

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 June 30, 2024

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 52,740,008 shares of the registrant’s Common Stock issued and outstanding as of July 29, 2024.

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 June 30, 2024 and December 31, 2023	3
Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2024 and 2023	4
Condensed Consolidated Statements of Comprehensive Loss for the Three and Six Months Ended June 30, 2024 and 2023	5
Condensed Consolidated Statements of Stockholders' Equity for the Three and Six Months Ended June 30, 2024 and 2023	6
Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2024 and 2023	8
Notes to Unaudited Condensed Consolidated Financial Statements	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	32
Item 3. Quantitative and Qualitative Disclosures About Market Risk	48
Item 4. Controls and Procedures	48
<u>PART II. OTHER INFORMATION</u>	50
Item 1. Legal Proceedings	50
Item 1A. Risk Factors	50
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	58
Item 3. Defaults Upon Senior Securities	58
Item 4. Mine Safety Disclosures	59
Item 5. Other Information	59
Item 6. Exhibits	60
Signatures	62

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

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,782	\$ 82,197
Marketable securities	133,089	153,221
Accounts receivable	66,161	51,061
Inventory	19,234	19,471
Prepaid and other current assets	6,343	7,763
Total current assets	320,609	313,713
Property and equipment, net	34,202	35,246
Operating leases right-of-use assets	27,188	29,891
Intangible assets, net	41,896	45,701
Goodwill	40,336	40,336
Restricted cash	588	586
Other assets	1,958	1,353
Total assets	\$ 466,777	\$ 466,826
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,874	\$ 12,872
Accrued compensation	25,004	19,703
Accrued and other liabilities	47,453	45,497
Total current liabilities	78,331	78,072
Deferred tax liability	50	136
Deferred payments for intangible assets	1,620	2,461
Operating lease liability, less current portion	25,386	28,278
Other liabilities	96,721	96,551
Total liabilities	202,108	205,498
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock: \$0.001 par value; 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; 52,617,443 and 51,503,377 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	50	49
Additional paid-in capital	969,427	946,511
Accumulated other comprehensive loss	(7,964)	(6,963)
Accumulated deficit	(696,844)	(678,269)
Total stockholders' equity	264,669	261,328
Total liabilities and stockholders' equity	\$ 466,777	\$ 466,826

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Testing services revenue	\$ 70,918	\$ 53,414	\$ 124,755	\$ 115,198
Product revenue	10,610	7,876	19,204	14,737
Patient and digital solutions revenue	10,746	9,011	20,364	17,628
Total revenue	92,274	70,301	164,323	147,563
Operating expenses:				
Cost of testing services	14,308	15,324	27,940	30,620
Cost of product	6,245	3,926	11,589	7,992
Cost of patient and digital solutions	7,393	6,637	14,351	13,241
Research and development	19,678	20,233	38,389	44,590
Sales and marketing	21,002	21,630	40,832	44,861
General and administrative	27,678	29,327	54,589	57,359
Restructuring costs	68	848	68	848
Total operating expenses	96,372	97,925	187,758	199,511
Loss from operations	(4,098)	(27,624)	(23,435)	(51,948)
Other income:				
Interest income, net	2,826	2,871	5,711	5,537
Change in estimated fair value of common stock warrant liability	—	3	—	10
Other expense, net	(100)	(271)	(390)	(2,245)
Total other income	2,726	2,603	5,321	3,302
Loss before income taxes	(1,372)	(25,021)	(18,114)	(48,646)
Income tax (expense) benefit	(22)	68	61	(56)
Net loss	\$ (1,394)	\$ (24,953)	\$ (18,053)	\$ (48,702)
Net loss per share (Note 3):				
Basic	\$ (0.03)	\$ (0.46)	\$ (0.35)	\$ (0.91)
Diluted	\$ (0.03)	\$ (0.46)	\$ (0.35)	\$ (0.91)
Weighted-average shares used to compute net loss per share:				
Basic	52,195,620	53,846,260	51,943,989	53,745,299
Diluted	52,195,620	53,846,260	51,943,989	53,745,299

