

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

or

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

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

CAREDX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

8000 Marina Boulevard, 4th Floor
Brisbane, California 94005
(Address of principal executive offices and zip code)
(415) 287-2300
(Registrant’s telephone number, including area code)

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

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 53,793,067 shares of the registrant’s Common Stock issued and outstanding as of May 8, 2023.

CareDx, Inc.
TABLE OF CONTENTS

	<u>Page No.</u>
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. Unaudited Condensed Consolidated Financial Statements	3
Condensed Consolidated Balance Sheets as of March 31, 2023 and December 31, 2022	3
Condensed Consolidated Statements of Operations for the Three Months Ended March 31, 2023 and 2022	4
Condensed Consolidated Statements of Comprehensive Loss for the Three Months Ended March 31, 2023 and 2022	5
Condensed Consolidated Statements of Stockholders' Equity for the Three Months Ended March 31, 2023 and 2022	6
Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2023 and 2022	8
Notes to Unaudited Condensed Consolidated Financial Statements	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	34
Item 3. Quantitative and Qualitative Disclosures About Market Risk	49
Item 4. Controls and Procedures	49
<u>PART II. OTHER INFORMATION</u>	51
Item 1. Legal Proceedings	51
Item 1A. Risk Factors	51
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	64
Item 3. Defaults Upon Senior Securities	65
Item 4. Mine Safety Disclosures	65
Item 5. Other Information	65
Item 6. Exhibits	66
Signatures	68

PART I. FINANCIAL INFORMATION
ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 74,660	\$ 89,921
Marketable securities	211,279	203,168
Accounts receivable	59,310	66,312
Inventory	18,018	19,232
Prepaid and other current assets	8,161	9,216
Total current assets	371,428	387,849
Property and equipment, net	35,506	35,529
Operating leases right-of-use assets	33,431	34,689
Intangible assets, net	45,637	43,051
Goodwill	39,615	37,523
Restricted cash	520	522
Other assets	2,080	3,828
Total assets	<u>\$ 528,217</u>	<u>\$ 542,991</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 12,861	\$ 9,942
Accrued compensation	12,082	16,902
Accrued and other liabilities	46,885	49,131
Total current liabilities	71,828	75,975
Common stock warrant liability	25	32
Deferred payments for intangible assets	4,089	2,418
Operating lease liability, less current portion	32,006	33,406
Other liabilities	248	249
Total liabilities	108,196	112,080
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock: \$0.001 par value; 100,000,000 shares authorized at March 31, 2023 and December 31, 2022; 53,712,654 shares and 53,583,301 shares issued at March 31, 2023 and December 31, 2022, respectively; 53,653,182 shares and 53,533,250 shares outstanding at March 31, 2023 and December 31, 2022, respectively	52	52
Additional paid-in capital	912,291	898,806
Accumulated other comprehensive loss	(7,439)	(7,503)
Accumulated deficit	(484,883)	(460,444)
Total stockholders' equity	420,021	430,911
Total liabilities and stockholders' equity	<u>\$ 528,217</u>	<u>\$ 542,991</u>

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

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

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Testing services revenue	\$ 61,784	\$ 66,444
Product revenue	6,861	6,788
Patient and digital solutions revenue	8,617	6,184
Total revenue	<u>77,262</u>	<u>79,416</u>
Operating expenses:		
Cost of testing services	15,296	17,628
Cost of product	4,066	4,399
Cost of patient and digital solutions	6,604	4,855
Research and development	24,357	21,880
Sales and marketing	23,231	23,148
General and administrative	28,032	26,559
Total operating expenses	<u>101,586</u>	<u>98,469</u>
Loss from operations	<u>(24,324)</u>	<u>(19,053)</u>
Other income (expense):		
Interest income, net	2,666	189
Change in estimated fair value of common stock warrant liability	7	27
Other expense, net	(1,974)	(823)
Total other income (expense)	<u>699</u>	<u>(607)</u>
Loss before income taxes	<u>(23,625)</u>	<u>(19,660)</u>
Income tax (expense) benefit	<u>(124)</u>	<u>12</u>
Net loss	<u>\$ (23,749)</u>	<u>\$ (19,648)</u>
Net loss per share (Note 3):		
Basic	<u>\$ (0.44)</u>	<u>\$ (0.37)</u>
Diluted	<u>\$ (0.44)</u>	<u>\$ (0.37)</u>
Weighted-average shares used to compute net loss per share:		
Basic	<u>53,643,216</u>	<u>53,015,459</u>
Diluted	<u>53,643,216</u>	<u>53,015,459</u>

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

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

	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (23,749)	\$ (19,648)
Other comprehensive loss:		
Foreign currency translation adjustments, net of tax	64	(420)
Net comprehensive loss	<u>\$ (23,685)</u>	<u>\$ (20,068)</u>

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, 2022	53,533,250	\$ 52	\$ 898,806	\$ (7,503)	\$ (460,444)	\$ 430,911
Issuance of common stock under employee stock purchase plan	47,025	—	456	—	—	456
Repurchase and retirement of common stock	(59,472)	—	—	—	(690)	(690)
RSU settlements, net of shares withheld	123,910	—	(785)	—	—	(785)
Issuance of common stock for services	7,649	—	93	—	—	93
Issuance of common stock for cash upon exercise of stock options	820	—	2	—	—	2
Employee stock-based compensation expense	—	—	13,719	—	—	13,719
Foreign currency translation adjustment	—	—	—	64	—	64
Net loss	—	—	—	—	(23,749)	(23,749)
Balance at March 31, 2023	53,653,182	\$ 52	\$ 912,291	\$ (7,439)	\$ (484,883)	\$ 420,021

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, 2021	52,923,360	\$ 52	\$ 853,683	\$ (4,670)	\$ (383,189)	\$ 465,876
Issuance of common stock under employee stock purchase plan	25,852	—	999	—	—	999
RSU settlements, net of shares withheld	64,819	—	(1,482)	—	—	(1,482)
Issuance of common stock for services	1,249	—	58	—	—	58
Issuance of common stock for cash upon exercise of stock options	69,993	—	1,598	—	—	1,598
Employee stock-based compensation expense	—	—	10,563	—	—	10,563
Foreign currency translation adjustment	—	—	—	(420)	—	(420)
Net loss	—	—	—	—	(19,648)	(19,648)
Balance at March 31, 2022	53,085,273	\$ 52	\$ 865,419	\$ (5,090)	\$ (402,837)	\$ 457,544

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

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

	Three Months Ended March 31,	
	2023	2022
Operating activities:		
Net loss	\$ (23,749)	\$ (19,648)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	13,754	10,634
Revaluation of common stock warrant liability to estimated fair value	(7)	(27)
Depreciation and amortization	3,427	2,619
Asset impairments and write-downs	1,000	—
Amortization of right-of-use assets	1,337	915
Unrealized loss on long-term marketable equity securities	905	507
Revaluation of contingent consideration to estimated fair value	364	64
Amortization of premium on short-term marketable securities, net	(773)	139
Changes in operating assets and liabilities:		
Accounts receivable	7,664	(5,591)
Inventory	1,217	(1,060)
Prepaid and other assets	1,515	(567)
Operating leases liabilities, net	(1,333)	(969)
Accounts payable	2,590	(1,549)
Accrued compensation	(4,888)	(14,634)
Accrued and other liabilities	(2,352)	7,916
Change in deferred taxes	—	(217)
Net cash provided by (used in) operating activities	671	(21,468)
Investing activities:		
Acquisition of business, net of cash acquired	(4,562)	—
Acquisition of intangible assets	—	(100)
Purchases of short-term marketable securities	(86,310)	(148,522)
Maturities of short-term marketable securities	78,972	1,053
Purchase of corporate equity securities	(100)	—
Additions of capital expenditures, net	(2,771)	(8,463)
Net cash used in investing activities	(14,771)	(156,032)
Financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	456	999
Taxes paid related to net share settlement of restricted stock units	(656)	(1,482)
Proceeds from exercise of stock options	2	1,598
Payment of contingent consideration	(250)	(250)
Repurchase and retirement of common stock	(690)	—
Net cash (used in) provided by financing activities	(1,138)	865
Effect of exchange rate changes on cash and cash equivalents	(25)	45
Net decrease in cash, cash equivalents and restricted cash	(15,263)	(176,590)
Cash, cash equivalents, and restricted cash at beginning of period	90,443	348,696
Cash, cash equivalents, and restricted cash at end of period	\$ 75,180	\$ 172,106

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 Brisbane, 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, a donor-derived cell-free DNA (“dd-cfDNA”) solution for kidney transplant patients, AlloMap® Heart, a gene expression solution for heart transplant patients, AlloSure® Heart, a dd-cfDNA solution for heart transplant patients, and AlloSure® Lung, a dd-cfDNA solution for lung 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. The Company also provides digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management (“Ottr”) and XynManagement, Inc. (“XynManagement”), as well as the acquisitions of TransChart LLC (“TransChart”), MedActionPlan.com, LLC (“MedActionPlan”) The Transplant Pharmacy, LLC (“TTP”) in 2021 and HLA Data Systems, LLC (“HLA Data Systems”) in January 2023.

Testing Services

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a Local Coverage Determination (“LCD”) first issued by Palmetto MolDX (“MolDX”), which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian Healthcare Solutions, the Company’s Medicare Administrative Contractor (“Noridian”). The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, the Company received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753.

On March 2, 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection (the “Billing Article”). Prior to the Billing Article’s effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article will not be implemented until June 30, 2023. MolDX informed CareDx that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new billing article with an effective date of March 31, 2023 (the “Revised Billing Article” and together with the Billing Article, the “Billing Articles”). The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian has not yet adopted the new Billing Articles.

Although the Company believes the Billing Articles are inconsistent with the LCDs, Noridian’s and MolDX’s responses to public comments explaining the intended scope of various LCDs, and medical necessity, the Company determined to pause its Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow the Company further time to evaluate the implications of the Billing Article and update its billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx’s test order forms to capture the new information required under the Billing Article. Accordingly, the Company did not submit claims for approximately 3,200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million (the “Impacted March Tests”).

In the second quarter of 2023, the Company plans to submit claims for Medicare reimbursement for the Impacted March Tests, following the delivery by the Company of a letter to Noridian explaining, among other things, (i) the Company’s belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that the Company plans to submit claims for reimbursement for the Impacted March Tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing

is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article.

CareDx continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, CareDx is considering informing Noridian that until Noridian adopts the Revised Billing Article, CareDx will continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. The Company is also considering informing Noridian that (i) until June 30, 2023, it plans to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles.

AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

In May 2021 and March 2023, the Company purchased a minority investment of common stock in the biotechnology company Miromatrix Medical, Inc. (“Miromatrix”), for an aggregate amount of \$5.1 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 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. 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: 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.

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.

Patient and Digital Solutions

Following the acquisitions of both Ottr and XynManagement, the Company is a leading provider of transplant patient management 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. 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 the Company's 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, which was amended in April 2022, 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.

In November 2021, the Company acquired MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

In December 2021, the Company acquired TTP, a transplant focused pharmacy located in Mississippi. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S.

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 \$484.9 million at March 31, 2023. As of March 31, 2023, the Company had cash, cash equivalents and marketable securities of \$285.9 million and no debt outstanding.

At-the-Market Equity Offering

On April 14, 2022, the Company entered into a sales agreement (the “Sales Agreement”) with Jefferies, LLC as sales agent (“Jefferies”), pursuant to which the Company may offer and sell, from time to time, through Jefferies, up to \$200.0 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. Jefferies is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Jefferies under the Sales Agreement. Any shares of common stock offered and sold pursuant to the Sales Agreement will be issued and sold pursuant to our Registration Statement on Form S-3ASR (File No. 333-239049), filed with the SEC on June 9, 2020 (the “Registration Statement”), including a base prospectus dated June 9, 2020, and a prospectus supplement dated April 14, 2022. The Registration Statement will expire on June 9, 2023.

Stock Repurchase Program

On December 3, 2022, the Company's Board of Directors approved a stock repurchase program (the “Repurchase Program”), whereby the Company may purchase up to \$50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of the Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three months ended March 31, 2023, the Company purchased an aggregate of 59,472 shares of its common stock under the Repurchase Program for an aggregate purchase price of \$0.7 million. As of March 31, 2023, \$48.7 million remained available for future share repurchase under the Repurchase Program.

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, 2022, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (the "SEC") on February 27, 2023. 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, 2022 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 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, 2022 has been derived from audited consolidated financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three months ended March 31, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023.

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 patient and digital solutions 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 or an asset acquisition; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended March 31, 2023 and 2022, approximately 42% and 54%, respectively, of total revenue was derived from Medicare.

As of March 31, 2023 and December 31, 2022, approximately 26% and 27%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either March 31, 2023 or December 31, 2022.

Marketable Securities

The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of March 31, 2023, 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, which were 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 March 31, 2023, 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. Unrealized gains and losses from the reevaluation of the long-term marketable debt securities, if any, are included in other comprehensive gain (loss) in the condensed consolidated statement of comprehensive income (loss). 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.

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 income (expense), net, in the condensed consolidated statements of operations.

Leases

The Company adopted Accounting Standard Codification ("ASC") Topic 842, *Leases* and 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. The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's facility leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for leases with an initial term of 12 months or less.

