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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 52,802,200 shares of the registrant's Common Stock issued and outstanding as of October 26, 2021.

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PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 353,082	$ 134,669
Marketable securities	10,199	90,034
Accounts receivable	56,181	34,624
Inventory	18,800	10,012
Prepaid and other current assets	6,413	3,758
Total current assets	444,675	273,097
Property and equipment, net	18,719	10,704
Operating leases right-of-use assets	18,316	15,228
Intangible assets, net	48,367	44,355
Goodwill	26,051	23,857
Restricted cash	210	270
Other assets	6,834	1,000
Total assets	$ 563,172	$ 368,511
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,894	$ 9,653
Accrued compensation	24,243	18,466
Accrued and other liabilities	30,599	20,602
Refund liability - CMS advance payment (Note 1)	—	20,496
Total current liabilities	69,736	69,217
Deferred tax liability	678	1,299
Common stock warrant liability	195	447
Deferred payments for intangible assets	2,084	3,560
Operating lease liability, less current portion	17,876	16,069
Other liabilities	456	240
Total liabilities	91,025	90,832
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at September 30, 2021 and December 31, 2020; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at September 30, 2021 and December 31, 2020; 52,776,733 shares and 49,441,166 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	52	49
Additional paid-in capital	843,226	632,253
Accumulated other comprehensive loss	(4,093)	(2,096)
Accumulated deficit	(367,038)	(352,527)
Total stockholders' equity	472,147	277,679
Total liabilities and stockholders' equity	$ 563,172	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Testing services revenue	$ 66,464	$ 45,529	$ 190,635	$ 113,264
Product revenue	6,521	5,383	19,160	13,369
Digital and other revenue	2,604	2,457	7,382	6,917
Total revenue	75,589	53,369	217,177	133,550
Operating expenses:				
Cost of testing services	18,038	11,900	51,756	30,631
Cost of product	4,919	3,705	13,771	9,635
Cost of digital and other	1,879	1,210	4,861	3,966
Research and development	19,439	12,474	54,479	35,616
Sales and marketing	21,370	13,870	56,421	37,727
General and administrative	18,671	13,117	50,216	35,436
Total operating expenses	84,316	56,276	231,504	153,011
Loss from operations	(8,727)	(2,907)	(14,327)	(19,461)
Other income (expense):				
Interest income, net	20	29	147	146
Change in estimated fair value of common stock warrant liability	88	79	50	(990)
CARES Act Provider Relief Fund	—	—	—	4,813
Other expense, net	(3,440)	(254)	(906)	(572)
Total other (expense) income	(3,332)	(146)	(709)	3,397
Loss before income taxes	(12,059)	(3,053)	(15,036)	(16,064)
Income tax benefit	162	235	525	865
Net loss	$ (11,897)	$ (2,818)	$ (14,511)	$ (15,199)
Net loss per share (Note 3):				
Basic	$ (0.23)	$ (0.06)	$ (0.28)	$ (0.33)
Diluted	$ (0.23)	$ (0.06)	$ (0.28)	$ (0.33)
Weighted-average shares used to compute net loss per share:				
Basic	52,681,451	49,010,680	52,034,450	45,526,810
Diluted	52,681,451	49,010,680	52,034,450	45,526,810

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (11,897)	$ (2,818)	$ (14,511)	$ (15,199)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax	(937)	962	(1,997)	853
Net comprehensive loss	$ (12,834)	$ (1,856)	$ (16,508)	$ (14,346)

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
RSU settlements, net of shares withheld	160,286	—	(6,638)	—	—	(6,638)
Issuance of common stock for services	23,163	—	59	—	—	59
Issuance of common stock for cash upon exercise of stock options	427,059	—	6,833	—	—	6,833
Issuance of common stock for cash upon exercise of warrants	3,132	—	205	—	—	205
Employee stock-based compensation expense	—	—	9,322	—	—	9,322
Foreign currency translation adjustment	—	—	—	443	—	443
Net loss	—	—	—	—	(1,927)	(1,927)
Balance at June 30, 2021	52,552,761	51	838,089	(3,156)	(355,141)	479,843
Issuance of common stock under ESPP	21,412	—	1,301	—	—	1,301
RSU settlements, net of shares withheld	118,466	—	(8,707)	—	—	(8,707)
Issuance of common stock for services	4,008	—	75	—	—	75
Issuance of common stock for cash upon exercise of stock options	80,086	1	1,894	—	—	1,895
Employee stock-based compensation expense	—	—	10,574	—		10,574
Foreign currency translation adjustment	—	—	—	(937)	—	(937)
Net loss	—	—	—	—	(11,897)	(11,897)
Balance at September 30, 2021	52,776,733	$ 52	$ 843,226	$ (4,093)	$ (367,038)	$ 472,147

