	(245)	(63)	(182)
Total other expense	(92)	(372)	280
Loss before income taxes	(950)	(6,123)	5,173
Income tax benefit	263	300	(37)
Net loss	$ (687)	$ (5,823)	$ 5,136

Testing Services Revenue

Testing services revenue increased by $27.8 million, or 89%, for the three months ended March 31, 2021 compared to the same period in 2020. This increase is primarily due to an increase of more than 18,000 AlloSure Kidney, AlloMap Heart and AlloSure Heart patient results provided in the three months ended March 31, 2021, compared to the same period in 2020.

Product Revenue

Product revenue increased by $1.1 million, or 23%, for the three months ended March 31, 2021, compared to the same period in 2020. The increase is primarily due to an increase in sales of NGS HLA typing products, including AlloSeq Tx 17, which was awarded CE mark approval in May 2020.

Digital and Other Revenue

Digital and other revenue increased by $0.1 million, or 4%, for the three months ended March 31, 2021 compared to the same period in 2020, primarily due to the acquisition of TransChart in January 2021.

Cost of Testing Services

Cost of testing services increased by $8.6 million, or 108%, for the three months ended March 31, 2021, compared to the same period in 2020, primarily due to increased testing volume, increased personnel-related expenses and the costs of providing RemoTraC, which was launched in late March 2020 in response to the COVID-19 pandemic.

Cost of Product

Cost of product increased by $0.4 million, or 14%, for the three months ended March 31, 2021, compared to the same period in 2020. The increase is primarily due to increased product sales and freight costs.

Cost of Digital and Other

Cost of digital and other increased by $0.2 million, or 15%, for the three months ended March 31, 2021, compared to the same period in 2020, primarily due to an increase in personnel-related costs.

Research and Development

Research and development expenses increased by $6.0 million, or 60%, for the three months ended March 31, 2021, compared to the same period in 2020, primarily due to an increase in personnel-related costs of $2.5 million, an increase of $1.1 million in clinical studies, an increase in stock-based compensation expense of $0.6 million, an increase in consulting and outside service fees of $0.5 million, an increase in reagents and consumables of $0.5 million and a $0.4 million increase in license and collaboration fees.

Sales and Marketing

Sales and marketing expenses increased by $3.7 million, or 32%, for the three months ended March 31, 2021, compared to the same period in 2020, primarily due to an increase in personnel-related costs of $3.6 million, an increase in stock-based compensation expense of $0.7 million and an increase in consulting and professional fees of $0.7 million. These increases were partially offset by a decrease in tradeshows and lower travel costs of $1.3 million due to COVID-19.

General and Administrative

General and administrative expenses increased by $5.2 million, or 52%, for the three months ended March 31, 2021, compared to the same period in 2020. This increase was primarily due to legal fees of $2.1 million related to litigation and general legal expenses, an increase of $1.6 million in personnel-related costs, an increase in stock-based compensation expense of $0.8 million and an increase of $0.4 million in consulting and professional fees.

Change in Estimated Fair Value of Common Stock Warrant Liability

The change in estimated fair value of common stock warrant liability decreased from a loss of $0.4 million for the three months ended March 31, 2020 to income of $27 thousand for the three months ended March 31, 2021, resulting in a net change of $0.4 million, or 107%.

The income of $27 thousand in the three months ended March 31, 2021 reflects a remeasurement gain of $27 thousand for the change in the fair value of our common stock warrant liability.

The $0.4 million expense in the three months ended March 31, 2020 reflects a change in the fair value of our common stock warrant liability and a charge for warrants exercised during the period. In the three months ended March 31, 2020, warrants to purchase approximately 272,000 shares of common stock with an average exercise price of $1.12 per share were exercised.

Cash Flows for the Three Months Ended March 31, 2021 and 2020

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

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (33,630)	$ (3,055)
Investing activities	19,079	(1,704)
Financing activities	189,228	(735)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(23)	(552)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 174,654	$ (6,046)

Operating Activities

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

Cash used in operating activities for the three months ended March 31, 2021 was $33.6 million. Our net loss of $0.7 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $6.5 million in stock-based compensation expense and $2.0 million of depreciation and amortization expense. Net operating assets decreased by $21.6 million, and Refund liability - CMS advance payment decreased by $20.5 million.

Cash used in operating activities for the three months ended March 31, 2020 was $3.1 million. Our net loss of $5.8 million was our primary use of cash in operating activities and included a number of noncash items. Our noncash items included a $4.3 million stock-based compensation expense, a $0.4 million loss on the revaluation of common stock warrant liability to estimated fair value and $1.6 million of depreciation and amortization expense. Net operating assets decreased by $4.3 million.

Investing Activities

For the three months ended March 31, 2021, net cash provided by investing activities of $19.1 million was primarily related to the maturities of marketable securities of $25.1 million. These proceeds were partially offset by the acquisition of TransChart, net of cash acquired of $3.5 million, $1.2 million related to payments for acquired intangibles and $1.3 million related to additions of capital expenditures, net.