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	\$ (1,394)	\$ (24,953)	\$ (18,053)	\$ (48,702)
Other comprehensive gain (loss):				
Foreign currency translation adjustment, net of tax	144	(1,011)	(1,001)	(947)
Comprehensive loss	<u>\$ (1,250)</u>	<u>\$ (25,964)</u>	<u>\$ (19,054)</u>	<u>\$ (49,649)</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, 2023	51,503,377	\$ 49	\$ 946,511	\$ (6,963)	\$ (678,269)	\$ 261,328
Issuance of common stock under employee stock purchase plan	73,759	—	532	—	—	532
Repurchase and retirement of common stock	(55,500)	—	—	—	(522)	(522)
RSU settlements, net of shares withheld	252,662	—	(668)	—	—	(668)
Issuance of common stock for services	6,813	—	56	—	—	56
Issuance of common stock for cash upon exercise of stock options	1,501	—	8	—	—	8
Employee stock-based compensation expense	—	—	13,295	—	—	13,295
Foreign currency translation adjustment, net of tax	—	—	—	(1,145)	—	(1,145)
Net loss	—	—	—	—	(16,659)	(16,659)
Balance at March 31, 2024	51,782,612	49	959,734	(8,108)	(695,450)	256,225
RSU settlements, net of shares withheld	811,360	1	(3,601)	—	—	(3,600)
Issuance of common stock for services	4,935	—	49	—	—	49
Issuance of common stock for cash upon exercise of stock options	18,536	—	123	—	—	123
Employee stock-based compensation expense	—	—	13,122	—	—	13,122
Foreign currency translation adjustment, net of tax	—	—	—	144	—	144
Net loss	—	—	—	—	(1,394)	(1,394)
Balance at June 30, 2024	52,617,443	\$ 50	\$ 969,427	\$ (7,964)	\$ (696,844)	\$ 264,669

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, net of tax	—	—	—	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
Repurchase and retirement of common stock	(12,000)	—	—	—	(67)	(67)
RSU settlements, net of shares withheld	362,710	—	(1,508)	—	—	(1,508)
Issuance of common stock for services	3,647	—	36	—	—	36
Issuance of common stock for cash upon exercise of stock options	2,930	—	6	—	—	6
Issuance of common stock upon exercise of warrants	3,132	—	26	—	—	26
Employee stock-based compensation expense	—	—	12,663	—	—	12,663
Foreign currency translation adjustment, net of tax	—	—	—	(1,011)	—	(1,011)
Net loss	—	—	—	—	(24,953)	(24,953)
Balance at June 30, 2023	54,013,601	\$ 52	\$ 923,514	\$ (8,450)	\$ (509,903)	\$ 405,213

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)

	Six Months Ended June 30,	
	2024	2023
Operating activities:		
Net loss	\$ (18,053)	\$ (48,702)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Stock-based compensation	26,514	26,454
Depreciation and amortization	7,364	7,093
Asset impairments and write-downs	—	1,000
Amortization of right-of-use assets	2,816	2,652
Unrealized loss on long-term marketable equity securities	—	852
Revaluation of contingent consideration to estimated fair value	529	488
Amortization of premium and accretion of discount on short-term marketable securities, net	821	(2,091)
Revaluation of common stock warrant liability to estimated fair value	—	(10)
Changes in operating assets and liabilities:		
Accounts receivable	(15,207)	15,225
Inventory	(225)	12
Prepaid and other assets	769	2,101
Operating lease liabilities, net	(2,882)	(2,677)
Accounts payable	(6,920)	14
Accrued compensation	5,504	(2,528)
Accrued and other liabilities	2,693	289
Change in deferred taxes	(86)	—
Net cash provided by operating activities	3,637	172
Investing activities:		
Acquisitions of business, net of cash acquired	—	(4,562)
Purchases of short-term marketable securities	(93,212)	(135,271)
Maturities of short-term marketable securities	112,523	145,643
Purchase of corporate equity securities	—	(100)
Additions of capital expenditures	(3,277)	(5,133)
Net cash provided by investing activities	16,034	577
Financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	532	456
Taxes paid related to net share settlement of restricted stock units	(4,266)	(2,164)
Proceeds from exercise of warrants	—	4
Proceeds from exercise of stock options	131	7
Payment of contingent consideration on acquisitions	(2,000)	(250)
Repurchase and retirement of common stock	(522)	(757)
Net cash used in financing activities	(6,125)	(2,704)
Effect of exchange rate changes on cash and cash equivalents	41	(118)
Net increase (decrease) in cash, cash equivalents and restricted cash	13,587	(2,073)
Cash, cash equivalents and restricted cash at beginning of period	82,783	90,443
Cash, cash equivalents and restricted cash at end of period	\$ 96,370	\$ 88,370