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

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

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

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

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

	Nine Months Ended September 30,	
	2021	2020
Operating activities:		
Net loss	$ (14,511)	$ (15,199)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	26,583	17,424
Revaluation of common stock warrant liability to estimated fair value	(50)	990
Depreciation and amortization	6,301	5,052
Amortization of right-of-use assets	2,187	1,896
Unrealized loss on long-term marketable equity securities	167	—
Revaluation of contingent consideration to estimated fair value	(35)	301
Amortization of premium on short-term marketable securities, net	930	—
Changes in operating assets and liabilities:		
Accounts receivable	(21,580)	(5,359)
Inventory	(9,417)	(3,608)
Prepaid and other assets	(2,072)	(681)
Operating leases liabilities, net	(1,677)	(1,096)
Accounts payable	400	3,831
Accrued compensation	2,711	1,501
Accrued and other liabilities	7,688	1,581
Refund liability - CMS advance payment	(20,496)	20,496
Change in deferred taxes	(589)	(879)
Net cash (used in) provided by operating activities	(23,460)	26,250
Investing activities:		
Acquisition of business, net of cash acquired	(3,500)	—
Acquisition of intangible assets	(6,700)	(3,250)
Purchases of long-term marketable securities	(5,500)	—
Maturities of short-term marketable securities	78,905	—
Additions of capital expenditures, net	(7,711)	(6,670)
Net cash provided by (used in) investing activities	55,494	(9,920)
Financing activities:		
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	188,855	134,684
Proceeds from issuance of common shares in "at-the-market" equity offering, net of issuance costs paid	—	23,451
Proceeds from issuance of common stock under employee stock purchase plan	2,139	1,082
Taxes paid related to net share settlement of restricted stock units	(15,376)	(4,003)
Proceeds from exercise of warrants	4	343
Proceeds from exercise of stock options	10,920	3,764
Principal payments on finance lease obligations	(66)	(136)
Net cash provided by financing activities	186,476	159,185
Effect of exchange rate changes on cash and cash equivalents	(157)	64
Net increase in cash, cash equivalents and restricted cash	218,353	175,579
Cash, cash equivalents, and restricted cash at beginning of period	134,939	38,479
Cash, cash equivalents, and restricted cash at end of period	$ 353,292	$ 214,058

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 solution for heart transplant patients. The Company has initiated several clinical studies to generate data on its existing and planned future testing services. In April 2020, the Company announced its first biopharma research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. The Company also offers high-quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. In 2019, the Company began providing digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management ("Ottr, Inc.") and XynManagement, Inc. ("XynManagement"), as well as the acquisition of TransChart LLC ("TransChart") in 2021.

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 several private payers, including 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.

In May 2021, the Company purchased a minority investment of common stock in the biotechnology company Miromatrix Medical, Inc. ("Miromatrix"), for $5.0 million, and the investment is marked to market. Miromatrix works to eliminate the need for an organ transplant waiting list through the development of implantable engineered biological organs.

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 for a multimodality surveillance solution. The Company has not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare.

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 TxAccess, 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.

In June 2021, the Company acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

Also in June 2021, the Company entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. Together, the Company and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system. The Company has agreed to potential future milestone payments.

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 9,000 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.

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 increased sales volumes throughout 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 virtual platforms. Although the executive orders that placed certain restrictions on operations in San Mateo County and the State of California, where the Company's laboratory and headquarters are located, were lifted effective June 15, 2021, new orders or restrictions may be adopted in the future depending upon the COVID-19 transmission rates in the Company's 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 $367.0 million at September 30, 2021. As of September 30, 2021, the Company had cash, cash equivalents and marketable securities of $363.3 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. During the quarter ended September 30, 2021, the Company was notified by HHS that the Provider Relief Fund Reporting Portal was open for reporting

on the use of Provider Relief Fund payments, and the Company completed and submitted a report indicating the use of the funds the Company received pursuant to the CARES Act.

June 2020 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.

January 2021 Underwritten 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 and nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

Use of Estimates

The preparation of unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the unaudited condensed consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to transaction price estimates used for testing services revenue; standalone fair value of digital revenue performance obligations; accrued expenses for clinical studies; inventory valuation; the fair value of issued common stock warrants and embedded derivatives; the fair value of assets and liabilities acquired in a business combination or an assets acquisition (including identifiable intangible assets acquired); the fair value of contingent consideration recorded in connection with a business combination; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended September 30, 2021 and 2020, approximately 61% and 58%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2021 and 2020, approximately 60% and 56%, respectively, of total revenue was derived from Medicare.

As of September 30, 2021 and December 31, 2020, approximately 29% and 28%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable on either September 30, 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 September 30, 2021, the Company's short-term 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 short-term marketable securities are classified as current assets on the condensed consolidated balance sheet.

The Company classifies its short-term 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. Short-term 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 short-term marketable securities are included in interest income (expense), net. The cost of securities sold will be determined using specific identification.

The Company considers investments in securities with remaining maturities of over one year as long-term investments. As of September 30, 2021, the Company's long-term marketable securities consisted of corporate equity securities and corporate debt securities. These long-term marketable securities are classified as other assets on the condensed consolidated balance sheet.

The Company classifies its long-term marketable debt securities as available-for-sale and reevaluates such designation at each balance sheet date. The Company records its long-term marketable equity securities at fair market value. Unrealized gains and losses from the remeasurement of the long-term marketable equity securities to fair value are included in other expense, net, in the condensed consolidated statements of operations. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on long-term marketable securities are included in interest income, net.

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 September 30, 2021, the Company's leases had remaining terms of 0.67 years to 7.42 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.

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force), which contains amendments that clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The amendments set forth in this ASU are effective for all entities

for annual periods beginning after December 15, 2021. Early application of the amendments in this ASU is permitted for all entities. The amendments in this ASU should be applied prospectively. The Company plans to adopt the standard on January 1, 2022. The Company is in the process of assessing the impact that this new standard will have on its 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss used to compute basic and diluted net loss per share	$ (11,897)	$ (2,818)	$ (14,511)	$ (15,199)
Denominator:				
Weighted-average shares used to compute basic and diluted net loss per share	52,681,451	49,010,680	52,034,450	45,526,810
Net loss per share:				
Basic and diluted	$ (0.23)	$ (0.06)	$ (0.28)	$ (0.33)

The following potentially dilutive securities have been excluded from diluted net loss per share as of September 30, 2021 and 2020 because their effect would be antidilutive:

	Three and Nine Months Ended September 30,	
	2021	2020
Shares of common stock subject to outstanding options	1,989,286	3,082,273
Shares of common stock subject to outstanding common stock warrants	3,132	14,445
Restricted stock units	1,810,257	1,912,397
Total common stock equivalents	3,802,675	5,009,115