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

As of March 31, 2023, the Company's leases had remaining terms of 0.67 years to 9.85 years, some of which include options to extend the lease term.

Revenue

The Company recognizes revenue from testing services, product sales and patient and digital solutions revenue in the amount that reflects the consideration that it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step 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

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

The healthcare providers that order the tests and on whose behalf the Company provides testing services are generally not responsible for the payment of these services. The first and second revenue recognition criteria are satisfied when the Company receives a test requisition form with payer information from the healthcare provider. Generally, the Company bills third-party payers upon delivery of an AlloSure Kidney, AlloMap Heart, AlloSure Heart or AlloSure Lung test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer. The Company has used the portfolio approach under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, to identify financial classes of payers. Revenue recognized for Medicare and other contracted payers is based on the agreed current reimbursement rate per test, adjusted for historical collection trends where applicable. The Company estimates revenue for non-contracted payers and self-payers using transaction prices determined for each financial class of payers using history of reimbursements. This includes analysis of an average reimbursement per test and a percentage of tests reimbursed. This estimate requires significant judgment.

The Company monitors revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Changes in transaction price estimates are updated quarterly based on actual cash collected or changes made to contracted rates.

On March 2, 2023, MolDX issued a new Billing Article, with an effective date of March 31, 2023. The Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap and requires the Company to implement new processes to address requirements related to Medicare claim submissions. ASC 606-10-25-1 requires the Company to assess whether it is probable that it will collect substantially all of the consideration to which it will be entitled. Based upon the Company's review of the Billing Article, it was determined to pause Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 that created uncertainty around the collection of the claims. Accordingly, the Company did not recognize revenue for approximately 3,200 AlloSure Kidney tests aggregating to \$8.9 million for the three months ended March 31, 2023.

Product Revenue

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. The Company generally has a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue is mainly derived from a combination of software as a service ("SaaS") and perpetual software license agreements entered into with various transplant centers, which are the Company's customers for this class of revenue. The main performance obligations in connection with the Company's SaaS and perpetual software license agreement are the following: (i) implementation services and delivery of the perpetual software license are considered a single performance obligation, and (ii) post contract support. The Company allocates the transaction price to each performance obligation based on relative stand-alone selling prices of each distinct performance obligation. Digital revenue in connection with perpetual software license agreements is recognized over time based on the Company's satisfaction of each distinct performance obligation in each agreement.

Perpetual software license agreements typically require advance payments from customers upon the achievement of certain milestones. The Company records deferred revenue in relation to these agreements when cash payments are received, or invoices are issued in advance of the Company's performance, and generally recognizes revenue over the contractual term, as performance obligations are fulfilled.

In addition, the Company derives patient and digital solutions revenue from software subscriptions and medication sales. The Company generally bills software subscription fees in advance. Revenue from software subscriptions is deferred and recognized ratably over the subscription term. The medication sales revenue is recognized based on the negotiated contract price with the governmental, commercial and non-commercial payers with any applicable patient co-pay. The Company recognizes revenue from medication sales when prescriptions are delivered.

Recent Accounting Pronouncements

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, which contains amendments that require annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model. The disclosures include (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. 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. The amendments in this ASU should be applied either (1) prospectively to all transactions within the scope of the amendments that are reflected in financial statements at the date of initial application and new transactions that are entered into after the date of initial application or (2) retrospectively to those transactions. The Company adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires that an entity recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC 606 as if it had originated the contracts. The amendments set forth in this ASU are effective for fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The amendments in this ASU should be applied prospectively to business combinations occurring on or after the effective date of the amendments. The Company adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no material impact on the Company's 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 adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

3. NET LOSS PER SHARE

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

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

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net loss used to compute basic and diluted net loss per share	\$ (23,749)	\$ (19,648)
Denominator:		
Weighted-average shares used to compute basic and diluted net loss per share	53,643,216	53,015,459
Net loss per share:		
Basic and diluted	\$ (0.44)	\$ (0.37)

The following potentially dilutive securities have been excluded from diluted net loss per share as of March 31, 2023 and 2022 because their effect would be antidilutive:

	Three Months Ended March 31,	
	2023	2022
Shares of common stock subject to outstanding options	3,248,696	2,091,422
Shares of common stock subject to outstanding common stock warrants	3,132	3,132
Restricted stock units	4,096,014	2,047,657
Total common stock equivalents	7,347,842	4,142,211

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 tables set forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of March 31, 2023 and December 31, 2022 (in thousands):

	March 31, 2023			
	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
Assets				
Cash equivalents:				
Money market funds	\$ 55,315	\$ —	\$ —	\$ 55,315
Long-term marketable securities:				
Corporate equity securities	1,272	—	—	1,272
Total	<u>\$ 56,587</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 56,587</u>
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 825	\$ 825
Long-term liabilities:				
Contingent consideration	—	—	4,089	4,089
Common stock warrant liability	—	—	25	25
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,939</u>	<u>\$ 4,939</u>

	December 31, 2022			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	\$ 66,594	\$ —	\$ —	\$ 66,594
Long-term marketable securities:				
Corporate equity securities	2,076	—	—	2,076
Total	<u>\$ 68,670</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 68,670</u>
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 1,025	\$ 1,025
Long-term liabilities:				
Contingent consideration	—	—	2,418	2,418
Common stock warrant liability	—	—	32	32
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,475</u>	<u>\$ 3,475</u>

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 and Contingent Consideration	
	\$ 3,475
Balance as of December 31, 2022	
Change in estimated fair value of common stock warrant liability	(7)
Change in estimated fair value of contingent consideration	421
Addition of estimated fair value of contingent consideration	1,300
Payments related to contingent consideration	(250)
Balance as of March 31, 2023	<u>\$ 4,939</u>

During March 2023, the Company wrote off \$1.0 million of its investment in convertible preferred shares from a private company which was carried at cost. This private company's operations are in the process of being liquidated. The fair value of this investment was based on Level 3 inputs.

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

- *Money market funds* – Investments in money market funds are classified within Level 1. Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. At March 31, 2023 and December 31, 2022, 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.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual

conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met multiplied by management's estimate of the probability of success at a discounted rate of 7% and 12% at March 31, 2023 and December 31, 2022, respectively. The significant input in the Level 3 measurement that is not supported by market activity is the Company's probability assessment of the achievement of the milestones. The value of the liability is subsequently remeasured to fair value at each reporting date, and the change in estimated fair value is recorded as a component of operating expenses until the milestones are paid, expire or are no longer achievable. Increases or decreases in the estimation of the probability percentage result in a directionally similar impact to the fair value measurement of the contingent consideration liability. The carrying amount of the contingent consideration liability represents its fair value.

- *Common stock warrant liability* – Common stock warrant liability is classified within Level 3. The Company utilizes intrinsic value to estimate the fair value of the warrants. The intrinsic value is computed as the difference between the fair value of the Company's common stock on the valuation date and the exercise price of the warrants. Increases (decreases) in the Company's stock price discussed above result in a directionally similar impact to the fair value of the common stock warrant liability.

5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

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

	March 31, 2023	March 31, 2022
Cash and cash equivalents	\$ 74,660	\$ 171,892
Restricted cash	520	214
Total cash, cash equivalents, and restricted cash at the end of the period	<u>\$ 75,180</u>	<u>\$ 172,106</u>

Marketable Securities

All short-term marketable securities were considered held-to-maturity at March 31, 2023. At March 31, 2023, 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 March 31, 2023. All short-term marketable securities with unrealized losses as of the balance sheet date have been in a loss position for less than twelve months. Contractual maturities of the short-term marketable securities were within one year or less at March 31, 2023.

The long-term marketable equity securities were recorded at fair market value with changes in the fair value recognized in earnings at March 31, 2023 and December 31, 2022. The long-term marketable debt securities were considered available-for-sale at March 31, 2023 and December 31, 2022. The contractual maturities 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):

	March 31, 2023		
	Amortized Cost	Unrealized Holding Losses	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 92,947	\$ 1,222	\$ 94,169
Corporate debt securities	118,332	113	118,445
Total short-term marketable securities	<u>211,279</u>	<u>1,335</u>	<u>212,614</u>
Long-term marketable securities:			
Corporate equity securities	5,100	(3,828)	1,272
Corporate debt securities	—	—	—
Total long-term marketable securities	<u>5,100</u>	<u>(3,828)</u>	<u>1,272</u>
Total	<u>\$ 216,379</u>	<u>\$ (2,493)</u>	<u>\$ 213,886</u>

	December 31, 2022		
	Amortized Cost	Unrealized Holding Losses	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 79,347	\$ 452	\$ 79,799
Corporate debt securities	123,821	(220)	123,601
Total short-term marketable securities	<u>203,168</u>	<u>232</u>	<u>203,400</u>
Long-term marketable securities:			
Corporate equity securities	5,000	(2,924)	2,076
Total long-term marketable securities	<u>5,000</u>	<u>(2,924)</u>	<u>2,076</u>
Total	<u>\$ 208,168</u>	<u>\$ (2,692)</u>	<u>\$ 205,476</u>

Contractual maturities of the marketable securities at each balance sheet date are as follows (in thousands):

	March 31, 2023	December 31, 2022
Within one year	\$ 211,279	\$ 203,168
After one year through five years	—	—
Total	\$ 211,279	\$ 203,168

6. BUSINESS COMBINATIONS

HLA Data Systems

In January 2023, the Company acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. The Company acquired HLA Data Systems with a combination of cash consideration paid upfront and contingent consideration with a fair value of \$1.3 million.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of \$0.4 million associated with the acquisition were expensed as incurred, and classified as part of general and administrative expenses in the condensed consolidated statement of operations.

Goodwill of \$2.1 million arising from the acquisition primarily consists of synergies from integrating HLA Data Systems' technology with the current testing and digital solutions offered by the Company. The acquisition of HLA Data Systems will provide a robust and comprehensive Laboratory Information Management System and support the laboratory workflows. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been assigned to the Company's existing operating segment.

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

	Estimated Fair Value	Estimated Useful Lives (Years)
Customer relationships	\$ 3,010	13
Developed technology	770	11
Trademarks	320	17
Total	\$ 4,100	

Customer relationships acquired by the Company represent the fair value of future projected revenue that is expected to be derived from sales of HLA Data Systems' products to existing customers. The customer relationships' fair value has been estimated utilizing a multi-period excess earnings method under the income approach, which reflects the present value of the projected cash flows that are expected to be generated by the customer relationships, less charges representing the contribution of other assets to those cash flows that use projected cash flows with and without the intangible asset in place. The economic useful life was determined based on the distribution of the present value of the cash flows attributable to the intangible asset.

The acquired developed technology represents the fair value of HLA Data Systems' proprietary software. The trademark acquired consists primarily of the HLA Data Systems brand and markings. The fair value of both the developed technology and the trademark were determined using the relief-from-royalty method under the income approach. This method considers the value of the asset to be the value of the royalty payments from which the Company is relieved due to its ownership of the asset. The royalty rates of 10% and 2% were used to estimate the fair value of the developed technology and the trademark, respectively.

A discount rate of 24% was utilized in estimating the fair value of these three intangible assets.

The pro forma impact of the HLA Data Systems 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.

Consideration Paid

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

		Total
Consideration		
Cash	\$	4,562
Total consideration	\$	4,562
Recognized amounts of identifiable assets acquired and liabilities assumed		
Current assets	\$	1,162
Identifiable intangible assets		4,100
Current liabilities		(786)
Other current liabilities		(699)
Contingent considerations		(1,300)
Other liabilities		(7)
Total identifiable net assets acquired		2,470
Goodwill		2,092
Total consideration	\$	4,562

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

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill is recorded when the purchase price of an acquisition exceeds the fair value of the net tangible and identified intangible assets acquired.

Goodwill is tested annually for impairment at the reporting unit level during the fourth quarter or earlier upon the occurrence of certain events or substantive changes in circumstances. There were no indicators of impairment in the three months ended March 31, 2023. The balance of the Company's goodwill was \$39.6 million as of March 31, 2023 and \$37.5 million as of December 31, 2022.

Intangible Assets

The following table presents details of the Company's intangible assets as of March 31, 2023 (\$ in thousands):

	March 31, 2023				
	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	\$ 36,517	\$ (15,931)	\$ (2,336)	\$ 18,250	7.5
Customer relationships	24,908	(7,852)	(2,067)	14,989	9.5
Commercialization rights	11,579	(3,549)	—	8,030	6.3
Trademarks and tradenames	4,860	(1,434)	(308)	3,118	9.2
Total intangible assets with finite lives	77,864	(28,766)	(4,711)	44,387	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	\$ 79,114	\$ (28,766)	\$ (4,711)	\$ 45,637	

The following table presents details of the Company's intangible assets as of December 31, 2022 (\$ in thousands):

	December 31, 2022				
	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	\$ 35,747	\$ (15,138)	\$ (2,369)	\$ 18,240	7.5
Customer relationships	21,898	(7,459)	(2,104)	12,335	9.0
Commercialization rights	11,579	(3,233)	—	8,346	6.6
Trademarks and tradenames	4,540	(1,345)	(315)	2,880	8.5
Total intangible assets with finite lives	73,764	(27,175)	(4,788)	41,801	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	\$ 75,014	\$ (27,175)	\$ (4,788)	\$ 43,051	

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. In 2022, the Company incurred additional costs related to this partnership of \$1.0 million. These are included within commercialization rights as of March 31, 2023.