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”) and The Transplant Pharmacy, LLC (“TTP”) in 2021, HLA Data Systems, LLC (“HLA Data Systems”) in January 2023 and MediGO, Inc. (“MediGO”) in July 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 then 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. In November 2020, Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MolDX to replace the former product-specific policies. The foundational LCD is titled “MolDX: Molecular Testing for Solid Organ Allograft Rejection” and the associated LCD numbers are L38568 (MolDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the same MolDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753. Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance, is covered, subject to certain limitations, for Medicare beneficiaries through the same MolDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993.

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. In December 2023, Miromatrix was acquired by United Therapeutics Corporation.

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 1,900 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 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.

In December 2021, the Company initiated the ALAMO study. ALAMO is a multicenter observational study and focuses on surveillance in lung transplant recipients within the first post-transplant year. Beyond demonstrating the clinical validity of AlloSure in detecting Acute Lung Allograft Dysfunction, a composite outcome of acute rejection and clinically meaningful infections, the study explores its clinical utility by capturing clinician decision-making processes to further demonstrate the practical clinical application of AlloSure. In addition, the study will collect samples to enable development of AlloMap Lung.

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.

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 and 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 with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation 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.

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. HLA Data Systems is a leader in the laboratory information management industry for human leukocyte antigen laboratories.

In July 2023, the Company acquired MediGO, an organ transplant supply chain and logistics company. MediGO provides access to donated organs by digitally transforming donation and transplantation workflows to increase organ utilization.

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 \$696.8 million at June 30, 2024. As of June 30, 2024, the Company had cash, cash equivalents and marketable securities of \$228.9 million and no debt outstanding.

Shelf Registration Statement

On May 10, 2023, the Company filed a universal shelf registration statement (File No. 333-271814) (the “Registration Statement”), and thereafter filed post-effective amendments on May 9, 2024 and May 23, 2024. The Securities and Exchange Commission (“SEC”) declared the Registration Statement effective on May 23, 2024, and as a result, the Company can sell from time to time up to \$250.0 million of shares of its common stock, preferred stock, debt securities, warrants, units or rights comprised of any combination of these securities, for the Company’s own account in one or more offerings under the Registration Statement. The terms of any offering under the Registration Statement will be established at the time of such offering and will be described in a prospectus supplement to the Registration Statement filed with the SEC prior to the completion of any such offering.

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 of shares of its 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 Company’s Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans and block trades and in privately negotiated transactions. During the six months ended June 30, 2024, the Company purchased an aggregate of 55,500 shares of its common stock under the Repurchase Program for an aggregate purchase price of \$0.5 million. There were no repurchases during the three months ended June 30, 2024. As of June 30, 2024, \$21.4 million remained available for future share repurchases under the Repurchase Program.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies and estimates used in the 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, 2023, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 28, 2024.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“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, 2023 has been derived from audited consolidated financial statements as of that date but does not include all of the financial information required by U.S. GAAP for complete financial statements. Operating results for the three and six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

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 assets and liabilities acquired in a

business combination or an asset 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 June 30, 2024 and 2023, approximately 42% and 44%, respectively, of total revenue was derived from Medicare. For the six months ended June 30, 2024 and 2023, approximately 38% and 43%, respectively, of total revenue was derived from Medicare.