4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

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

The following table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	$ 334,895	$ —	$ —	$ 334,895
Long-term marketable securities:				
Corporate equity securities	4,833	—	—	4,833
Corporate debt securities	—	500	—	500
Total	$ 339,728	$ 500	$ —	$ 340,228
Liabilities				
Common stock warrant liability	$ —	$ —	$ 195	$ 195

	December 31, 2020			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
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	(202)
Change in estimated fair value	(50)
Balance as of September 30, 2021	$ 195

As of September 30, 2021, the Company had one investment in convertible preferred shares carried at cost. 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 September 30, 2021 and December 31, 2020, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *Short-term marketable securities* – Investments in short-term 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.
- *Long-term marketable equity and debt securities* – Investments in long-term marketable equity securities are classified within Level 1. The securities are recorded at fair value based on readily available quoted market

prices in active markets. Investments in long-term marketable debt securities are classified within Level 2. The securities are recorded at fair value based on observable inputs for quoted prices for identical or similar assets in markets that are not active. Long-term marketable securities are located within other assets on the condensed consolidated balance sheets.

- *Common stock warrant liability* – Common stock warrant liability is classified within Level 3. The Company utilizes a binomial-lattice pricing model (the "Monte Carlo Simulation Model") that involves a market condition simulation to estimate the fair value of the warrants. The application of the Monte Carlo Simulation Model requires the use of a number of complex assumptions, including the Company's stock price, expected life of the warrants, stock price volatility determined from the Company's historical stock prices and stock prices of peer companies in the diagnostics industry, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of the warrants. Increases (decreases) in the assumptions discussed above result in a directionally similar impact to the fair value of the common stock warrant liability.

Common Stock Warrant Liability Valuation Assumptions:

	September 30, 2021	December 31, 2020
Private Placement Common Stock Warrant Liability		
Stock Price	$ 63.37	$ 72.45
Exercise Price	$ 1.12	$ 1.12
Remaining term (in years)	1.54	2.28
Volatility	66.00 %	73.00 %
Risk-free interest rate	0.19 %	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):

	September 30, 2021	December 31, 2020	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 353,082	$ 134,669	$ 213,798	$ 38,223
Restricted cash	210	270	260	256
Total cash, cash equivalents, and restricted cash at the end of the period	$ 353,292	$ 134,939	$ 214,058	$ 38,479

Marketable Securities

All short-term marketable securities were considered held-to-maturity at September 30, 2021 and December 31, 2020. As of September 30, 2021 and December 31, 2020, some of the Company's short-term marketable securities were in an unrealized loss position. The Company determined that it had the positive intent and ability to hold until maturity all short-term marketable securities that have been in a continuous loss position, thus there was no recognition of any other-than-temporary impairment as of September 30, 2021 and December 31, 2020. All short-term marketable securities with unrealized losses as of each balance sheet date have been in a loss position for less than twelve months. Contractual maturities of the short-term marketable securities are within one year or less as of September 30, 2021.

The long-term marketable equity securities were recorded at fair market value. The long-term marketable debt securities were considered available-for-sale at September 30, 2021. The contractual maturity of the long-term marketable debt securities are less than three years.

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 tables below (in thousands):

	September 30, 2021		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term marketable securities:			
Corporate debt securities	$ 10,199	$ (2)	$ 10,197
Total short-term marketable securities	10,199	(2)	10,197
Long-term marketable securities:			
Corporate equity securities	5,000	(167)	4,833
Corporate debt securities	500	—	500
Total long-term marketable securities	5,500	(167)	5,333
Total	$ 15,699	$ (169)	$ 15,530

	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 marketable securities at each balance sheet date are as follows (in thousands):

	September 30, 2021	December 31, 2020
Within one year	$ 10,199	$ 90,034
After one year through five years	500	—
Total	$ 10,699	$ 90,034

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. As a result of the acquisition, the Company recognized goodwill of $2.2 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 and nine months ended September 30, 2021. The balance of the Company's goodwill as of September 30, 2021 and December 31, 2020 was $26.1 million and $23.9 million, respectively.

Intangible Assets

The following table presents details of the Company’s intangible assets as of September 30, 2021 ($ in thousands):

	September 30, 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	$ 34,784	$ (11,264)	$ (1,312)	$ 22,208	8.3
Customer relationships	19,308	(5,666)	(1,010)	12,632	10.2
Commercialization rights	10,579	(1,749)	—	8,830	7.9
Trademarks and tradenames	2,380	(939)	(119)	1,322	9.2
Other	250	(125)	—	125	0.5
Total intangible assets with finite lives	$ 67,301	$ (19,743)	$ (2,441)	$ 45,117	
Acquired in-process technology	3,250	—	—	3,250	
Total intangible assets	$ 70,551	$ (19,743)	$ (2,441)	$ 48,367	

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 2021, the Company acquired commercialization rights in an exclusive partnership for comprehensive data analytics in relation to NGS-based metagenomics testing for infectious diseases. This is included within Commercialization rights as of September 30, 2021.

In June 2021, the Company acquired the Transplant Hero patient application. The patient application is included in Acquired and developed technology as of September 30, 2021.

Also in June 2021, the Company entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. As of September 30, 2021, the Company included $2.0 million in Acquired in-process technology for milestones related to the strategic agreement.

As of September 30, 2021, the Company included acquisitions of $7.5 million, which included $3.6 million of Acquired and developed technology, $2.5 million of Commercialization rights, $1.1 million of Customer relationships and $0.3 million of Other intangible assets.

Amortization of Intangible Assets

Amortization expense was $1.5 million and $1.2 million for the three months ended September 30, 2021 and 2020, respectively. For the three months ended September 30, 2021, expenses of $0.3 million, $0.4 million, $0.3 million and $0.5 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 September 30, 2020, expenses of $0.3 million, $0.4 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.