In June 2021, the Company acquired the Transplant Hero patient application. The patient application is included in Acquired and developed technology as of March 31, 2023.

In the fourth quarter of 2021, acquisition of intangible assets increased \$13.4 million primarily from business combinations. These acquisitions included \$4.7 million of Acquired and developed technology, \$2.5 million of Commercialization rights, \$3.7 million of Customer relationships, \$2.2 million of Trademarks and tradenames and \$0.3 million of Other intangible assets.

Amortization of Intangible Assets

Intangible assets are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of testing services, cost of product, cost of patient and digital solutions, and sales and marketing expenses in the condensed consolidated statements of operations.

The following table summarizes the Company's amortization expense of intangible assets (in thousands):

	Three Months Ended March 31,	
	2023	2022
Cost of testing services	\$ 329	\$ 329
Cost of product	418	453
Cost of patient and digital solutions	248	236
Sales & marketing	595	605
Total	<u>\$ 1,590</u>	<u>\$ 1,623</u>

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of March 31, 2023 (in thousands):

Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Patient and Digital Solutions	Sales and Marketing	Total
Remainder of 2023	\$ 987	\$ 1,263	\$ 761	\$ 1,850	\$ 4,861
2024	1,316	1,684	779	2,467	6,246
2025	1,316	1,684	610	2,467	6,077
2026	1,316	745	610	2,465	5,136
2027	1,316	745	610	2,451	5,122
Thereafter	2,825	3,299	1,605	9,216	16,945
Total future amortization expense	<u>\$ 9,076</u>	<u>\$ 9,420</u>	<u>\$ 4,975</u>	<u>\$ 20,916</u>	<u>\$ 44,387</u>

8. BALANCE SHEET COMPONENTSInventory

Inventory consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Finished goods	\$ 3,247	\$ 2,962
Work in progress	4,713	4,306
Raw materials	10,058	11,964
Total inventory	<u>\$ 18,018</u>	<u>\$ 19,232</u>

Accrued and Other Liabilities

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

	March 31, 2023	December 31, 2022
Clinical studies	\$ 13,883	\$ 14,816
Professional fees	8,262	6,115
Short-term lease liability	5,738	5,591
Deferred revenue	5,841	5,342
Deferred payments for intangible assets	2,641	2,062
Accrued royalty	2,087	4,633
Laboratory processing fees and materials	1,760	2,189
License and other collaboration fees	1,017	1,000
Contingent consideration	825	1,025
Accrued shipping expenses	459	489
Capital expenditures	—	1,316
Other accrued expenses	4,372	4,553
Total accrued and other liabilities	<u>\$ 46,885</u>	<u>\$ 49,131</u>

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 Brisbane, California; Columbus, Ohio; West Chester, Pennsylvania; Flowood, Mississippi; Gaithersburg, Maryland; Fremantle, Australia; and Stockholm, Sweden.

The Company's facility leases expire at various dates through 2033. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

As of March 31, 2023, the carrying value of the ROU asset was \$33.4 million. The related current and non-current liabilities as of March 31, 2023 were \$5.7 million and \$32.0 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the condensed consolidated balance sheets.

The following table summarizes the lease cost for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Operating lease cost	\$ 1,983	\$ 1,413
Total lease cost	\$ 1,983	\$ 1,413

	March 31, 2023
Other information:	
Weighted-average remaining lease term (in years)	6.05
Weighted-average discount rate (%)	7.1 %

In February and June 2022, the Company entered into various lease agreements to lease office buildings in California, Nebraska, and Australia with lease terms ranging from 2 to 10.5 years. Certain leases have options to renew the respective lease terms ranging from 5 to 10 years.

In June 2022, the Company modified the termination date of the lease agreement for its headquarters in South San Francisco, California from December 31, 2022 to July 15, 2022. As a result, the Company remeasured its lease liability using the current incremental borrowing rate and made an adjustment by reducing the ROU asset and lease liability by \$0.5 million.

Lease liabilities for the lease agreements made in February and June 2022 are recognized at the present value of the fixed lease payments using the current incremental borrowing rate at the lease commencement date. ROU assets are recognized based on the initial present value of the fixed lease payments.

The following table summarizes the ROU assets and lease liabilities for certain lease agreements which commenced in July 2022 (in thousands):

	March 31, 2023	December 31, 2022
ROU assets	\$ 13,776	\$ 14,321
Lease liabilities	14,773	15,302

The following table summarizes the ROU assets and lease liabilities for certain lease agreements which commenced in August 2022 (in thousands):

	March 31, 2023	December 31, 2022
ROU assets	\$ 5,698	\$ 5,814
Lease liabilities	5,937	6,005

Maturities of operating lease liabilities as of March 31, 2023 are as follows (in thousands):

Year Ending December 31,	Operating Leases
Remainder of 2023	\$ 5,854
2024	7,931
2025	7,681
2026	7,019
2027	7,166
Thereafter	10,604
Total lease payments	46,255
Less imputed interest	8,511
Present value of future minimum lease payments	37,744
Less operating lease liability, current portion	5,738
Operating lease liability, long-term portion	\$ 32,006

The following table summarizes the supplemental cash flow information related to leases for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used for operating leases	\$ 1,333	\$ 972

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. In March 2023, the Stanford License agreement was amended, which reduces the maximum royalty rate to a lower rate at which the Company may be liable to Stanford effective from April 2022. As a result, the Company reversed the excess liability in March 2023.

Illumina

On May 4, 2018, the Company entered into a license agreement with Illumina, Inc. (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 iBox.

Other Commitments

Pursuant to the Illumina Agreement, the Company has agreed to minimum purchase commitments of finished products and raw materials from Illumina, Inc. 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 commenced on March 7, 2022 and concluded on March 14, 2022, with the jury awarding the Company \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. Post-trial motion practice remains pending. The Company will not record the award until cash is received or the matter is otherwise resolved.

On July 19, 2022, the United States Court of Appeals for the Federal Circuit affirmed the Court's judgment dismissing the Company's patent infringement suit against Natera.

In addition, 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. This case was consolidated with the Company's patent infringement suit on February 4, 2020. 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. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera's U.S. Patents 10,655,180 and 11,111,544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera's U.S. Patent 10,526,658. On July 6, 2022, the Company moved to dismiss the rest of Natera's claims. On September 6, 2022, the Company withdrew its motion to dismiss. Discovery is ongoing. 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

As previously disclosed, in 2021, the Company 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 the Company's 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 the Company's accounting and public reporting practices. The Company also received an information request from a state regulatory agency. This state regulatory agency advised the Company that it has completed its review of the Company's business practices and determined that no further information or action is required. In late 2022, the Company received a request for information from a separate state regulatory agency concerning specimen collection by a vendor in the state. The Company 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 and the requests for information. 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 regulatory agency 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.

Olympios Matter

On April 15, 2022, a complaint was filed by Michael Olympios against the Company in the Superior Court of the State of California for the County of San Mateo (the "San Mateo County Court"). The complaint alleges that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olympios, and that the Company has defamed Dr. Olympios. Dr. Olympios also seeks to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olympios. The Company filed a motion to compel arbitration and dismiss the case. On April 25, 2022, the San Mateo County Court granted the Company's *ex parte* application to stay the case and advance the hearing date to June 10, 2022 for the motion to compel arbitration and dismiss. At the June 10, 2022 hearing, the San Mateo County Court found that the decision should be made by the arbitrator, and stayed the case. On July 19, 2022, Olympios filed a motion to withdraw from arbitration before JAMS, which was denied on August 18, 2022. The matter is currently proceeding in arbitration. The Company intends to vigorously pursue its arbitration proceeding against Olympios and to vigorously defend itself against Olympios' claims. The Company believes it has good and substantial support for its claims and good and

substantial defenses to the claims alleged in the suit by Olymbios, but there is no guarantee that the Company will prevail if the case continues. The Company has not recorded any liabilities for this suit.

Securities Class Action

On May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action in the U.S. District Court for the Northern District of California against the Company, Reginald Seeto, its President, Chief Executive Officer and member of the Company's Board of Directors, Ankur Dhingra, its former Chief Financial Officer, Marcel Konrad, its former interim Chief Financial Officer and former Senior Vice President of Finance & Accounting, and Peter Maag, its former President, former Chief Executive Officer, former Chairman of the Board and current member of the Company's Board of Directors. The action alleges that the Company and the individual defendants made materially false and/or misleading statements and/or omissions and that such statements violated Section 10(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder. The action also alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of the Company. The suit seeks to recover damages caused by the alleged violations of federal securities laws, along with the plaintiffs' costs incurred in the lawsuit, including their reasonable attorneys' and experts' witness fees and other costs.

On August 25, 2022, the court appointed an investor group led by the Oklahoma Police Pension and Retirement System as lead plaintiffs and appointed Saxena White P.A. and Robbins Geller Rudman & Dowd LLP as lead counsels. Plaintiffs filed an amended complaint on November 28, 2022. On January 27, 2023, defendants moved to dismiss all claims and to strike certain allegations in the amended complaint. A hearing on these motions is scheduled for May 16, 2023. The Company intends to defend itself vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suit, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for this suit.

Derivative Actions

On September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra, and other current and former members of the Company's Board of Directors (the "Edelman Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of the Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to the Company, violated Sections 14(a) and 20(a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by the Company as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

On December 8, 2022, the court stayed the Edelman Derivative Action until twenty (20) days after the earlier of the following events: (a) the securities class action is dismissed in its entirety with prejudice; (b) the motion to dismiss in the securities class action is denied; (c) a joint request by plaintiff and defendants to lift the stay; (d) notification that a related derivative action that has been filed is not stayed or is no longer stayed; or (e) notification that there has been a settlement reached in the securities class action or any related derivative action.

On February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra and other current and former members of the Company's Board of Directors (the "Stevenson Derivative Action"). The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by the Company as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

The Company intends to defend itself vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there are no guarantees that the Company will prevail.

Insurance Matter

In December 2022, the Company filed a lawsuit against its Directors and Officers liability insurance carriers in San Mateo County Superior Court. The Company seeks a declaration that costs and fees incurred by the Company in responding to governmental investigatory requests are covered under its policies. The Company also asserts breach of contract against its primary insurer Great American Insurance Company for denying the claim. The policies provide up to \$15 million in coverage limits. The Company intends to vigorously pursue its claims. The Company believes it has good and substantial support for its claims, but there is no guarantee that the Company will prevail in these claims.

10. 401(K) PLAN

The Company sponsors a 401(k) defined contribution plan (the "401(k) Plan") covering all U.S. employees under the Internal Revenue Code of 1986, as amended. Employee contributions to the 401(k) Plan 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 401(k) Plan of \$0.7 million for each of the three months ended March 31, 2023 and 2022.

11. WARRANTS

The Company issues common stock warrants in connection with debt or equity financings to lenders, placement agents and investors. Issued warrants are considered standalone financial instruments and the terms of each warrant are analyzed for equity or liability classification in accordance with U.S. GAAP. Warrants that are classified as liabilities usually have various features that would require net-cash settlement by the Company. Warrants that are not liabilities, derivatives and/or meet the exception criteria are classified as equity. Warrants liabilities are remeasured at fair value at each period end with changes in fair value recorded in the condensed consolidated statements of operations until expired or exercised. Warrants that are classified as equity are valued at their relative fair value on the date of issuance, recorded in additional paid in capital and not remeasured.

In the three months ended March 31, 2023 and 2022, no warrants to purchase shares of common stock were exercised.

As of March 31, 2023, 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
				<u>3,132</u>

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, 2022	1,490,462	2,921,925	\$ 28.13	3,094,396	\$ 37.39
Additional shares authorized	2,141,330	—	—	—	—
Common stock awards for services	(7,649)	—	—	—	—
RSUs granted	(1,262,588)	—	—	1,262,588	15.27
RSUs vested	—	—	—	(170,077)	52.76
Options granted	(418,564)	418,564	15.50	—	—
Options exercised	—	(820)	2.06	—	—
Repurchase of common stock under employee incentive plans	50,254	—	—	—	—
RSUs forfeited	91,291	—	—	(91,291)	36.78
Options forfeited	12,949	(12,949)	31.32	—	—
Options expired	78,024	(78,024)	33.81	—	—
Balance—March 31, 2023	<u>2,175,509</u>	<u>3,248,696</u>	\$ 26.52	<u>4,095,616</u>	\$ 29.87

The total intrinsic value of options exercised was \$0.0 million and \$1.0 million for the three months ended March 31, 2023 and 2022, respectively.

As of March 31, 2023, the total intrinsic value of outstanding RSUs was approximately \$38.8 million and there were \$74.2 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.65 years.

Options outstanding that have vested and are expected to vest at March 31, 2023 are as follows:

	Number of Shares Issued (In thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	1,273	\$ 25.39	5.72	\$ 1,558
Expected to vest	1,695	27.05	8.97	3
Total	2,968			\$ 1,561

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at March 31, 2023 for stock options that were in-the-money.

The total fair value of options that vested during the three months ended March 31, 2023 was \$4.2 million. As of March 31, 2023, there were approximately \$26.3 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 3.02 years.