As of June 30, 2024 and December 31, 2023, approximately 32% and 36%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either June 30, 2024 or December 31, 2023.

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 June 30, 2024, the Company's short-term marketable securities consisted of corporate debt securities with maturities of greater than three months but less than 12 months at the time of purchase, which were classified as current assets on the condensed consolidated balance sheets.

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, 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, net. The cost of securities sold is determined using specific identification.

The Company records its long-term marketable equity securities at fair market value. Unrealized gains and losses from the remeasurement of the long-term marketable equity securities to fair value are included in other expense, net, on the condensed consolidated statements of operations.

Leases

The Company determines if an arrangement is or contains a lease at contract inception. A right-of-use ("ROU") asset, representing the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the condensed consolidated balance sheets 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 June 30, 2024, the Company's leases had remaining terms of 0.25 years to 8.59 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 which is satisfied at the point in time when results of the test are provided to the healthcare provider.

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 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. These estimates require 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, the Company's discussions with payers, and other pertinent information. In addition, consistent with *ASC 606-10-25-1*, the Company continues to assess whether it is probable that it will collect substantially all of the consideration to which it will be entitled when determining if a contract with a customer exists.

In March and May 2023, MolDX issued a new billing article related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection. The billing article issued in May 2023 (the "Revised Billing Article") and together with the billing article issued in March 2023 (the "Billing Articles") impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, AlloMap Heart and AlloSure Lung, and required certain companies, including the Company, to implement new processes to address the requirements related to Medicare claim submissions. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 14, 2023, MolDX released a draft billing article (DA58019) to accompany the proposed draft LCD, which generally reflected the changes in coverage included in the Revised Billing Article. The comment period end date for this proposed LCD was September 23, 2023. The Company presented at public meetings regarding the proposed draft LCD held on September 18, 2023 and September 20, 2023, with MolDX and Noridian, respectively. The Company also submitted written comments on the proposed draft LCD.

On February 29, 2024, MolDX and Noridian released a revised version of the Revised Billing Article.

During the second quarter of 2024, based upon additional information gained through discussions with payers, the receipt of other information, and increasing cash reimbursements over a sustained period of time, the Company evaluated all relevant facts and circumstances and concluded a contract was established for specific tests in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. For the three months ended June 30, 2024, the Company recognized \$13.2 million in revenue for the tests performed in prior periods, as all performance obligations were satisfied at the time the contract was established.

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 in the contract. The 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

Patient and digital solutions revenue is primarily 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 agreements are the following: (i) implementation services and delivery of the perpetual software license, which 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

There were no recently adopted accounting standards which had a material effect on the Company's condensed consolidated financial statements and accompanying disclosures.