Amortization expense was $4.2 million and $3.5 million for the nine months ended September 30, 2021 and 2020, respectively. For the nine months ended September 30, 2021, expenses of $1.0 million, $1.4 million, $0.5 million and $1.3 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively. For the nine months ended September 30, 2020, expenses of $1.0 million, $1.2 million, $0.2 million and $1.1 million were amortized to cost of testing, cost of product, cost of digital and other and sales and marketing, respectively.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 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	$ 329	$ 473	$ 209	$ 498	$ 1,509
2022	1,316	1,894	836	1,804	5,850
2023	1,316	1,894	836	1,732	5,778
2024	1,316	1,894	600	1,732	5,542
2025	1,316	1,894	431	1,732	5,373
Thereafter	5,457	5,008	1,622	8,978	21,065
Total future amortization expense	$ 11,050	$ 13,057	$ 4,534	$ 16,476	$ 45,117

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Finished goods	$ 2,871	$ 1,702
Work in progress	2,806	2,936
Raw materials	13,123	5,374
Total inventory	$ 18,800	$ 10,012

Accrued and Other Liabilities

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

	September 30, 2021	December 31, 2020
Clinical studies	$ 9,632	$ 6,733
Short-term lease liability	3,822	2,033
Deferred revenue	3,409	3,530
Professional fees	2,980	1,529
Deferred payments for intangible assets	2,000	2,000
Capital expenditures	1,648	—
Accrued royalty	1,598	1,072
Test sample processing fees	1,295	416
Contingent consideration	642	738
Other accrued expenses	3,573	2,551
Total accrued and other liabilities	$ 30,599	$ 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 September 30, 2021, the carrying value of the ROU asset was $18.3 million. The related current and non-current liabilities as of September 30, 2021 were $3.8 million and $17.9 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the condensed consolidated balance sheets.

The following table summarizes the lease cost for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 1,345	$ 1,120	$ 3,757	$ 3,353
Finance lease cost	—	51	53	155
Total lease cost	$ 1,345	$ 1,171	$ 3,810	$ 3,508

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

	September 30, 2021
Other information:	
Weighted-average remaining lease term - Operating leases (in years)	6.18
Weighted-average remaining lease term - Finance leases (in years)	0.00
Weighted-average discount rate - Operating leases (%)	10.1 %
Weighted-average discount rate - Finance leases (%)	— %

Maturities of operating lease liabilities as of September 30, 2021 are as follows (in thousands):

Year Ending December 31,	Operating Leases
Remainder of 2021	$ 1,387
2022	5,539
2023	4,209
2024	4,216
2025	3,980
Thereafter	10,256
Total lease payments	29,587
Less imputed interest	7,889
Present value of future minimum lease payments	21,698
Less operating lease liability, current portion	3,822
Operating lease liability, long-term portion	$ 17,876

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. The trial date is not currently set.

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.

United States Department of Justice and United States Securities and Exchange Commission Investigations

The Company recently received a civil investigative demand (CID) from the United States Department of Justice (DOJ) requesting that the Company produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the United States Securities and Exchange Commission (SEC) in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. The Company also received an information request from a state regulatory agency and may receive additional requests for information from the DOJ, SEC, or other regulatory and governmental agencies regarding similar or related subject matters. The Company does not believe that the CID, the SEC subpoena or the state regulatory agency information request raise any issues regarding the safety or efficacy of any of the Company's products or services and are cooperating fully with the investigations. Although the Company remains committed to compliance with all applicable laws and regulations, it cannot predict the outcome of the DOJ or SEC investigations, the state law information request, or any other requests or investigations that may arise in the future regarding these or other subject matters.

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 $0.4 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively. The Company incurred expenses related to contributions to the plan of $1.2 million and $0.6 million for the nine months ended September 30, 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 September 30, 2021, no warrants to purchase shares of common stock were exercised. In the nine months ended September 30, 2021, warrants to purchase approximately 3,000 shares of common stock were exercised for cash proceeds of $4 thousand.

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

As of September 30, 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	3,132
				3,132

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	1,878,866	$ 28.42
Additional shares authorized	1,977,647	—	—	—	—
Common stock awards for services	(2,998)	—	—	—	—
RSUs granted	(797,290)	—	—	797,290	79.36
RSUs vested	—	—	—	(639,335)	24.82
Options granted	(187,514)	187,514	80.40	—	—
Options exercised	—	(646,724)	17.05	—	—
Repurchase of common stock under employee incentive plans	216,813	—	—	—	—
RSUs forfeited	226,564	—	—	(226,564)	40.29
Options forfeited	214,115	(214,115)	27.67	—	—
Options expired	7,787	(7,787)	24.66	—	—
Balance—September 30, 2021	2,328,092	1,989,286	$ 28.42	1,810,257	$ 50.94

The total intrinsic value of options exercised was $4.2 million and $39.2 million for the three and nine months ended September 30, 2021, respectively. The total intrinsic value of options exercised was $4.0 million and $8.0 million for the three and nine months ended September 30, 2020, respectively.

As of September 30, 2021, the total intrinsic value of outstanding RSUs was approximately $114.7 million and there were $74.4 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 3.09 years.

Options outstanding that have vested and are expected to vest at September 30, 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	930	$ 19.07	6.69	$ 41,278
Expected to vest	954	36.87	8.34	28,184
Total	1,884			$ 69,462

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at September 30, 2021 for stock options that were in-the-money.