2014 Employee Stock Purchase Plan

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

During the offering period in 2022 that ended on December 31, 2022, 47,025 shares were purchased pursuant to the ESPP for aggregate proceeds of \$0.5 million from the issuance of such shares, which occurred on January 2, 2023.

Valuation Assumptions

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

	Three Months Ended March 31,	
	2023	2022
Employee stock options		
Expected term (in years)	6.0	6.0
Expected volatility	78.63%	76.93%
Risk-free interest rate	3.46%	1.65%
Expected dividend yield	—%	—%
Employee stock purchase plan		
Expected term (in years)	0.5	0.5
Expected volatility	77.88%	67.79%
Risk-free interest rate	4.94%	1.06%
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.

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

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

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense relating to employee and non-employee stock-based awards for the three months ended March 31, 2023 and 2022, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Cost of testing services	\$ 479	\$ 19
Cost of product	360	128
Cost of patient and digital solutions	402	192
Research and development	1,962	2,190
Sales and marketing	3,737	3,123
General and administrative	6,814	4,982
Total	<u>\$ 13,754</u>	<u>\$ 10,634</u>

No tax benefit was recognized related to stock-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of stock-based compensation expense were capitalized for the periods presented.

13. INCOME TAXES

The Company's effective tax rate may vary from the U.S. federal statutory tax rate due to the change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits, and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income.

For the three months ended March 31, 2023 and 2022, the Company recorded an income tax expense of \$0.1 million and an income tax benefit of \$12,000, respectively. The income tax expense of \$0.1 million is primarily attributable to the U.S. current tax expense. 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. consolidated net deferred tax assets. The Company has also placed a valuation allowance on the net deferred tax assets of its Sweden operations. Accordingly, the U.S. and Sweden net deferred tax assets have been offset by a full valuation allowance.

14. SEGMENT REPORTING

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

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

	Three Months Ended March 31,	
	2023	2022
Testing services revenue		
United States	\$ 61,647	\$ 66,223
Rest of World	137	221
	<u>\$ 61,784</u>	<u>\$ 66,444</u>
Product revenue		
United States	\$ 3,727	\$ 3,613
Europe	2,461	2,242
Rest of World	673	933
	<u>\$ 6,861</u>	<u>\$ 6,788</u>
Patient and digital solutions revenue		
United States	\$ 8,506	\$ 6,153
Europe	84	10
Rest of World	27	21
	<u>\$ 8,617</u>	<u>\$ 6,184</u>
Total United States	<u>\$ 73,880</u>	<u>\$ 75,989</u>
Total Europe	<u>\$ 2,545</u>	<u>\$ 2,252</u>
Total Rest of World	<u>\$ 837</u>	<u>\$ 1,175</u>
Total	<u><u>\$ 77,262</u></u>	<u><u>\$ 79,416</u></u>

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

	March 31, 2023	December 31, 2022
Long-lived assets:		
United States	\$ 34,917	\$ 35,020
Europe	498	405
Rest of World	91	104
Total	<u><u>\$ 35,506</u></u>	<u><u>\$ 35,529</u></u>

15. RESTRUCTURING

In January 2023, the Company announced a restructuring plan that is intended to optimize costs and simplify its organizational and corporate structure. The restructuring plan includes the discontinuation of the Company's operations in Fremantle, Australia, terminating its employees in that location and vacating its facilities there. As a result of this plan, the Company incurred \$0.06 million in restructuring charges for the three months ended March 31, 2023. The Company expects to complete the closure of its Australia location in June 2024.

16. SUBSEQUENT EVENT

U.S. Restructuring Plan

In May 2023, the Company announced a reduction of its U.S. workforce to simplify and streamline its organization and strengthen the overall effectiveness of its operations. The restructuring charges are primarily related to employee severance pay and related costs.

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, 2022, filed with the Securities and Exchange Commission, or the SEC, on February 27, 2023.

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:

- our ability to generate revenue and increase the commercial success of our current and future testing services, products and patient and digital solutions;
- our ability to obtain, maintain, continue and expand reimbursement coverage from payers for our current and other future testing services, if any, including with respect to AlloSure Kidney;
- our plans and ability to continue updating our testing services, products and patient 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;
- our plans with respect to certain future Medicare reimbursement submissions;
- our ability to remediate the material weaknesses in our internal control over financial reporting of December 31, 2022; 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, 2022, filed with the SEC on February 27, 2023. 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 patient and digital healthcare solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients.

Highlights for the Three Months Ended March 31, 2023 and Recent Highlights

- Delivered record number of patient test results for AlloMap® and AlloSure® of approximately 49,900 tests, growing year-over-year by 17%, and exceeding year-over-year market growth of 10%.
- Reported revenue of \$77.3 million, a decrease of 3% year-over-year. This excludes approximately \$8.9 million in revenue associated with approximately 3,200 AlloSure Kidney Medicare tests that the Company did not submit for reimbursement in Q1 2023 (the “Impacted March Tests”), and plans to submit in Q2 2023. This was to allow the Company further time to understand and evaluate the implications of the new Billing Article related to the Local Coverage Determination covering AlloSure Kidney entitled Molecular Testing for Solid Organ Allograft Rejection (the “Billing Article”) issued in early March 2023.

Including the revenue associated with the Impacted March Tests, total revenue would have been \$86.2 million and testing services revenue would have been \$70.7 million, increases of 9% and 6% year-over-year, respectively, which would have been the highest ever quarterly revenues for the Company and its Testing Services business.

- Achieved record revenues of \$8.6 million for Patient and Digital Solutions business, an increase of 39% year-over-year.
- Reported GAAP net loss of \$23.7 million, non-GAAP net loss of \$5.8 million and adjusted EBITDA loss of \$6.4 million. Including revenue associated with the Impacted March Tests, the Company would have achieved a positive adjusted EBITDA of \$2.5 million.
- Maintained strong balance sheet with \$285.9 million in cash and cash equivalents and marketable securities, with no debt. Generated \$0.7 million in net cash from operating activities compared to \$21.5 million of cash used in operating activities in the first quarter of 2022. This represents the second consecutive quarter where the Company generated positive cash from its operating activities.
- Achieved cash collections at 110% of revenue for testing services, representing an approximate 10% year-over-year increase, and demonstrating continued strong operational progress on this key initiative.
- Strong transplant ecosystem support in response to the Billing Article from leading professional and patient societies, including the American Society of Transplantation, American Society of Transplant Surgeons, and the International Society for Heart and Lung Transplantation.
- Leading patient groups, including the Transplant Life Foundation, Transplant Recipients International Organization (TRIO), Transplant Families, and the Heart Brothers Foundation announced in a press release the results of a survey

from over 1,000 patients, as well as caregivers and family members that 95% of patients surveyed are concerned that a new Medicare Billing Article limits coverage of non-invasive post-transplant tests.

Testing Services

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our donor-derived cell-free DNA, or dd-cfDNA offering built on a next generation sequencing, or NGS, platform. In transplantation, more than 100 papers from over 50 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, or SNP, approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable, high-quality test to differentiate dd-cfDNA.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a Local Coverage Determination, or LCD, first issued by Palmetto MolDX, or MolDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian Healthcare Solutions, our Medicare Administrative Contractor, or Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841.

On March 2, 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Article. Prior to the Billing Article's effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article will not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new billing article with an effective date of March 31, 2023, or the Revised Billing Article, and together with the Billing Article, the Billing Articles. The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian has not yet adopted the new Billing Articles.

Although we believe the Billing Articles are inconsistent with the LCDs, Noridian's and MolDX's responses to public comments explaining the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx's test order forms to capture the new information required under the Billing Article. Accordingly, we did not submit claims for approximately 3200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million, or the Impacted March Tests.

In the second quarter of 2023, we plan to submit claims for Medicare reimbursement for the Impacted March Tests, following the delivery by us of a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we plan to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Although we plan to submit claims for Medicare reimbursement for the Impacted March Tests, there is a risk that the claims are denied or that any reimbursement of such claims is subject to forfeiture.

AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis.

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long-term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated. AlloSure 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 was published in the American Journal of Transplant, or AJT, and the outcomes of 1,000 patients were published in Kidney International.

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 iBox in one surveillance solution. We have not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or 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, more than 3,000 patients have been enrolled into the study.

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. The Revised Billing Article impacts Medicare coverage for AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, though acknowledged that the Billing Article is a change as to its previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. As previously discussed, Noridian has not adopted the Billing Articles. We continued the Medicare reimbursement submissions for AlloMap Heart following the issuance of the new Billing Articles. In addition, we are considering informing Noridian that until Noridian adopts the Revised Billing Article, we will continue to submit AlloMap Heart tests for reimbursement only when used in conjunction with AlloSure Heart. We are also considering informing Noridian that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

In October 2020, we received a final Palmetto MoDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian 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. The Revised Billing Article impacts Medicare coverage for AlloSure Heart and requires certain companies, including CareDx, to implement new processes to address requirements related to Medicare claim submissions. We continued the Medicare reimbursement submissions for AlloSure Heart following the issuance of the Billing Articles. In addition, we are considering informing Noridian that until Noridian adopts the Revised Billing Article, we will continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. We are also considering informing Noridian that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without confirming whether they meet the Revised Billing Article's parameters, there is a risk that any reimbursement of such claims are subject to forfeiture.

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 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 International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

HeartCare includes the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap 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.

The most recent ISHLT guidelines published in 2022 reinforced their use of AlloMap Heart, and referenced the combined use of AlloSure Heart and AlloMap Heart for surveillance purposes.

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 is being 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 MoDx Technology Assessment program seeking coverage and reimbursement for AlloSure Lung and since then we have been in active discussions with Palmetto. In October 2021, we launched AlloSure Lung as part of the CHEST 2021 Annual Meeting. We have gained early adoption with some commercial payers.

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. AlloCell is being commercialized through research

agreements with biopharma companies developing cell therapies. In 2021, we executed multiple additional agreements with biopharma therapeutics companies to use AlloCell in research and clinical studies.

In July 2021, we launched the Assessing Chimerism and Relapse of Bone marrow/ HCT transplant using AlloHeme Testing, or ACROBAT study. The ACROBAT study is a prospective, multicenter, observational cohort study to evaluate the use of AlloHeme, a microchimerism NGS tool to predict post-transplant relapse in patients with allogeneic hematopoietic cell transplants, or HCT. This study is currently enrolling patients.

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.

Our historical product portfolio includes QTYPE and Olerup SSP. 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.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, Inc., or Illumina, 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 was discontinued in December 2021 and we have progressively converted existing customers to AlloSeq. 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. AlloSeq HCT received CE mark authorization in May 2022.

In March 2021, we acquired certain assets of BFS Molecular S.R.L., or 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.

In May 2022, we commercially launched Tx9, a high throughput version of Tx17 for HLA typing in high volume laboratories. Tx9 received CE mark authorization in August 2022.

Patient and Digital Solutions

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

On May 7, 2019, we acquired 100% of the outstanding common stock of Ottr. Ottr was formed in 1993 and is a leading provider of transplant patient management 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. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Access, 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.

In June 2021, we entered into a strategic agreement, which was amended in April 2022, 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.

In November 2021, we acquired MedActionPlan.com, LLC, or MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

In December 2021, we acquired the Transplant Pharmacy, or TTP, a transplant focused pharmacy located in Mississippi. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S. In January 2023, we acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. HLA Data Systems is a leader in the laboratory information management industry for human leukocyte antigen laboratories.

Financial Operations Overview

Revenue

We derive our revenue from testing services, products sales, patient and digital solutions 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, AlloSure Heart and AlloSure Lung tests, which represented 80% and 84% of our total revenue for the three months ended March 31, 2023 and 2022, 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.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a LCD first issued by MoIDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MoIDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753.

On March 2, 2023, MoIDX issued the Billing Article, with an effective date of March 31, 2023. Prior to the Billing Article's effective date, MoIDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article will not be implemented until June 30, 2023. MoIDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MoIDX issued a the Revised Billing Article. The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new

processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, though acknowledged that the Billing Article is a change as to our previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. Noridian has not adopted the new Billing Articles.

Although we believe the Billing Articles are inconsistent with the LCDs, Noridian's and MolDX's responses to public comments explaining the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx's test order forms to capture the new information required under the Billing Article. Accordingly, we did not submit claims for approximately 3200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million, or the Impacted March Tests.

In the second quarter of 2023, we plan to submit claims for Medicare reimbursement for the Impacted March Tests, following the delivery by us of a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we plan to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Although we plan to submit claims for Medicare reimbursement for the Impacted March Tests, there is a risk that the claims are denied or that any reimbursement of such claims is subject to forfeiture.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we are considering informing Noridian that until Noridian adopts the Revised Billing Article, we will continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. We are also considering informing Noridian that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without confirming whether they meet the Revised Billing Article's parameters, there is a risk that any reimbursement of such claims are subject to forfeiture.

AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

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 months ended March 31, 2023 and 2022. 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.

Patient and Digital Solutions Revenue

Our patient and digital solutions revenue is mainly derived from sales of our Ottr software, XynQAPI, MedActionPlan, TTP, TransChart and Tx Access licenses, services and SaaS agreements across the digital portfolio, as well as our pharmacy sales at TTP. Patient and digital solutions revenue represented 11% and 7% of total revenue for the three months ended March 31, 2023 and 2022, 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;
- Stock-based compensation; and
- Common stock warrant liability.