Effective in Future Periods

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires enhanced disclosure of significant segment expenses. All current annual disclosures about a reportable segment's profit or loss and assets will also be required in interim periods. The new guidance also requires disclosure of the title and position of the Chief Operating Decision Maker ("CODM") and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The amendments set forth in this ASU are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The amendments should be applied retrospectively to all prior periods presented in the financial statements. This ASU will be effective for the Company's annual disclosures in fiscal year 2024 and interim-period disclosures in fiscal year 2025. The Company is currently evaluating the potential effect that the updated standard will have on its financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 340): Improvements to Income Tax Disclosures*, which requires annual disclosures in the rate reconciliation table to be presented using both percentages and reporting currency amounts, and this table must include disclosure of specific categories. Additional information will also be required for reconciling items that meet a quantitative threshold. The new guidance also requires enhanced disclosures of income taxes paid, including the amount of income taxes paid disaggregated by federal, state and foreign taxes and the amount of income taxes paid disaggregated by individual jurisdictions that exceed a quantitative threshold. The amendments should be applied on a prospective basis, but retrospective application is permitted. The amendments set forth in this ASU are effective for annual periods beginning after December 15, 2024 for public entities. This guidance will be effective for the Company's annual disclosures in fiscal year 2025. The Company is currently evaluating the potential effect that the updated standard will have on its financial statement 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss used to compute basic and diluted net loss per share	\$ (1,394)	\$ (24,953)	\$ (18,053)	\$ (48,702)
Denominator:				
Weighted-average shares used to compute basic and diluted net loss per share	52,195,620	53,846,260	51,943,989	53,745,299
Net loss per share:				
Basic and diluted	\$ (0.03)	\$ (0.46)	\$ (0.35)	\$ (0.91)

The following potentially dilutive securities have been excluded from diluted net loss per share as of June 30, 2024 and 2023 because their effect would be antidilutive:

	Three and Six Months Ended June 30,	
	2024	2023
Outstanding common stock options	3,783,013	3,383,661
Outstanding restricted stock units	6,663,430	5,190,029
Total common stock equivalents	10,446,443	8,573,690

4. FAIR VALUE MEASUREMENTS

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

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

The following table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of June 30, 2024 and December 31, 2023 (in thousands):

	June 30, 2024			
	Fair Value Measured Using			Total Balance
	(Level 1)	(Level 2)	(Level 3)	
Assets				
Cash equivalents:				
Money market funds	\$ 60,187	\$ —	\$ —	\$ 60,187
Total	\$ 60,187	\$ —	\$ —	\$ 60,187
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 4,743	\$ 4,743
Long-term liabilities:				
Contingent consideration	—	—	1,620	1,620
Total	\$ —	\$ —	\$ 6,363	\$ 6,363

	December 31, 2023			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	\$ 60,525	\$ —	\$ —	\$ 60,525
Total	\$ 60,525	\$ —	\$ —	\$ 60,525
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 5,469	\$ 5,469
Long-term liabilities:				
Contingent consideration	—	—	2,461	2,461
Total	\$ —	\$ —	\$ 7,930	\$ 7,930

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)
Contingent Consideration	
Balance as of December 31, 2023	\$ 7,930
Change in estimated fair value of contingent consideration on business combination	529
Change in estimated fair value of contingent consideration on asset acquisition	(96)
Payments related to contingent consideration	<u>(2,000)</u>
Balance as of June 30, 2024	<u>\$ 6,363</u>

During March 2023, the Company wrote off \$1.0 million of its investment in convertible preferred shares of Cibiltech SAS ("Cibiltech"), which was carried at cost. Cibiltech's operations have been liquidated. The fair value of this investment was based on Level 3 inputs.

In July 2023, the Company entered into a Securities Holders' Agreement (the "Agreement") with a private entity based in France. The private entity was established to continue Cibiltech's activity, which consists of designing, developing, publishing, promoting, distributing, and marketing of software related to predictive solutions, monitoring and/or remote monitoring in the field of human organ allotransplantation, allografting, and chronic organ diseases. The private entity retained all assets of Cibiltech, including its licenses. Pursuant to the Agreement, the Company agreed to invest a certain amount in the private entity, in order to continue the commercialization of the iBox technology. The Company's investment is in the form of ordinary and Class B shares carried at cost. This investment is not considered material to the Company's condensed consolidated financial statements.

In December 2023, Miromatrix was acquired by United Therapeutics Corporation. The Company tendered and sold all of its shares of Miromatrix to United Therapeutics Corporation in the transaction for \$2.5 million. The Company recognized a \$1.5 million gain from the disposal of Miromatrix and recorded as other income (expense), net at December 31, 2023. There was no outstanding investment in Miromatrix as of June 30, 2024.