The total fair value of options that vested during the three and nine months ended September 30, 2021 was $3.6 million and $9.3 million, respectively. As of September 30, 2021, there were approximately $21.9 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.59 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 2021 that ended on June 30, 2021, 21,412 shares were purchased for aggregate proceeds of $1.3 million from the issuance of shares, which occurred on July 2, 2021. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Employee stock options				
Expected term (in years)	6.0	6.0	5.9	6.0
Expected volatility	78.27%	77.24%	77.84%	76.12%
Risk-free interest rate	0.85%	0.36%	0.77%	0.69%
Expected dividend yield	—%	—%	—%	—%
Employee stock purchase plan				
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	68.73%	93.17%	58.31%	75.36%
Risk-free interest rate	0.05%	0.17%	0.08%	0.98%
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 and nine months ended September 30, 2021 and 2020, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of testing services	$ 750	$ 431	$ 1,715	$ 1,101
Cost of product	156	97	446	289
Cost of digital and other	217	124	555	338
Research and development	1,986	1,224	5,284	3,490
Sales and marketing	3,853	1,623	8,144	4,175
General and administrative	3,677	3,249	10,439	8,031
Total	$ 10,639	$ 6,748	$ 26,583	$ 17,424

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 and nine months ended September 30, 2021, the Company recorded an income tax benefit of $0.2 million and $0.5 million, respectively, compared to $0.2 million and $0.9 million for the three and nine months ended September 30, 2020, respectively. The income tax benefit of $0.2 million and $0.5 million for the three and nine months ended September 30, 2021, respectively, is primarily attributable to the recognition of deferred tax assets from foreign losses. The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income, and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets. The Company has also placed a valuation allowance on the 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Testing services revenue				
United States	$ 66,096	$ 45,439	$ 189,956	$ 112,976
Rest of World	368	90	679	288
	$ 66,464	$ 45,529	$ 190,635	$ 113,264
Product revenue				
United States	$ 3,595	$ 2,755	$ 9,555	$ 6,032
Europe	2,227	1,950	7,138	5,448
Rest of World	699	678	2,467	1,889
	$ 6,521	$ 5,383	$ 19,160	$ 13,369
Digital and other revenue				
United States	$ 2,530	$ 2,409	$ 7,225	$ 6,745
Europe	31	24	72	64
Rest of World	43	24	85	108
	$ 2,604	$ 2,457	$ 7,382	$ 6,917
Total United States	$ 72,221	$ 50,603	$ 206,736	$ 125,753
Total Europe	$ 2,258	$ 1,974	$ 7,210	$ 5,512
Total Rest of World	$ 1,110	$ 792	$ 3,231	$ 2,285
Total	$ 75,589	$ 53,369	$ 217,177	$ 133,550

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

	September 30, 2021	December 31, 2020
Long-lived assets:		
United States	$ 17,925	$ 9,888
Europe	525	351
Rest of World	269	465
Total	$ 18,719	$ 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 and Nine Months Ended September 30, 2021 and Recent Highlights

- Achieved revenue of $75.6 million for the three months ended September 30, 2021, increasing 42% year-over-year
- Grew testing services volume 86% year-over-year, with approximately 40,000 AlloSure and AlloMap patient results provided in the quarter - highlighted by an approximately 90% attach rate for HeartCare
- Expanded patient referrals over 30% sequentially through TxAccess, to approximately 38,000
- Received first commercial AlloSure Lung coverage, followed by commercial launch of AlloSure Lung, the first dd-cfDNA test available for lung transplant patients, in October
- Announced publication of KidneyCare validation study in Kidney360 – Multicenter study validating AlloMap and demonstrating the complementary value with AlloSure for detecting rejection

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 Blue 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 supporting 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 in 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. ("Illumina"), or the Illumina Agreement, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS products and technologies for use in transplantation diagnostic testing.

On June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark 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 certain assets of 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 TxAccess, 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.

In June 2021, we acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

Also in June 2021, we entered into a strategic agreement with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

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 9,000 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. 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 increased sales volumes throughout 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 virtual platforms.

Although the executive orders that placed certain restrictions on operations in San Mateo County and the State of California, where our laboratory and headquarters are located, were lifted effective June 15, 2021, new orders or restrictions may be adopted in the future 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% of our total revenue for each of the three and nine months ended September 30, 2021, and 85% of our total revenue for each of the three and nine months ended September 30, 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 and QTYPE products. Product revenue represented 9% of our total revenue for each of the three and nine months ended September 30, 2021, and 10% of our total revenue for each of the three and nine months ended September 30, 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, TransChart and TxAccess licenses, services and SaaS agreements across the digital portfolio. Digital and other revenue represented 3% of our total revenue for each of the three and nine months ended September 30, 2021, and 5% of our total revenue for each of the three and nine months ended September 30, 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 and nine months ended September 30, 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 September 30, 2021 and 2020

(In thousands)

	Three Months Ended September 30,		
	2021	2020	Change
Revenue:			
Testing services revenue	$ 66,464	$ 45,529	$ 20,935
Product revenue	6,521	5,383	1,138
Digital and other revenue	2,604	2,457	147
Total revenue	75,589	53,369	22,220
Operating expenses:			
Cost of testing services	18,038	11,900	6,138
Cost of product	4,919	3,705	1,214
Cost of digital and other	1,879	1,210	669
Research and development	19,439	12,474	6,965
Sales and marketing	21,370	13,870	7,500
General and administrative	18,671	13,117	5,554
Total operating expenses	84,316	56,276	28,040
Loss from operations	(8,727)	(2,907)	(5,820)
Other income (expense):			
Interest income, net	20	29	(9)
Change in estimated fair value of common stock warrant liability	88	79	9
Other expense, net	(3,440)	(254)	(3,186)
Total other expense	(3,332)	(146)	(3,186)
Loss before income taxes	(12,059)	(3,053)	(9,006)
Income tax benefit	162	235	(73)
Net loss	$ (11,897)	$ (2,818)	$ (9,079)

Testing Services Revenue

Testing services revenue increased by $20.9 million, or 46%, for the three months ended September 30, 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 September 30, 2021, compared to the same period in 2020.