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our unaudited condensed consolidated financial statements during the three months ended March 31, 2023 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, 2022, filed with the SEC on February 27, 2023.

Recently Issued Accounting Standards

Refer to Note 2, Summary of Significant Accounting Policies - Recent Accounting Pronouncements, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position and cash flows.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

(In thousands)

	Three Months Ended March 31,		Change
	2023	2022	
Revenue:			
Testing services revenue	\$ 61,784	\$ 66,444	\$ (4,660)
Product revenue	6,861	6,788	73
Patient and digital solutions revenue	8,617	6,184	2,433
Total revenue	77,262	79,416	(2,154)
Operating expenses:			
Cost of testing services	15,296	17,628	(2,332)
Cost of product	4,066	4,399	(333)
Cost of patient and digital solutions	6,604	4,855	1,749
Research and development	24,357	21,880	2,477
Sales and marketing	23,231	23,148	83
General and administrative	28,032	26,559	1,473
Total operating expenses	101,586	98,469	3,117
Loss from operations	(24,324)	(19,053)	(5,271)
Other income (expense):			
Interest income, net	2,666	189	2,477
Change in estimated fair value of common stock warrant liability	7	27	(20)
Other expense, net	(1,974)	(823)	(1,151)
Total other income (expense)	699	(607)	1,306
Loss before income taxes	(23,625)	(19,660)	(3,965)
Income tax (expense) benefit	(124)	12	(136)
Net loss	\$ (23,749)	\$ (19,648)	\$ (4,101)

Testing Services Revenue

Testing services revenue decreased by \$4.7 million, or (7)%, for the three months ended March 31, 2023 compared to the same period in 2022. The decrease is primarily due to our determination, in light of the Billing Article, to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update our billing processes for AlloSure Kidney by educating clinicians and working with centers to update the test order forms to capture the new information required under the Billing Article. The decrease in revenue was primarily driven by non-submission of approximately 3200 AlloSure Kidney tests in the quarter representing approximately \$8.9 million in revenues. Overall, volume of tests increase of 17% year-over-year and an improvement in cash collections help partially offset this impact.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue increased by \$2.4 million, or 39%, for the three months ended March 31, 2023 compared to the same period in 2022, primarily due to an increase in pharmacy revenue of \$1.3 million and an increase in software revenue of \$1.2 million.

Cost of Testing Services

Cost of testing services decreased by \$2.3 million, or (13)%, for the three months ended March 31, 2023, compared to the same period in 2022. The decrease is primarily due to a reduction in royalty expense because of an amendment to the Stanford License agreement, which reduced the maximum royalty rate on AlloSure tests done from April 2022 and resulted in a reversal of the excess liability in March 2023, partially offset by an increase in sample and consumable costs due to high volume growth.

Cost of Product

Cost of product decreased by \$0.3 million, or (8)%, for the three months ended March 31, 2023, compared to the same period in 2022. The decrease is primarily due to adjustments in production variance.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by \$1.7 million, or 36%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase is primarily due to cost of goods from sales in the pharmacy business.

Research and Development

Research and development expenses increased by \$2.5 million, or 11%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase is primarily due to an increase in personnel-related costs, including stock-based compensation of \$0.6 million, an increase in clinical trial-related expense of \$1.2 million and an increase in other expenses of \$0.6 million.

General and Administrative

General and administrative expenses increased by \$1.5 million, or 6%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase is primarily due to an increase in personnel-related costs, including stock-based compensation expense of \$1.3 million, and an increase in rent and utility expense of \$0.7 million, partially offset by a decrease in legal expenses of \$0.7 million.

Other expense, net

Other expense, net decreased by \$1.2 million for the three months ended March 31, 2023, compared to the same period in 2022, primarily due to \$1.0 million in investment write-off.

Interest income, net

Interest income, net increased by \$2.5 million for the three months ended March 31, 2023, compared to the same period in 2022. The increase is primarily due to interest income earned on U.S. agency securities and corporate debt securities.

Income tax (expense) benefit

Income tax (expense) benefit decreased by \$0.1 million for the three months ended March 31, 2023, compared to the same period in 2022. The decrease is primarily attributable to the U.S. current tax expense.

Cash Flows for the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 671	\$ (21,468)
Investing activities	(14,771)	(156,032)
Financing activities	(1,138)	865
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(25)	45
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (15,263)</u>	<u>\$ (176,590)</u>

Operating Activities

Net cash provided by 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 provided by operating activities for the three months ended March 31, 2023 was \$0.7 million. Net operating assets increased \$4.4 million. Our noncash items included \$13.8 million in stock-based compensation expense, \$3.4 million of depreciation and amortization expense, \$1.3 million of amortization of right-of-use assets, \$0.9 million of unrealized loss on long-term marketable equity securities, \$1.0 million of asset impairment and write-downs and \$0.8 million of amortization of premium on short-term marketable securities, net.

Cash used in operating activities for the three months ended March 31, 2022 was \$21.5 million. Our net loss of \$19.6 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included

\$10.6 million in stock-based compensation expense, \$2.6 million of depreciation and amortization expense and \$0.9 million of amortization of right-of-use assets. Net operating assets decreased \$16.7 million.

Investing Activities

For the three months ended March 31, 2023, net cash used in investing activities of \$14.8 million was primarily related to the purchases of marketable securities of \$86.3 million and \$2.8 million related to additions of capital expenditures, net. These payments were offset by maturities of marketable securities of \$79.0 million.

For the three months ended March 31, 2022, net cash used in investing activities of \$156.0 million was primarily related to the purchases of marketable securities of \$148.5 million and \$8.5 million related to additions of capital expenditures, net.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2023 of \$1.1 million was primarily due to taxes paid related to net share settlements of restricted stock units of \$0.7 million, repurchase and retirement of common stock of \$0.7 million and payments of contingent consideration \$0.3 million. These payments were partially offset by proceeds from issuances of common stock under our employee stock purchase plan of \$0.5 million.

Net cash provided by financing activities for the three months ended March 31, 2022 of \$0.9 million was primarily related to proceeds from exercises of stock options of \$1.6 million and proceeds from issuances of common stock under our employee stock purchase plan of \$1.0 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of \$1.5 million and payments of contingent consideration \$0.3 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 \$484.9 million at March 31, 2023. As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$285.9 million and no debt outstanding.

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. \$30.0 billion

At-the-Market Equity Offering

On April 14, 2022, 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 \$200.0 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. Jefferies is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Jefferies under the Sales Agreement. Any shares of common stock offered and sold pursuant to the Sales Agreement will be issued and sold pursuant to our Registration Statement on Form S-3ASR (File No. 333-239049), filed with the SEC on June 9, 2020, or the Registration Statement, including a base prospectus dated June 9, 2020, and a prospectus supplement dated April 14, 2022. The Registration Statement will expire on June 9, 2023.

Stock Repurchase Program

On December 3, 2022, our Board of Directors approved our Stock Repurchase Program, or the Repurchase Program, whereby we may purchase up to \$50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of our Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three months ended March 31, 2023, we purchased an aggregate of 59,472 shares of our common stock under the Repurchase Program for an aggregate purchase price of \$0.7 million. As of March 31, 2023, \$48.7 million remained available for future share repurchases under the Repurchase Program.

Factors Affecting Our Performance

The Number of AlloMap Heart, AlloSure Lung, 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, AlloSure Lung, 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.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a LCD first issued by MolDX”, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753.

On March 2, 2023, MolDX issued the Billing Article. Prior to the Billing Article’s effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article will not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued the Revised Billing Article. The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian has not yet adopted the new Billing Articles.

Although we believe the Billing Articles are inconsistent with the LCDs, Noridian’s and MolDX’s responses to public comments explaining the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx’s test order forms to capture the new information required under the Billing Article. Accordingly, we did not submit claims for approximately 3200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million, or the Impacted March Tests.

In the second quarter of 2023, we plan to submit claims for Medicare reimbursement for the Impacted March Tests, following the delivery by us of a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we plan to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Although we plan to submit claims for Medicare reimbursement for the Impacted March Tests, there is a risk that the claims are denied or that any reimbursement of such claims is subject to forfeiture.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we are considering informing Noridian that until Noridian adopts the Revised Billing Article, we will continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. We are also considering informing Noridian that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without confirming whether they meet the Revised Billing Article’s parameters, there is a risk that any reimbursement of such claims are subject to forfeiture.

AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

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 varied, 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. See the discussion above under "The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report".

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 froze then-current (2020) CMS CLFS rates through 2021. Further, the CARES Act delayed 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.

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. See the discussion above under "The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report". 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. See the discussion above under "The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report".

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.

Our historical product portfolio includes QTYPE and Olerup SSP. 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.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in transplantation diagnostic testing. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA was discontinued in December 2021 and we have progressively converted existing customers to AlloSeq. 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, which 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. AlloSeq HCT received CE mark authorization in May 2022.

Continued Growth of Patient and Digital Sales

The growth of our patient and digital revenues is tied to the continued successful implementation of our Ottr, MedActionPlan and XynQAPI software businesses, as well as continued support and maintenance of existing MedActionPlan, Ottr and XynManagement customers. The Ottr software, TransChart, Tx Access 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. In addition, patient solutions offered by TTP in Flowood, Mississippi include hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. With the addition of HLA Data Systems, we are now able to support HLA laboratories in managing their day-to-day workflow.

Development of Additional Services and Products

Our development pipeline includes other transplant diagnostic solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. We expect to invest in research and development in order to develop additional products. Our success in developing new products and services will be important in our efforts to grow our business by expanding the potential market for our services and products and diversifying our sources of revenue.

Timing of Research and Development Expenses

Our spending on research and development may vary substantially from quarter to quarter. We conduct clinical studies to validate our new products, as well as on-going clinical and outcome studies to further the published evidence to support our commercialized tests. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.

Contractual Obligations

For a discussion regarding our significant contractual obligations as of March 31, 2023 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.

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 \$285.9 million at March 31, 2023, which consisted of bank deposits, money market funds and corporate debt securities, and we had cash and cash equivalents of \$293.1 million at December 31, 2022, 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 \$2.9 million on our condensed consolidated financial statements.

Foreign Currency Exchange Risk

We have operations in Sweden and Australia and sell to other countries throughout the world. As a result, we are subject to significant foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in U.S. dollars and the Euro. Our patient and digital solutions revenue is primarily denominated in U.S. dollars. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona, the Euro, and the Australian Dollar, which are also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at March 31, 2023, would have negatively impacted our financial results for the three months ended March 31, 2023 by \$0.4 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(e) and 15d-15(e) promulgated under the Exchange Act, as of March 31, 2023. 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, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2023, in light of the material weaknesses identified in our internal control over financial reporting described below, our disclosure controls and procedures were not effective at the reasonable assurance level and are not 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.

Previously Reported Material Weaknesses

As disclosed in Item 9A, “Controls and Procedures” within our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on February 27, 2023, the following material weaknesses were identified as of December 31, 2022:

General Information Technology Controls. We did not design and maintain effective general information technology controls (“GITCs”), for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology (“IT”), program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) Computer and Network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement account balances and disclosures.

Purchase Order Approval Workflow. We did not design and maintain effective process-level control activities related to procurement to ensure appropriate approval of purchase orders, which could affect the amount and classification of costs capitalized or expensed.

COSO Framework. We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an adequate process in place to complete our assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner.

After giving full consideration to these material weaknesses, and the additional analyses and other procedures we performed to ensure that our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q were prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, our management has concluded that our condensed consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. GAAP.

Management's Plan to Remediate the Material Weaknesses

Our management has been engaged in developing and implementing remediation plans to address the material weaknesses described above. These remediation efforts are ongoing and are expected to include the following:

- Enhancing the design and control procedures of the GITCs to ensure that the control activities related to GITCs are functioning appropriately;
- Improving the control environment in relation to personnel training and accountability of Sarbanes-Oxley Act of 2002 ("SOX") control activities;
- Hiring additional personnel in the IT and Finance and Accounting departments with an appropriate level of knowledge and experience to effectively execute our processes and procedures; and
- Expanding controls and/or applying appropriate procedures to address the design and operation of internal controls related to the procure-to-pay process.

In 2023 to date, we have hired three additional full time and contractors resources in our IT and Finance and Accounting departments to support our remediation efforts. We expect, and are planning, to continue adding incremental staffing in these departments throughout the year. We are in the process of developing and delivering SOX compliance training to control owners and are also actively working on and updating the design of our controls and controls procedures to ensure we address the root causes of the material weaknesses. We have also enhanced our communication by frequently holding meetings with key management personnel and members of the Audit Committee to discuss the SOX program. In regards to the procure-to-pay process, we are implementing a new automated control for the purchase order approval workflow and a new accounts payable system. In addition, we are investing in and implementing other systems that will assist us in monitoring the timely execution of controls, and we expect to continue to implement these throughout the remaining part of the year.

We are committed to continuing to implement a strong system of controls and believe that our ongoing remediation efforts particularly in the improvement of our control environment will result in significant improvements to our system of controls and that we believe will remediate the material weaknesses. However, material weaknesses are not considered remediated until the new controls have been operational for a period of time, are tested, and management concludes that these controls are operating effectively. This remediation process will require resources and time to implement. We will continue to monitor the effectiveness of these remediation measures, and we will make any changes to the design of our remediation plans and take such other actions that we deem appropriate given the circumstances.