For the three months ended March 31, 2020, net cash used in investing activities was $1.7 million, related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 of $189.2 million was primarily related to $188.7 million of proceeds from the issuance of shares of common stock in an underwritten offering, net of issuance costs, proceeds from exercises of stock options of $2.2 million and proceeds from issuances of common stock under our employee stock purchase plan of $0.7 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $2.3 million.

Net cash used in financing activities for the three months ended March 31, 2020 of $0.7 million was primarily related to repurchases of common stock under employee incentive plans of $1.5 million, partially offset by proceeds from issuances of common stock under our employee stock purchase plan of $0.4 million, proceeds from exercises of warrants of $0.3 million and proceeds from exercises of stock options of $0.2 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 $353.2 million at March 31, 2021. As of March 31, 2021, we had cash, cash equivalents and marketable securities of $374.3 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. With our continuing growth, we may require additional financing in the future to fund working capital and our development of future products. Additional financing might include issuance of equity securities, including through underwritten public offerings or “at-the-market” offerings, debt offerings or financings or a combination of these financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. We believe our existing cash balance and expected cash from existing operations, including cash from current license agreements and future license and collaboration agreements, or a combination of these, will be sufficient to meet our anticipated cash requirements for the next 12 months.

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, or the CARES Act. Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services, or CMS, expanded its 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 submitted a request to the appropriate Medicare Administrative Contractor and met 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.

During December 2020, we reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021. We recorded the amount as Refund liability - CMS advance payment on the condensed consolidated balance sheet as of December 31, 2020.

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 statements of operations.

We are complying with the key terms and provisions of the CARES Act Provider Relief Fund which includes, among other things, the requirement that we maintain appropriate records and cost documentation. We have registered with HHS to submit financial data indicating our use of the funds we received pursuant to the CARES Act Provider Relief Fund. We will be notified by HHS when the Provider Relief Fund Reporting Portal is open for reporting on the use of Provider Relief Fund payments.

Underwritten Public Offering of Common Stock

On June 15, 2020, we sold 4,492,187 shares of common stock (which included 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.

Public Offering of Common Stock

On January 25, 2021, we sold 1,923,077 shares of our common stock through an underwritten public offering at a public offering price of $91.00 per share. The net proceeds to us from the offering were approximately $164.0 million, after deducting underwriting discounts and commissions and offering expenses.

On February 11, 2021, we sold 288,461 shares of our common stock pursuant to the full exercise of the overallotment option granted to the underwriters in connection with the offering. The net proceeds to us from the full exercise of the underwriters' overallotment option were approximately $24.7 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 AlloMap Heart, AlloSure Kidney and AlloSure Heart Tests We Receive and Report

The growth of our testing services business is tied to the number of AlloSure Kidney, AlloMap Heart and AlloSure 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 ISHLT 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, included 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, 2025, and the preceding data collection period will become January 1 through June 30, 2024.

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, several BCBS plans and UnitedHealthcare.

Reimbursement for AlloSure Kidney

On September 26, 2017, we received notice that the MolDX Program 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

In October 2020, we received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

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 Inc.'s NGS product line for use in transplantation diagnostic testing. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina’s TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines 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 authorization 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 authorization 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 has the potential to 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 implementation of our Ottr and XynQAPI software businesses, as well as continued support and maintenance of existing Ottr, Inc. 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

For a discussion regarding our significant contractual obligations as of March 31, 2021 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, please refer to Note 9 of the condensed consolidated financial statements, and the section entitled “Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources”, respectively, included elsewhere in this Quarterly Report on Form 10-Q.

Off-Balance Sheet Arrangements

Not required.

Foreign Operations

The accompanying unaudited condensed consolidated balance sheets contain certain recorded assets in foreign countries, namely Stockholm, Sweden 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, cash equivalents and marketable securities of $374.3 million and $224.7 million at March 31, 2021 and December 31, 2020, 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 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $0.9 million on our condensed consolidated financial statements.

Foreign Currency Exchange Risk

We have operations in Sweden and 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 March 31, 2021, would have negatively impacted our financial results for the three months ended March 31, 2021 by less than $0.3 million and our product revenue by $0.3 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 March 31, 2021. 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 March 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended March 31, 2021 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 9, *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, 2020, filed with the SEC on February 24, 2021, 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, 2020, filed with the SEC on February 24, 2021, 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

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

We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the quarter ended March 31, 2021, our net loss was $0.7 million. As of March 31, 2021, we had an accumulated deficit of $353.2 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and digital solutions, including additional expenses in connection with our continuing development and commercialization of KidneyCare, HeartCare, AlloSeq, AiTraC and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC;
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a public company; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

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

We may require additional financing.