Product Revenue

Product revenue increased by $1.1 million, or 21%, for the three months ended September 30, 2021, compared to the same period in 2020, primarily due to growth from the NGS typing products.

Digital and Other Revenue

Digital and other revenue increased by $0.1 million, or 6%, for the three months ended September 30, 2021 compared to the same period in 2020.

Cost of Testing Services

Cost of testing services increased by $6.1 million, or 52%, for the three months ended September 30, 2021, compared to the same period in 2020. The increase is primarily due to increased testing volume, the related increased reagents, consumables and shipping expenses and personnel-related costs and stock-based compensation expense.

Cost of Product

Cost of product increased by $1.2 million, or 33%, for the three months ended September 30, 2021, compared to the same period in 2020. The increase is primarily due to increased product revenue, personnel-related costs and stock-based compensation expense.

Cost of Digital and Other

Cost of digital and other increased by $0.7 million, or 55%, for the three months ended September 30, 2021, compared to the same period in 2020. The increase is primarily due to increased personnel-related costs of $0.4 million, stock-based compensation expense of $0.1 million and amortization expense of $0.1 million related to new intangibles added during 2021.

Research and Development

Research and development expenses increased by $7.0 million, or 56%, for the three months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in headcount and personnel-related costs of $2.9 million, an increase in research and development services and other expenses of $2.0 million, an increase in stock-based compensation expense of $0.8 million, an increase in reagents and consumables of $0.7 million, and an increase in clinical studies of $0.4 million.

Sales and Marketing

Sales and marketing expenses increased by $7.5 million, or 54%, for the three months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in headcount and personnel-related costs of $2.8 million, an increase in stock-based compensation expense of $2.2 million and an increase in marketing programs and travel costs of $1.9 million.

General and Administrative

General and administrative expenses increased by $5.6 million, or 42%, for the three months ended September 30, 2021, compared to the same period in 2020. This increase was primarily due to an increase in legal expenses of $1.7 million, an increase in headcount and personnel-related expenses of $1.2 million, an increase in consulting expenses of $1.0 million, an increase in travel and other costs of $0.7 million and an increase in stock-based compensation expense of $0.4 million.

Other income (expense)

Other expense, net decreased by $3.2 million for the three months ended September 30, 2021, compared to the same period in 2020, primarily due to the unrealized loss on the investment in Miromatrix.

Comparison of the Nine Months Ended September 30, 2021 and 2020

(In thousands)

	Nine Months Ended September 30,		
	2021	2020	Change
Revenue:			
Testing services revenue	$ 190,635	$ 113,264	$ 77,371
Product revenue	19,160	13,369	5,791
Digital and other revenue	7,382	6,917	465
Total revenue	217,177	133,550	83,627
Operating expenses:			
Cost of testing services	51,756	30,631	21,125
Cost of product	13,771	9,635	4,136
Cost of digital and other	4,861	3,966	895
Research and development	54,479	35,616	18,863
Sales and marketing	56,421	37,727	18,694
General and administrative	50,216	35,436	14,780
Total operating expenses	231,504	153,011	78,493
Loss from operations	(14,327)	(19,461)	5,134
Other income (expense):			
Interest income, net	147	146	1
Change in estimated fair value of common stock warrant liability	50	(990)	1,040
CARES Act Provider Relief Fund	—	4,813	(4,813)
Other expense, net	(906)	(572)	(334)
Total other (expense) income	(709)	3,397	(4,106)
Loss before income taxes	(15,036)	(16,064)	1,028
Income tax benefit	525	865	(340)
Net loss	$ (14,511)	$ (15,199)	$ 688

Testing Services Revenue

Testing services revenue increased by $77.4 million, or 68%, for the nine months ended September 30, 2021 compared to the same period in 2020. This increase is primarily due to an increase of more than 56,000 AlloSure Kidney, AlloMap Heart and AlloSure Heart patient results provided in the nine months ended September 30, 2021, compared to the same period in 2020.

Product Revenue

Product revenue increased by $5.8 million, or 43%, for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to growth from the NGS typing products.

Digital and Other Revenue

Digital and other revenue increased by $0.5 million, or 7%, for the nine months ended September 30, 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 $21.1 million, or 69%, for the nine months ended September 30, 2021, compared to the same period in 2020. The increase is primarily due to increased testing volume, the related increased reagents, consumables and shipping expenses, and personnel-related costs and stock-based compensation expense.

Cost of Product

Cost of product increased by $4.1 million, or 43%, for the nine months ended September 30, 2021, compared to the same period in 2020. The increase is primarily due to increased product revenue, personnel-related costs and stock-based compensation expense.

Cost of Digital and Other

Cost of digital and other increased by $0.9 million, or 23%, for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in personnel-related costs and amortization of newly acquired intangibles.

Research and Development

Research and development expenses increased by $18.9 million, or 53%, for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in headcount and personnel-related costs of $7.1 million, an increase in reagents and consumables of $2.5 million, an increase in consulting and professional fees of $2.4 million, an increase in clinical studies of $2.2 million, an increase in stock-based compensation expense of $1.8 million, an increase in research and development and other costs of $1.4 million and an increase in software expense of $1.2 million.

Sales and Marketing

Sales and marketing expenses increased by $18.7 million, or 50%, for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in headcount and personnel-related costs of $9.6 million, an increase in stock-based compensation expense of $4.0 million, an increase in marketing programs and travel costs of $3.2 million and an increase in consulting and professional fees of $1.2 million.

General and Administrative

General and administrative expenses increased by $14.8 million, or 42%, for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to an increase in legal expenses of $4.9 million, an increase in headcount and personnel-related costs of $4.4 million, an increase in stock-based compensation expense of $2.4 million, an increase in consulting and professional fees of $1.8 million and an increase in software expense of $0.6 million.