Changes in Internal Control over Financial Reporting

Other than the changes associated with the material weaknesses and remediation actions noted above, there have been no changes in our internal control over financial reporting during the quarter ended March 31, 2023 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*, under the caption “Litigation and Indemnification Obligations”, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission or the SEC, on February 27, 2023, 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, 2022, filed with the SEC on February 27, 2023, other than those listed below. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially and adversely affect our business.

Risks Related to Our Business

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

We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the quarter ended March 31, 2023, our net loss was \$23.7 million. As of March 31, 2023, we had an accumulated deficit of \$484.9 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 patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of KidneyCare, HeartCare, AlloSeq, AiTraC and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC;
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a public company; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

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

We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance.

For the quarter ended March 31, 2023, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 53% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

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 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 on June 17, 2016 and the new market based rates took effect on January 1, 2018. The Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Under PAMA, the reimbursement rate for AlloMap Heart is currently \$3,240 for Medicare beneficiaries.

On September 26, 2017, we announced that the Molecular Diagnostic Services, or MolDX, Program developed by Palmetto GBA, or Palmetto, has set AlloSure Kidney reimbursement at \$2,841. AlloSure Kidney began to be reimbursed for kidney transplants covered by Medicare across the United States on October 9, 2017, the effective date of the Palmetto local coverage determination, or LCD.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through an LCD first issued by Palmetto MolDX, or MolDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian Healthcare Solutions, the Company's Medicare Administrative Contractor, or Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753.

On March 2, 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Article. Prior to the Billing Article's effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article will not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new billing article with an effective date of March 31, 2023, or the Revised Billing Article, and together with the Billing Article, the Billing Articles. The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian has not yet adopted the new Billing Articles.

Although we believe the Billing Articles are inconsistent with the LCDs, Noridian's and MolDX's responses to public comments explaining the intended scope of various LCDs, and medical necessity, we determined to pause its Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update its billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update our test order forms to capture the new information required under the Billing Article. Accordingly, we did not submit claims for approximately 3200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million, or the Impacted March Tests.

In the second quarter of 2023, we plan to submit claims for Medicare reimbursement for the Impacted March Tests, following the delivery by our of a letter to Noridian explaining, among other things, (i) we believe that the Billing Articles impose new restrictions on Medicare coverage for our tests from those contained in the existing LCDs, (ii) that we plan to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is

intended to identify those tests as falling outside the parameters of the Revised Billing Article. Although we plan to submit claims for Medicare reimbursement for the Impacted March Tests, there is a risk that the claims are denied or that any reimbursement of such claims is subject to forfeiture.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we are considering informing Noridian that until Noridian adopts the Revised Billing Article, we will continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. We are also considering informing Noridian that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Billing Article, or where the reason for testing is not specified by the ordering physician, will either be held pending the receipt of additional information regarding medical necessity or submitted with a test description that is intended to identify those tests as falling outside the parameters of the Billing Articles. There is a risk that claims submitted for reimbursement through June 30, 2023 for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles subject to forfeiture.

If an AlloMap Heart, AlloSure Kidney or AlloSure Heart reimbursement rate that is significantly lower than the current rate is set by CMS or MolDx in the future, it could cause us to discontinue AlloMap Heart, AlloSure Kidney or AlloSure Heart testing for Medicare patients because providing tests at a substantially lowered reimbursement rate may not be economically viable. In addition, our revenues for AlloSure Kidney in 2023 are expected to be materially lower than in prior periods as a result of lower overall testing volumes in 2023 due to the impact of the Billing Articles. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations.

If future reimbursement price levels are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. We may also not be able to maintain or increase the portion of our tests reimbursed by Medicare for a variety of other reasons, including changes in reimbursement practices and general policy shifts, including the Billing Articles.

On a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractors, or MAC, services. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U.S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloMap Heart, AlloSure Kidney or AlloSure Heart at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloSure Kidney, AlloMap Heart or AlloSure Heart could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

Any decision by CMS or its local contractors to reduce or deny coverage for our tests, including as a result of the Billing Articles or otherwise, would have a significant adverse effect on our revenue and results of operations and ability to operate and raise capital. Any such decision could also cause affected clinicians treating Medicare covered patients to reduce or discontinue the use of our tests.

Our financial results currently are largely dependent on sales of AlloSure Kidney, AlloMap Heart and AlloSure Lung tests and products, and we will need to generate sufficient revenues from these and other solutions and tests we develop to grow our business.

We expect that sales of testing services and products will account for a substantial portion of our revenue for at least the next two years. If we are unable to increase sales of our testing services or products or successfully develop and commercialize other solutions, tests or enhancements, or if we do not recommence our Medicare reimbursement submissions for AlloSure Kidney in the near term or at the same levels in place prior to the Billing Articles, our revenues and ability to achieve profitability would be impaired, and the market price of our common stock could decline.

Health insurers and other third-party payers may decide to revoke coverage of our existing test, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects.

Successful commercialization of AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart depends, in large part, on the availability of coverage and adequate reimbursement from government and private payers. Favorable third-party payer coverage and reimbursement are essential to meeting our immediate objectives and long-term commercial goals.

For new diagnostic testing services, each private and government payer decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may be likely not to order

a diagnostic test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic testing service, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

Coverage and reimbursement by a commercial payer may depend on a number of factors, including a payer's determination that our current and future testing services are:

- not experimental or investigational;
- medically necessary or redundant;
- lead to improved patient outcomes;
- appropriate for the specific recipient;
- cost-saving or cost-effective; and
- supported by peer-reviewed publications.

Third-party payers have in the past disallowed, and may in the future disallow, in whole or in part, requests for reimbursement based on determinations that the member is not eligible for coverage, certain amounts are not reimbursable under plan coverage or were for services provided that were not medically necessary or were redundant or not coupled with other specified tests or services or additional supporting documentation is necessary. Retroactive adjustments may change amounts realized from third-party payers. We are also subject to claims reviews and/or audits by such payers, including governmental audits of our Medicare claims, and have in the past been required to repay these payers in certain circumstances where a preliminary finding was made that we were incorrectly reimbursed. We may also in the future be required to repay these payers if a finding is made that we were incorrectly reimbursed.

In addition, several payers and other entities conduct technology assessments of new medical tests and devices and provide and/or sell the results of their assessments to other parties. These assessments may be used by third-party payers and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure. We have received a negative technology assessment from at least one of these entities and could receive more.

If third-party payers decide not to cover our diagnostic testing services or if they offer inadequate payment amounts, our ability to generate revenue from AlloSure Kidney, AlloMap Heart, AlloSure Heart and future solutions could be limited. Payment for diagnostic tests furnished to Medicare beneficiaries is typically made based on a fee schedule set by CMS. In recent years, payments under these fee schedules have decreased and may decrease further.

Any third-party payer may stop or lower payment at any time, which could substantially reduce our revenue. See the risk factor above titled *"We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance"*.

Since each payer makes its own decision as to whether to establish a policy to reimburse for a test, seeking payer coverage and other approvals is a time-consuming and costly process. We cannot be certain that adequate coverage and reimbursement for AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or future solutions will be provided in the future by any third-party payer.

Reimbursement for AlloSure Kidney, AlloMap Heart and AlloSure Heart comes primarily from Medicare and private third party payers such as insurance companies and managed care organizations. The reimbursement process can take six months or more to complete depending on the payer. AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a LCD first issued by MoIDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MoIDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. See the discussion regarding the Billing Articles under the risk factor above titled *"We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance"*.

Coverage policies approving AlloMap Heart have been adopted by many of the largest private payers. Many of the payers with positive coverage policies have also entered into contracts with us to formalize pricing and payment terms. We continue to work with third-party payers to expand and seek such coverage and to appeal denial decisions based on existing and ongoing studies, peer reviewed publications, support from physician and patient groups and the growing number of AlloMap Heart tests that have been reimbursed by public and private payers. There are no assurances that the current policies will not be modified in the future. If our test is considered on a policy-wide level by major third-party payers, whether at our request or on their own initiative, and our test is determined to be ineligible for coverage and reimbursement by such payers, if we do not submit for

Medicare reimbursement for AlloSure Kidney for certain prior or future periods or if the Billing Articles limit Medicare reimbursement for AlloSure Heart or AlloMap Heart commencing on June 30, 2023, our collection efforts and potential for revenue growth could be adversely impacted.

Our Medicare Part B coverage for AlloSure Kidney and AlloMap Heart is included in a formal local coverage decision for molecular diagnostics. However, any change in this coverage decision or other future adverse coverage decisions by the CMS, including with respect to coding or as a result of the Billing Articles, could substantially reduce our revenue.

Medicare reimbursements currently comprise a significant portion of our revenue. Our current Medicare Part B reimbursement was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the national coverage certainty afforded by a formal coverage determination by CMS. This means that Medicare contractors, including our California Medicare contractor, currently may continue to develop their own coverage and reimbursement policies with respect to our technology.

Until 2016, AlloMap Heart was billed using an unlisted Current Procedural Terminology, or CPT, code, but in 2016 a new CPT Category 1 Multianalyte Assays with Algorithmic Analyses, or MAAA, code was added that specifically describes the test. Further, pursuant to MolDX billing requirements, the AlloMap Heart test also has been assigned a McKesson Diagnostics Z code™, which is included on all Medicare claims.

If in the future CMS makes a determination not to pay for this code, or for any MAAA codes, this could be harmful to our business, and could have negative spillover implications that prevent or limit coverage by other third-party payers that might mirror aspects of Medicare payment criteria.

Since the launch of AlloSure Kidney in October 2016, and at the instruction of the MolDX Program of Palmetto, the test has been billed utilizing an unlisted CPT code. If in the future CMS makes a determination to no longer provide coverage for services billed with an unlisted CPT code, our ability to bill and obtain reimbursement from public and private payers could be negatively impacted. In addition, the Billing Article indicates that we will need to obtain additional “Z” codes for AlloSure Kidney in order to submit for future Medicare reimbursement. In addition, there can be no assurance that any of our tests or other offerings currently being promoted or on the market or being leveraged by clinicians or patients without FDA clearance or approval will continue to be allowed without such clearance or approval.

We are and 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. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury awarding us \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. As of the date of this report, the post-trial motion practice remains pending. We will not record the award until cash is received or the matter is otherwise resolved.

On July 19, 2022, the United States Court of Appeals for the Federal Circuit affirmed the Court’s judgment dismissing our patent infringement suit against Natera.

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. This case was consolidated with our patent infringement suit on February 4, 2020. 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. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera’s U.S. Patents 10,655,180 and 11,111,544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera’s U.S. Patent 10,526,658. On July 6, 2022, we moved to dismiss the rest of Natera’s claims. On September 6, 2022, we withdrew the motion to dismiss. Discovery is ongoing. 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.

Furthermore, on May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action in the U.S. District Court for the Northern District of California against us, Reginald Seeto, our President, Chief Executive Officer

and member of our Board of Directors, Ankur Dhingra, our former Chief Financial Officer; Marcel Konrad, our former interim Chief Financial Officer and former Senior Vice President of Finance & Accounting; and Peter Maag, our former President, former Chief Executive Officer, former Chairman of the Board and current member of our Board of Directors. The action alleges that we and the individual defendants made materially false and/or misleading statements and/or omissions and that such statements violated Section 10(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 10b-5 promulgated thereunder. The action also alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of our Company. The suit seeks to recover damages caused by the alleged violations of federal securities laws, along with the plaintiffs' costs incurred in the lawsuit, including their reasonable attorneys' and experts' witness fees and other costs. We intend to defend ourselves vigorously, and believe that we have good and substantial defenses to the claims alleged in the suit, but there is no guarantee that we will prevail.

On August 25, 2022, the court appointed an investor group led by the Oklahoma Police Pension and Retirement System as lead plaintiffs and appointed Saxena White P.A. and Robbins Geller Rudman & Dowd LLP as lead counsels. Plaintiffs filed an amended complaint on November 28, 2022. On January 27, 2023, defendants moved to dismiss all claims and to strike certain allegations in the amended complaint. A hearing on these motions is scheduled for May 16, 2023. We intend to defend ourselves vigorously, and believes that we have good and substantial defenses to the claims alleged in the suit, but there is no guarantee that we will prevail.