As of March 31, 2021, we had cash, cash equivalents and marketable securities of $374.3 million and an accumulated deficit of $353.2 million. On January 25, 2021, we completed an underwritten public offering of common stock, and on February 11, 2021, we sold additional shares of common stock pursuant to the underwriters' full exercise of an overallotment option granted to the underwriters in connection with the offering. The aggregate net proceeds to us, including the shares sold pursuant to the underwriters' full exercise of the overallotment option, were approximately $188.7 million, after deducting underwriting discounts and commissions and offering expenses. We may require additional financing in the future to fund working capital, pay our obligations as they come due and fund our acquisitions of complementary businesses and assets. Additional financing might include issuance of equity securities, debt, cash from collaboration agreements, or a combination of these. However, there can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us.

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

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

For example, we recently became aware that in October 2020, prior to terminating employment and joining a competitor of ours with which we are in current litigation, a former employee of ours downloaded certain of our confidential and privileged information without permission. After our claims against this former employee were filed, the former employee subsequently brought various claims against us. We are in the process of reviewing and, with the assistance of counsel, are continuing to conduct certain interviews and gather information. We intend to vigorously pursue and defend against these matters. Although we believe we have strong claims against, and good and substantial defenses to the claims made by, the former employee, there is no guarantee that we will prevail in these matters. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

Risks Related to Acquisitions, Partnerships and Investments

Our portfolio of marketable securities is significant and subject to market, interest and credit risk that may reduce its value.

At March 31, 2021, we had $65.0 million in marketable securities invested through a professional investment management firm. These investments are primarily in corporate debt securities, but our investments also include money market funds that meet the criteria of our investment policy, which is focused on the preservation of our capital, maintaining liquidity and providing diversification. Changes in the value of this portfolio could adversely affect our earnings, and these investments are subject to general credit, liquidity and market and interest rate risks. In particular, the value of our investments may decline due to increases or decreases in interest rates, downgrades of debt securities included in our portfolio, instability in the global financial markets that reduces the liquidity of securities included in our portfolio and other factors, including unexpected or unprecedented events such as the COVID-19 pandemic. Each of these events may cause us to record charges to reduce the carrying value of our investment portfolio or sell investments for less than our acquisition cost, and could have a material adverse impact on our financial condition and operating results.

Risks Related to Our Intellectual Property

Our competitive position depends on maintaining intellectual property protection.

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

Our patent position for AlloMap Heart is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and resting leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of April 27, 2021, we had 28 issued U.S. patents related to transplant rejection and autoimmunity. We have five issued U.S. patents covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart. The expiration dates of these patents range from 2021 to 2024. We have five additional patents covering additional genes or gene variants for diagnosing transplant rejection.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to a U.S. patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This patent has an expiration date of November 5, 2030. A second patent included in the license from Stanford was issued in December 2017 and further covers the use of dd-cfDNA to diagnose and predict transplant status or outcome. A third and fourth patent were issued from this Stanford set in June 2019 and December 2019, respectively, covering the use of dd-cfDNA to diagnose and predict transplant status or outcome. Both patents have the same 2030 expiration date as the original Stanford patent. In April 2021, three additional patents were issued from the license from Stanford, each of which expire in 2030.

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

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

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

We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we or our licensors, as applicable, were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own or exclusively license and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a United States patent application covering an invention that is similar to, or the same as, an invention that we own or license, we or our licensors may have to participate in an interference or other proceeding in the PTO or a court to determine priority of invention in the United States for pre-AIA applications and patents.

For post-AIA applications and patents, we or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in our inability to obtain or retain any United States patent rights with respect to such invention.

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. From January 4, 2021 to April 30, 2021, our closing stock price has ranged from $57.62 to $95.60 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. From January 4, 2021 to April 30, 2021, our closing stock price has ranged from $57.62 to $95.60 per share. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on 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 March 31, 2021:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)
January 1, 2021 - January 31, 2021	28,121	(1)	$ 24.76
February 1, 2021 - February 28, 2021	46,034	(1)	31.50
March 1, 2021 - March 31, 2021	279	(1)	26.24
Total	74,434		—

(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.
10.1(11)#	Offer Letter, dated February 11, 2021, between CareDx, Inc. and Ankur Dhingra.
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.
(11)	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on March 11, 2021.
#	Indicates management contract or compensatory plan or arrangement.
*	Filed herewith.
**	Furnished herewith.

SIGNATURES

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

CAREDX, INC.
(Registrant)

Date: May 5, 2021

By: /s/ REGINALD SEETO, MBBS
Reginald Seeto, MBBS
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ ANKUR DHINGRA
Ankur Dhingra
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, Reginald Seeto, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CareDx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2021

By: /s/ Reginald Seeto, MBBS
Reginald Seeto, MBBS
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, Ankur Dhingra, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CareDx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2021

By: /s/ Ankur Dhingra
Ankur Dhingra
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 March 31, 2021 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/ Reginald Seeto, MBBS
Reginald Seeto, MBBS
President and Chief Executive Officer
(Principal Executive Officer)
Date: May 5, 2021

By: /s/ Ankur Dhingra
Ankur Dhingra
Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: May 5, 2021

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.