Change in Estimated Fair Value of Common Stock Warrant Liability

The change in estimated fair value of common stock warrant liability increased from a loss of $1.0 million for the nine months ended September 30, 2020 to a gain of less than $0.1 million for the nine months ended September 30, 2021, resulting in a net change of $1.0 million, or 105%.

The gain of less than $0.1 million in the nine months ended September 30, 2021 is comprised of a remeasurement gain of $0.3 million for the change in the fair value of our common stock warrant liability and a remeasurement charge of $0.2 million for warrants exercised during the period.

CARES Act Provider Relief Fund

The CARES Act Provider Relief Fund decreased by $4.8 million, or 100%, for the nine months ended September 30, 2021, compared to the same period in 2020, due to the CARES Act payment we received in April 2020.

Other income (expense)

Other expense, net decreased $0.3 million for the nine months ended September 30, 2021, compared to the same period in 2020, primarily due to the unrealized loss on the investment in Miromatrix and foreign currency exchange rate losses.

Cash Flows for the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (23,460)	$ 26,250
Investing activities	55,494	(9,920)
Financing activities	186,476	159,185
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(157)	64
Net increase in cash, cash equivalents and restricted cash	$ 218,353	$ 175,579

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 nine months ended September 30, 2021 was $23.5 million. Our net loss of $14.5 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $26.6 million in stock-based compensation expense, $6.3 million of depreciation and amortization expense and $2.2 million of amortization of right-of-use assets. Cash used in operating activities was also due to an increase in accounts receivable of $21.6 million, a decrease in Refund liability - CMS advance payment of $20.5 million and a decrease in net operating assets of $3.0 million.

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

Investing Activities

For the nine months ended September 30, 2021, net cash provided by investing activities of $55.5 million was primarily related to the maturities of marketable securities of $78.9 million. These proceeds were partially offset by the acquisition of TransChart, net of cash acquired of $3.5 million, $6.7 million related to payments for acquired intangibles, $5.5 million related to purchases of long-term marketable securities and $7.7 million related to additions of capital expenditures, net.

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

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 of $186.5 million was primarily related to $188.9 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 $10.9 million and proceeds from issuances of common stock under our employee stock purchase plan of $2.1 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $15.4 million.

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

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $367.0 million at September 30, 2021. As of September 30, 2021, we had cash, cash equivalents and marketable securities of $363.3 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. During the quarter ended September 30, 2021, we were notified by HHS that the Provider Relief Fund Reporting Portal was open for reporting on the use of Provider Relief Fund payments, and we completed and submitted a report indicating our use of the funds we received pursuant to the CARES Act.

June 2020 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.

January 2021 Underwritten 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 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, 2022. The next 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, UnitedHealthcare, several BCBS plans and regional plans across the US.

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'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, TransChart, TxAccess 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 September 30, 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 $363.3 million and $224.7 million at September 30, 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 $2.7 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 September 30, 2021, would have negatively impacted our financial results for the nine months ended September 30, 2021 by $0.2 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 September 30, 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 September 30, 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 September 30, 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 Securities and Exchange Commission or 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

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

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

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any interruption in manufacturing or our supply 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. Additionally, collaborators at research hospitals may be subject to limitations with respect to accessing their laboratories and sample banks which could impact timelines for research and product development dependent on external collaborations. Limits on the ability of individuals to move freely during a pandemic may also negatively impact recruiting new staff necessary to expand our operations.

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

Management is actively monitoring the effect of the global situation on our financial condition, liquidity, operations, suppliers, industry and workforce. While there have recently been vaccines developed and administered, and the spread of COVID-19 may eventually be contained or mitigated, we cannot predict the timing of the vaccine roll-out globally or the continued efficacy of such vaccines, and we do not yet know how businesses, clinics, patients or our partners will operate in a post COVID-19 environment. The ultimate impact of the COVID-19 pandemic on our business, operations, or the global economy as a whole, remains highly uncertain, and a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

As the administration of the vaccine program increases and cases decline, we continue to evaluate and refine our return to work strategy. We also continue to monitor the World Health Organization and Centers for Disease Control and Prevention

guidelines, as well as other federal, state and local guidance, as we adapt and as some of our employees have returned to in-person work.

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 September 30, 2021, our net loss was $11.9 million. As of September 30, 2021, we had an accumulated deficit of $367.0 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 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 September 30, 2021, we had cash, cash equivalents and marketable securities of $363.3 million and an accumulated deficit of $367.0 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.

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

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18,

2020 in the U.S. District Court for the District of Delaware, or the Court, alleging we 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 the Court to amend its counterclaims to include additional allegations regarding purportedly false claims we made with respect to AlloSure, and the Court granted Natera's request. On September 28, 2021, the Court confirmed that the false advertising case against Natera will proceed to trial. The trial date is not currently set.

In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us 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 we have infringed Natera's patents, an order preliminarily and permanently enjoining us from any further infringement of such patents and unspecified damages. Trial is not currently scheduled. We intend to defend both of these matters vigorously, and believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

Litigation is inherently unpredictable. It is possible that an adverse result in one or more of these possible future events could have a material adverse effect on us including increased expenses to defend, settle or resolve such litigation.

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

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

In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us in the U.S. would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including California, Florida, Maryland, New York, Rhode Island and Pennsylvania, which can take a significant amount of time and result in delays in our ability to begin operations at that facility.