Additionally, on September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Edelman Derivative Action, against us as nominal defendant and Reginald Seeto, our President, Chief Executive Officer and member of our Board of Directors, Ankur Dhingra, our former Chief Financial Officer, Peter Maag, our former President, former Chief Executive Officer, former Chairman of the Board and current member of our Board of Directors, and the other members of our Board of Directors. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of our Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to us, violated Sections 14(a) and 20(a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

In addition, on February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Stevenson Derivative Action, against us as nominal defendant and Reginald Seeto, Ankur Dhingra, Peter Maag and other current and former members of our Board of Directors. The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the individual defendants breached their fiduciary duties as our directors and/or officers and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the Edelman Derivative Action and the Stevenson Derivative Action, 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.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Historically, our financial results have been, and we expect that our operating results will continue to be, subject to quarterly fluctuations. Our net income (loss) and other operating results will be affected by numerous factors, including:

- our ability to successfully market and sell our testing services and products;
- our ability to successfully commercialize new diagnostic solutions;
- the amount of our research and development expenditures;
- the timing of cash collections from third-party payers;
- the extent to which our current and future solutions, if any, are eligible for coverage and reimbursement from third-party payers;
- the process of integrating new acquisitions, and the associated potential disruption to our business;

- changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business, including as a result of the Billing Articles;
- our decision to recommence Medicare reimbursement submissions for AlloSure Kidney;
- our decision to issue future financial guidance and the terms of such guidance;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved or that otherwise may affect our intellectual property position;
- announcements by our competitors of new or competitive products;
- regulatory or legal developments affecting our test or competing products;
- total operating expenses; and
- changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Transplant centers may not adopt AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or our other solutions due to historical practices or due to more favorable reimbursement policies associated with other means of monitoring transplants.

Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute rejection in kidney and heart transplant recipients by utilizing biopsies. Many clinicians use AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloSure Kidney, AlloSure Lung, AlloMap Heart or AlloSure Heart as biopsy alternatives, per se, if treatment center administrators view our test as an alternative to a biopsy but believe they would derive more revenue from the performance of biopsies, such administrators may be motivated to reduce or avoid the use of our test. While biopsies are less common for monitoring kidney transplant patients, there are transplant centers that manage patients with protocol biopsies, which could impact AlloSure Kidney revenue. We cannot provide assurance that our efforts will increase the use of our test by new or existing customers. Our failure to increase the frequency of use of our test by new and existing customers would adversely affect our growth and revenues.

Our past revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline.

From 2021 to 2022, our revenue grew from \$296.4 million to \$321.8 million, which represents annual growth of 9%. In the future, our revenue may not grow at all and it may decline. We believe that our future revenue will depend on, among other factors:

- the continued usage and acceptance of our current and future solutions;
- demand for our testing services, products and patient and digital solutions;
- the introduction and acceptance of new or enhanced products or services by us or by competitors;
- our ability to maintain reimbursement for AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart and secure reimbursement for our future solutions;
- our decision to recommence Medicare reimbursement submissions for AlloSure Kidney;
- our decision to issue future financial guidance and the terms of such guidance;
- our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies;
- our ability to attract, retain and motivate qualified personnel;
- the initiation, renewal or expiration of significant contracts with our commercial partners;
- pricing changes by us, our suppliers or our competitors; and
- general economic conditions and other factors.

We may not be successful in our efforts to manage any of the foregoing, and any failure to be successful in these efforts could materially and adversely affect revenue growth. You should not consider our past revenue growth to be indicative of future growth.

If we are unable to raise additional capital on acceptable terms in the future, it may limit our ability to develop and commercialize new diagnostic solutions and technologies, and we may have to curtail or cease operations.

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$285.9 million and an accumulated deficit of \$484.9 million. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- develop other solutions for clinical surveillance in transplantation;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of AlloSure Kidney, AlloSure Lung, KidneyCare, AlloMap Heart, AlloSure Heart, HeartCare, our products and patient and digital solutions or enhancements to those tests, products and patient and digital solutions;
- acquire or license products or technologies including through acquisitions; and
- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our new solutions;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional FDA or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all, and might include the issuance of equity securities, debt, cash from collaboration agreements, or a combination of these. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock and would result in dilution to our stockholders. Moreover, we have the ability to sell up to \$200.0 million of additional shares of our common stock to the public through an “at the market” offering pursuant to a Sales Agreement we entered into with Jefferies, LLC on April 14, 2022. Any shares of common stock issued in the at-the-market offering will result in dilution to our existing stockholders. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

Our operating results may be adversely affected by unfavorable economic and market conditions.

Many of the countries in which we operate, including the U.S. and several of the members of the European Union, or EU, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. On June 23, 2016, the United Kingdom, or the UK, held a referendum pursuant to which voters elected to leave the EU, commonly

referred to as Brexit. The UK formally left the EU on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, and the UK is in the process of negotiating trade deals with other countries, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; increased inflation globally and in the U.S. in particular; the government closure of Silicon Valley Bank and potential liquidity concerns at other financial institutions; a potential economic recession; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our tests and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

Our current or future restructuring plans, including our recent decision to discontinue our operations in Fremantle, Australia, may not optimize costs and simplify our organizational and corporate structure and may materially impair our business operations.

In January 2023, we announced a restructuring plan intended to optimize costs and simplify our organizational and corporate structure. Our restructuring plan includes the discontinuation of our operations in Fremantle, Australia, terminating our employees in that location and vacating our facilities there. The winding down of our operations in Australia has, and any additional restructuring efforts may, divert management's attention, increase expenses on a short term basis and lead to potential issues with employees, customers, or suppliers. If we do not complete these activities in a timely manner; or do not realize anticipated cost savings, synergies and efficiencies; or business disruption occurs during or following such activities; or we incur unanticipated charges, our business, financial condition, operating results, and cash flows may be materially impaired.

Risks Related to Billing and Reimbursement

Billing complexities associated with obtaining payment or reimbursement for our current and future solutions may negatively affect our revenue, cash flows and profitability.

Billing for clinical laboratory testing services is complex. In cases where we do not have a contract in place requiring the payment of a fixed fee per test, we perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we do receive a fixed fee per test, we may still have disputes over pricing and billing. We receive payment from individual recipients and from a variety of payers, such as commercial insurance carriers and governmental programs, primarily Medicare. Each payer typically has different billing requirements.

Among the factors complicating our billing of third-party payers are:

- disputes among payers regarding which party is responsible for payment;
- disparity in coverage among various payers;
- different process, information and billing requirements among payers; and
- incorrect or missing billing information, which is required to be provided by the prescribing clinician.

See the discussion of the Billing Articles under the risk factor above titled *"Health insurers and other third-party payers may decide to revoke coverage of our existing test, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects"*.

Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental

programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. In addition, we are subject to and expect to continue to be subject to one or more audits under the CMS Recovery Audit Contractor, or RAC, program, the CMS Targeted Probe and Educate, or TPE, program, the Unified Program Integrity Contractors, or UPIC, program and other federal and state audits. Following two rounds of TPE audit in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us it was making a referral to CMS given disagreement as to the interpretation of the applicable LCDs. We appealed claims which had a basis for appeal and those claims were denied. We continue to pursue appeals of these claims consistent with our statutory rights. We have met with CMS to discuss the difference in interpretation and intend to continue this dialogue regarding our position that the Noridian interpretation is inconsistent with the LCD, MolDX's and Noridian's prior associated responses to public comments, and medical necessity. We expect further intensification of the regulatory environment surrounding the healthcare industry, as third-party firms engaged by CMS and others conduct extensive pre and post-payment audits of claims data as well as medical and other records in order to identify improper payments to healthcare providers under the Medicare and Medicaid programs. We could be forced to expend considerable resources responding to these audits or other inquiries. These billing complexities, and the resulting uncertainty in obtaining payment for AlloSure Kidney, AlloMap Heart, AlloSure Heart and future solutions, as well as the results of Noridian's referral to CMS and any audits or inquiries evaluating the medical necessity of our services creates a risk that our claims are denied or that any historical reimbursement of such claims is subject to forfeiture and could negatively affect our revenue, cash flows and profitability.

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 quiescent leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of March 31, 2023, we had 20 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have one issued U.S. patent covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart, which will expire in March 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease, which will expire between August 2024 and September 2029.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, four in 2021, two in 2022 and one in 2023, that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents will expire between 2030 and 2032.

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. This ruling 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. On March 29, 2023, we entered into an agreement with Stanford whereby we agreed, among other things, to seek a review from the United States Supreme Court, or the Review. During the pendency of the Review, certain of our licensing payment and reporting obligations to Stanford with respect to licensed products sold in the U.S., and our right to terminate the Exclusive Agreement upon 30 days' advance notice to Stanford, are suspended. However, there can be no assurance that the Review will be granted or that any decision by the Supreme Court will be granted in our favor. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the United States Supreme Court, have rendered decisions that impact the scope of

patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. In the *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (Fed. Cir. 2015) case, a federal court recently determined that a cfDNA product for fetal testing was not eligible for patent protection. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a “sufficient” additional feature for this purpose is uncertain. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

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

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

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

Risks Related to Our Common Stock

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

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. From January 3, 2023 to March 31, 2023, our closing stock price ranged from \$8.83 to \$17.61 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 FDA 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;
- share repurchases completed by us; and
- general market conditions.

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

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

Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the 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, 2022, filed with the SEC on February 27, 2023, 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;
- our prior decision to withdraw our revenue guidance for fiscal 2023;
- our decision to issue future financial guidance and the terms of such guidance; and
- general economic conditions and slow or negative growth of our markets.

If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you.

Our executive officers, directors and holders of 5% or more of our outstanding common stock (based on the most recent public filings), and entities affiliated with them, beneficially own in the aggregate approximately 62.1% of our common stock as of May 8, 2023. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

We may elect to repurchase shares of our common stock, which might limit our ability to pursue other growth opportunities.

On December 3, 2022, our board of directors authorized a stock repurchase program, whereby we may purchase up to \$50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022, or the Repurchase Program. The Repurchase Program may be carried out at the discretion of a committee of our Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. Any repurchase of shares of our common stock under the Repurchase Program will depend on several factors, including, but not limited to, results of operations, capital requirements, financial conditions, available capital from operations or other sources, including debt, and the market price of our common stock. In addition, on August 16, 2022, the U.S. enacted the Inflation Reduction Act of 2022, which, among other things, imposes an excise tax of 1% tax on the fair market value of net stock repurchases made after December 31, 2022. Therefore, there is no assurance with respect to the amount, price or timing of any such repurchases. We may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing shares of our common stock.

During the three months ended March 31, 2023, we purchased an aggregate of 59,472 shares of our common stock under the Repurchase Program for an aggregate purchase price of \$0.7 million. As of March 31, 2023, \$48.7 million remained available for future share repurchase under the Repurchase Program. In the event we make any additional stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our Board of Directors may modify or amend the Repurchase Program, or adopt a new stock repurchase program, at any time at its discretion without stockholder approval.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2022. If we are unable to remediate these material weaknesses and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner.

Effective internal control over financial reporting is necessary for us to provide reasonable assurance regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States. In connection with the preparation of our consolidated financial statements as of December 31, 2022 and for the year then ended, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management concluded that we had the following material weaknesses as of December 31, 2022:

- **General Information Technology Controls.** We did not design and maintain effective general information technology controls (“GITCs”), for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology (“IT”), program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) Computer and Network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement account balances and disclosures.

- **Purchase Order Approval Workflow.** We did not design and maintain effective process-level control activities related to procurement to ensure appropriate approval of purchase orders, which could affect the amount and classification of costs capitalized or expensed.
- **Committee of Sponsoring Organizations of the Treadway Commission (COSO) Framework.** We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an adequate process in place to complete its assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner.

These material weaknesses have not been remediated as of the date of this Quarterly Report on Form 10-Q. Our management has been engaged in developing and implementing remediation plans to address the material weaknesses described above. However, the material weaknesses will not be fully remediated until management can demonstrate the full effectiveness of controls over a sufficient period of time, and we can give no assurance on the success of such measures or the outcome of our assessment of these measures at this time.

If the steps we take to remediate the material weaknesses are ineffective, these material weaknesses could result in material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filings of our required periodic reports. This might lead to investors losing confidence in the accuracy and completeness of our financial reports, the market price of the common stock could be adversely affected, and we could become subject to litigation or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities, which could require additional financial and management resources.

Furthermore, if we identify any new material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate our existing material weaknesses or avoid potential future material weaknesses.

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 or withheld to satisfy certain tax withholding obligations during the three months ended March 31, 2023:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
January 1, 2023 - January 31, 2023	29,991 (1)	\$ 12.92	17,702 (4)	\$ 49.1 (4)
February 1, 2023 - February 28, 2023	40,422 (2)	16.45	9,220 (4)	49.0 (4)
March 1, 2023 - March 31, 2023	39,313 (3)	10.05	32,550 (4)	48.7 (4)
Total	109,726		59,472 (4)	

(1) Comprised of: (a) 12,289 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$13.06 which represents the average fair market value of common stock on the date of withholding, and (b) 17,702 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$12.81.

(2) Comprised of: (a) 31,202 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$16.85 which represents the average fair market value of common stock on the date of withholding, and (b) 9,220 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$15.11.

(3) Comprised of: (a) 6,763 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$10.74 which represents the average fair market value of common stock on the date of withholding, and (b) 32,550 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$9.91.

(4) On December 3, 2022, our Board of Directors approved our stock repurchase program, authorizing us to purchase up to \$50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of our Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions.

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*#	CareDx, Inc. Outside Director Compensation Policy, effective April 1, 2023.
10.2*†	Agreement Regarding Payment of Royalties and Amendment to the Amended and Restated Exclusive License, by and between The Board of Trustees of the Leland Stanford Junior University and the Registrant, entered into on March 29, 2023.
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.
#	Indicates management contract or compensatory plan or arrangement.
*	Filed herewith.

**

Furnished herewith.

†

Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

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.

Date: May 10, 2023

CAREDX, INC.
(Registrant)

By: /s/ REGINALD SEETO, MBBS

Reginald Seeto, MBBS
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ ABHISHEK JAIN

Abhishek Jain
Chief Financial Officer
(Principal Accounting and Financial Officer)

CareDx, Inc.**OUTSIDE DIRECTOR COMPENSATION POLICY****Most Recently Amended Effective as of April 1, 2023**

CareDx, Inc. (the “**Company**”) believes that the granting of equity and cash compensation to its members of the Board of Directors (the “**Board**,” and members of the Board, the “**Directors**”) represents an effective tool to attract, retain and reward Directors who are not employees of the Company (the “**Outside Directors**”). This Outside Director Compensation Policy (the “**Policy**”) is intended to formalize the Company’s policy regarding cash compensation and grants of equity to its Outside Directors. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given such term in the Company’s 2014 Equity Incentive Plan (the “**Plan**”). Each Outside Director will be solely responsible for any tax obligations incurred by such Outside Director as a result of the equity and cash payments such Outside Director receives under this Policy.

1. Retainers**BOARD MEMBERSHIP**

Chairman of Board: \$80,000 Annual Retainer

Outside Directors (including Chairman): \$45,000 Annual Retainer

AUDIT & FINANCE COMMITTEE

Annual compensation for Audit & Finance Committee members is as follows:

Chairman of Committee: \$20,000 Annual Retainer

Committee Members (other than Chairman) \$10,000 Annual Retainer

COMPENSATION & HUMAN CAPITAL COMMITTEE

Annual compensation for the Compensation & Human Capital Committee is as follows:

Chairman of Committee: \$15,000 Annual Retainer

Committee Members (other than Chairman) \$7,500 Annual Retainer

GOVERNANCE & NOMINATING COMMITTEE

Compensation for the Governance & Nominating Committee is as follows:

Chairman of Committee: \$10,000 Annual Retainer

Committee Members (other than Chairman): \$5,000 Annual Retainer

SCIENCE & TECHNOLOGY COMMITTEE

Compensation for the Science & Technology Committee is as follows:

Chairman of Committee: \$10,000 Annual Retainer

Committee Members (other than Chairman): \$5,000 Annual Retainer

There are no per meeting attendance fees for attending Board, Audit & Finance Committee, Compensation & Human Capital Committee, Governance & Nominating Committee and/or Science & Technology Committee meetings.

Retainers (other than chairman retainers) will be paid quarterly in arrears on a prorated basis.

The retainers will be paid in shares of Company common stock (“**Shares**”) and/or in cash. Each Director can elect the ratio of Shares to cash for the payment of these retainers by notifying the Company in writing (with email notification being sufficient). Such elections will be effective commencing in the first quarter after the quarter in which they are made. For purposes of determining the payment of the retainer, Shares will be valued at the average closing price in the quarter for which the retainer is paid.

2. Equity Compensation

Outside Directors will be entitled to receive all types of Awards (except Incentive Stock Options) under the Plan (or the applicable equity plan in place at the time of grant), including discretionary Awards not covered under this Policy. All grants of Awards to Outside Directors pursuant to Section 2 of this Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(1) No Discretion. No person will have any discretion to select which Outside Directors will be granted any Awards under this Policy or to determine the number of Shares to be covered by such Awards.

(2) Appointment Awards. Subject to Section 11 of the Plan, upon an Outside Director's appointment to the Board, such Outside Director automatically will be granted (i) a Nonstatutory Stock Option to purchase Shares having a grant date fair value of \$100,000, rounded down to the nearest whole share (the "**NSO Appointment Award**"), and (ii) Restricted Stock Units having a grant date fair value of \$100,000, rounded down to the nearest whole share (the "**RSU Appointment Award**"). Subject to Section 5 below and Section 14 of the Plan, each NSO Appointment Award will vest in thirty-six (36) equal, monthly installments beginning with the first monthly anniversary after the grant date, and each RSU Appointment Award will vest in three (3), equal, annual installments beginning with the first annual anniversary after the grant date. Each NSO Appointment Award and RSU Appointment Award will vest fully upon a Change in Control (as defined in the Plan), in each case, provided that the Outside Director continues to serve as a Service Provider through the applicable vesting date or Change in Control, as applicable.

(c) Annual Awards. Subject to Section 11 of the Plan, on the first business day after each Annual Meeting of the Company's stockholders (the "**Annual Meeting**") beginning with the 2019 Annual Meeting, each Outside Director automatically will be granted (i) a Nonstatutory Stock Option to purchase Shares having a grant date fair value of \$150,000, rounded down to the nearest whole share (the "**Annual NSO Award**"), and (ii) Restricted Stock Units having a grant date fair value of \$150,000, rounded down to the nearest whole share (the "**Annual RSU Award**"). Subject to Section 5 below and Section 14 of the Plan, each Annual NSO Award will vest in twelve (12) equal, monthly installments beginning with the first monthly anniversary after the grant date, and each Annual RSU Award will vest in one (1) installment on the one year anniversary of the grant date. Each Annual NSO Award and Annual RSU Award will vest fully upon a Change in Control (as defined in the Plan), in each case, provided that the Outside Director continues to serve as a Service Provider through the applicable vesting date or Change in Control, as applicable.

(d) Terms Applicable to all Options Granted Under this Policy. The per Share exercise price for all other Options granted under this Outside Director Compensation Policy will be one hundred percent (100%) of the Fair Market Value on the grant date.

3. Travel Expenses

Each Outside Director's reasonable, customary and documented travel expenses to Board meetings will be reimbursed by the Company.

4. Additional Provisions

All provisions of the Plan not inconsistent with this Policy will apply to Awards granted to Outside Directors.

5. Adjustments

In the event that any dividend or other distribution (whether in the form of cash, Shares, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of Shares or other securities of the Company or other change in the corporate structure of the Company affecting the Shares occurs, the Administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Policy, will adjust the number of Shares issuable pursuant to Awards granted under this Policy.

6. Revisions

The Board in its discretion may change and otherwise revise the terms of Awards granted under this Policy, including, without limitation, the number of Shares subject thereto, for Awards of the same or different type granted on or after the date the Board determines to make any such change or revision.

*****Certain identified information has been omitted from this exhibit because it is both (i) not material and (ii) information that the Registrant treats as private or confidential. Such omitted information is indicated by brackets (“[...***...]”) in this exhibit. *****

AGREEMENT REGARDING PAYMENT OF ROYALTIES AND AMENDMENT TO THE AMENDED AND RESTATED EXCLUSIVE LICENSE

Effective the 3rd day of February 2023, THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY (“Stanford”), an institution of higher education having powers under the laws of the State of California, and CareDx, Inc. (“CareDx”), a Delaware corporation with an address at 8000 Marine Blvd., Brisbane, California 94005, agree as follows:

1. BACKGROUND

- a. Stanford and ImmuMetrix, Inc. are parties to a January 27, 2014 Amended and Restated Exclusive Agreement (the “License Agreement”).
- b. CareDx acquired ImmuMetrix, Inc. on June 14, 2014 and assumed ImmuMetrix Inc.’s rights and obligations under the License Agreement.
- c. In 2019, CareDx initiated litigation against Natera, Inc. and Eurofins Viracor, Inc. in the U.S. District Court for the District of Delaware (Docket Nos. 19-cv-567 and 19-cv-1804) alleging infringement of United States Patent Number 8,703,652, United States Patent Number 9,845,497, and United States Patent Number 10,329,607 (the “Patents”) and Stanford was added as necessary party for standing purposes in accordance with the terms of the License Agreement.
- d. On September 28, 2021, the District Court granted Natera’s and Eurofins’ motion for summary judgment, declaring that the Patents were invalid.
- e. On July 18, 2022, in Decision 2022-1027, the United States Court of Appeals for the Federal Circuit affirmed the District Court’s decision and the parties’ petition for reconsideration or an en banc review was denied.
- f. On September 8, 2022, CareDx and Stanford entered into a letter agreement entitled “**AGREEMENT REGARDING PAYMENT OF ROYALTIES**” **as amended** (“Letter Agreement”) governing the payment and reporting obligations of CareDx during the Litigation, now expired.
- g. CareDx and Stanford wish to seek *Supreme Court* review of the Federal Circuit’s July 18, 2022 decision (“Appeal”).

2. Pursuit of *Supreme Court* Appeal And Amendment to the License Agreement

- a. CareDx has instructed the parties’ counsel to seek Supreme Court review of the Federal Circuit’s decision. CareDx shall be responsible for the legal fees and costs of both parties associated with the initial *certiorari* petition.
- b. If the *cert* petition is granted, the parties shall [...***...] all legal fees and costs of both parties incurred in pursuit of the appeal post *cert* petition [...***...].
- c. Subject to compliance with Sections B.1 and B.2 above, until completion of the Supreme Court Review, any licensing payment and reporting obligations by CareDx for Licensed Products sold in the US under the License Agreement shall be suspended and shall

become payable only as expressly set forth in Section B. 5 or 6 below. The Supreme Court's review shall be deemed completed upon a written denial of the petition for *certiorari* review or, if the petition is granted, the issuance of a *Supreme Court* decision or dismissal of the case as improvidently granted.

- d. During the pendency of the Supreme Court's review, CareDx's right to terminate pursuant to Section 15.1 of the License Agreement is suspended.
 - e. If the Federal Circuit's decision is fully reversed or vacated with respect to any of the patents in suit by the Supreme Court, CareDx shall pay a [...***...] % earned royalty on Net Sales of: (a) any Licensed Product that was sold prior to the decision for which no royalty has been paid ("Past Royalties"); and (b) any Licensed Product sold following the Supreme Court's decision until the termination of the License Agreement ("Future Royalties"). Payment of earned royalties for Past Royalties will be due [...***...], and payment for Future Royalties will be made in a manner that is consistent with prior practice under Paragraph 8.1 of the License Agreement. For purposes of this Agreement and the License Agreement only, CareDx agrees to treat AlloSure products as royalty bearing Licensed Products. Stanford will not rely on such treatment herein as an admission that they are Licensed Products; however, this does not limit Stanford's ability to rely on any other past, present, or future statements, acts, or omissions for such purpose. This Section applies to CareDx sales globally and to Net Sales of each Licensed Product sold by a sublicensee. This Section B.5 shall constitute the parties' entire agreement with respect to earned royalty rate for Future Royalties and the [...***...] % royalty rate may not be further reduced or adjusted unless this Section B.5 is amended in writing by the parties. For the avoidance of doubt, the newly amended royalty rate shall not result in any adjustment or refund for royalties that were paid prior to the date of this Agreement.
 - f. If the *cert* petition for review is denied or dismissed, or if the petition is granted but the Supreme Court's decision does not fully reverse or vacate with respect to any of the patents in suit [...***...]. Within [...***...] following [...***...], CareDx will pay Stanford on Past Royalties in an amount equal to [...***...] % of the earned royalty that would otherwise be owed to Stanford under the License Agreement at [...***...]. For example, if \$[...] of earned royalty is owed under the License Agreement at [...***...], CareDx would only need to pay Stanford \$[...] upon [...***...]. [...***...]. This payment shall constitute the parties' entire agreement with respect to [...***...] and, upon payment, CareDx shall be released from any further obligation to pay Past Royalties arising out of the Licensing Agreement.
 - g. This Agreement may only be terminated upon mutual written agreement of the parties. The parties hereby acknowledge and agree that the License Agreement is amended as expressly set forth herein. All terms not defined in this Agreement shall have the meaning set forth in the License Agreement, except as amended or clarified herein. This Agreement contains the entire understanding of the parties with respect to the matters set forth herein. In the event of any conflict or inconsistency between the terms of this Agreement, the License Agreement, the Letter Agreement, or any prior letter agreement(s) or amendment thereof between the parties concerning the License Agreement and litigation described herein, the terms set forth in this Agreement shall control. This Agreement hereby incorporates by reference Sections 16-19 of the License Agreement.
 - h. In the event that Stanford enters into negotiations for the rights to the Licensed Patents with third parties, Stanford will notify CareDx.
-

In witness hereof, this Agreement is signed by the duly authorized representatives of the parties.

The Board of Trustees of the Leland Stanford Junior University

Signature: /s/ Sunita Rajdev

Print Name: Sunita Rajdev

Title: Director – Life Sciences, OTL

Date: 29-Mar-2023

CareDx, Inc.

Signature: /s/ Reginald Seeto, MBBS

Print Name: Reginald Seeto, MBBS

Title: President & CEO

Date: 29-Mar-2023

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

I, Reginald Seeto, certify that:

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

Date: May 10, 2023

By: /s/ Reginald Seeto, MBBS

Reginald Seeto, MBBS
Chief Executive Officer
(Principal Executive Officer)

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

I, Abhishek Jain, certify that:

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

Date: May 10, 2023

By: /s/ Abhishek Jain

Abhishek Jain

Chief Financial Officer

(Principal Accounting and Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the “Company”) for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company

By: /s/ Reginald Seeto, MBBS
 Reginald Seeto, MBBS
 President and Chief Executive Officer
(Principal Executive Officer)
 Date: May 10, 2023

By: /s/ Abhishek Jain
 Abhishek Jain
 Chief Financial Officer
(Principal Accounting and Financial Officer)
 Date: May 10, 2023

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.