If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time-consuming and costly to train, equip and use a third-party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart or future solutions following validation and other required procedures. We cannot be certain that we would be able to find another CLIA-certified facility willing or able to adopt AlloSure Kidney, AlloMap Heart, AlloSure Heart or future solutions or able to comply with the required quality and regulatory standards, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

Since the onset of the COVID-19 pandemic, federal, state and local governments have imposed various quarantines, shelter-in-place and similar government orders, including several orders that have impacted operations in. San Mateo County, where our laboratory and headquarters are located. These orders and others may be further modified, amended and adopted depending upon the COVID-19 transmission rates in our county and state, as well as other factors. If the operations in our laboratory are deemed non-essential, or if sufficient numbers of our laboratory staff are infected with COVID-19 and are unable to perform their roles, we may not be able to perform our tests for the duration of any shelter-in-place order or while we have insufficient numbers of laboratory staff, either of which could negatively impact our business, operating results and financial condition.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in

our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, these investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. In addition, an application, data security or network incident may allow unauthorized access to our systems or data or our customers' data, disable access to our service, harm our reputation, create additional liability and adversely impact our financial results.

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, as a result of the COVID-19 pandemic, we may face increased cybersecurity risks due to our reliance on internet technology which may create additional opportunities for cybercriminals to exploit vulnerabilities. While we maintain monitoring practices and protections for our information technology to reduce these risks and test our systems on an ongoing basis for any potential threats, there can be no assurance that these efforts will prevent a cyber-attack or other security breach.

Third parties have attempted, and may in the future attempt, to fraudulently induce employees, contractors or consumers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and/or physical facilities in order to gain access to our data or our critical information, which could result in significant legal and financial exposure. In addition, a contractor or other third party with whom we do business, as well as parties with which we do not do business, may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. While we still continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third party training regarding phishing, malware, and other cyber risks, monitoring of networks and systems and maintenance of back up of protective systems), which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shut downs due to attack by hackers or breaches, phishing scams, ransomware, systems failures, computer viruses or other malfeasance. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

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

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U.S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, the California Consumer Privacy Act, or the CCPA, took effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. The CCPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business. Internationally, the General Data Protection Regulation, or the GDPR, took effect in May 2018 within the European Economic Area, or the EEA, and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico and Australia, have also implemented laws relating to data privacy and protection. Although we believe that we are complying with the GDPR and similar laws, these laws are still relatively new.

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 September 30, 2021, we had $10.2 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.

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

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

- federal and state laws and regulations regarding billing and claims payment applicable to clinical laboratories and/or regulatory agencies enforcing those laws and regulations;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented to the government, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or making a false statement material to a false or fraudulent claim;

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services, including clinical laboratory services, reimbursed by Medicare if the physician (or a member of the physician's family) has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- state laws regarding prohibitions on fee-splitting;
- the federal health care program exclusion statute; and
- state and foreign law equivalents of each of the above federal laws and regulations, such as anti-kickback, false claims, and self-referral laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. We recently received a civil investigative demand (CID) from the United States Department of Justice (DOJ) requesting that we produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the United States Securities and Exchange Commission (SEC) in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. We also received an information request from a state regulatory agency and may receive additional requests for information from the DOJ, SEC, or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the SEC subpoena or the state regulatory agency information request raise any issues regarding the safety or efficacy of any of our products or services and are cooperating fully with the investigations. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of the DOJ or SEC investigations, the state law information request, or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, if any governmental body, such as the DOJ or SEC, determines that we have not complied with applicable securities or other laws, such governmental body could initiate a proceeding against us, which may ultimately lead to significant penalties and other relief assessed against us, including monetary fines. We may expend significant financial and managerial resources in connection with responding to the CID, the SEC subpoena and other information requests. Any of the foregoing consequences could seriously harm our business and our financial 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 July 16, 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 expires in 2030.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. For example, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid. The Court’s finding does not have any impact on our ability to continue providing AlloSure, and we have appealed the decision. However, if the Court’s invalidity ruling is upheld, it may limit our ability to prevent Natera and other competitors and third parties from developing and marketing products similar to ours and we may not be able to prevent Natera and others from developing or selling products that are covered by our products or technologies, without payment to us. 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.

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 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 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 September 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 September 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 for the year ended December 31, 2020, filed with the SEC on February 24, 2021, 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 SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- public health emergencies, including the COVID-19 pandemic; and
- general economic conditions and slow or negative growth of our markets.

Our amended and restated bylaws designate the federal district courts of the United States of America as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. This provision does not apply to claims brought pursuant to the Securities Exchange Act of 1934, as amended, or the rules and regulations promulgated thereunder, or any other claim for which the U.S. federal courts have exclusive jurisdiction. Any person or entity holding, owning or otherwise acquiring any interest in any security of our company shall be deemed to have notice of and consented to this provision. The enforceability of similar choice

of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. This choice-of-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to this exclusive forum provision, particularly if the stockholder does not reside in or near Delaware. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or operating results.

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

Issuer Purchases of Equity Securities

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding obligations during the three months ended September 30, 2021:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)
July 1, 2021 - July 31, 2021	18,540	(1)	$ 32.38
August 1, 2021 -August 31, 2021	16,177	(1)	30.45
September 1, 2021 - September 30, 2021	4,971	(1)	6.24
Total	39,688		—

(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)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of CareDx, Inc., filed June 17, 2021.
3.3(3)	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)#	Promotion Letter, dated July 12, 2021, between CareDx, Inc. and Alex Johnson.
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
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)
(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 3.1 to the Registrant's Form 8-K filed with the SEC on June 21, 2021.
(3)	Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed with the SEC on June 21, 2021.
(4)	Incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K filed with the SEC on March 31, 2015.
(5)	Incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021.
(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 4.5 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021.
(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 4.7 to the Registrant's Form 10-Q filed with the SEC on July 29, 2021.
(11)	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed with the SEC on July 20, 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: October 28, 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: October 28, 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: October 28, 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 September 30, 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: October 28, 2021

By: /s/ Ankur Dhingra
Ankur Dhingra
Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: October 28, 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.