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 June 30, 2024 and December 31, 2023, money market funds were included as cash and cash equivalents in 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 based on management's

estimate of the probability of success and projected revenues for revenue-based considerations at discounted rates ranging from 7% to 12% at June 30, 2024 and from 6% to 12% at December 31, 2023. 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 income or expense within operating expenses in the condensed consolidated statements of operations until the milestones are paid, expire or are no longer achievable. Increases or decreases in the estimation of the probability percentage results 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.

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):

	June 30, 2024	June 30, 2023
Cash and cash equivalents	\$ 95,782	\$ 87,786
Restricted cash	588	584
Total cash, cash equivalents and restricted cash at the end of the period	<u>\$ 96,370</u>	<u>\$ 88,370</u>

Marketable Securities

All short-term marketable securities were considered held-to-maturity at June 30, 2024. At June 30, 2024, 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. The Company assesses whether the decline in value of short-term marketable securities is temporary or other-than-temporary. In making its assessment, the Company evaluates the current market and interest rate environment as well as specific issuer information. There was no recognition of any other-than-temporary impairment at June 30, 2024. All short-term marketable securities with unrealized losses as of the balance sheet date have been in a loss position for less than 12 months. Contractual maturities of the short-term marketable securities were within one year or less.

The amortized cost, gross unrealized holding gains 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):

	June 30, 2024		
	Amortized Cost	Unrealized Holding Gains, Net	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 90,403	\$ 1,268	\$ 91,671
Corporate debt securities	42,686	365	43,051
Total short-term marketable securities	<u>\$ 133,089</u>	<u>\$ 1,633</u>	<u>\$ 134,722</u>
	December 31, 2023		
	Amortized Cost	Unrealized Holding Gains, Net	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 80,468	\$ 2,038	\$ 82,506
Corporate debt securities	72,753	711	73,464
Total short-term marketable securities	<u>\$ 153,221</u>	<u>\$ 2,749</u>	<u>\$ 155,970</u>

6. BUSINESS COMBINATIONS AND ASSET ACQUISITION

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 statements 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	<u>\$ 4,100</u>	

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 has been included in the Company's condensed consolidated statements of operations from the acquisition date.

MediGO

In July 2023, the Company acquired MediGO, an organ transplant supply chain and logistics company. MediGO provides access to donated organs by digitally transforming donation and transplantation workflows to increase organ utilization. The Company acquired MediGO with a combination of cash consideration paid upfront and contingent consideration with a fair value of \$0.3 million.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of \$0.3 million associated with the acquisition were expensed as incurred, and classified as part of general and administrative expenses in the condensed consolidated statements of operations.

Goodwill of \$0.6 million arising from the acquisition primarily consists of synergies from integrating MediGO's technology with the current testing and digital solutions offered by the Company. The acquisition of MediGO will provide a comprehensive software platform that optimizes complex logistics from referral to recovery and during the critical movement of organs and teams and gives organ procurement organizations and transplant centers the ability to unify decentralized stakeholders, coordinate resources and make vital decisions with the goal of increasing organ utilization and improving equity and access to transplantation. 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	\$ 810	17
Developed technology	850	12
Trademarks	360	17
Total	<u>\$ 2,020</u>	

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

The acquired developed technology represents the fair value of MediGO's proprietary software. The trademark acquired consists primarily of the MediGO 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 25% was utilized in estimating the fair value of these three intangible assets.

The pro forma impact of the MediGO 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.

Combined Consideration Paid

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

	Total
Consideration	
Cash and contingent considerations	\$ 6,682
Total consideration	<u>\$ 6,682</u>
Recognized amounts of identifiable assets acquired and liabilities assumed	
Current assets	\$ 1,413
Identifiable intangible assets	6,120
Current liabilities	(1,060)
Other current liabilities	(810)
Contingent considerations	(1,620)
Other liabilities	(7)
Total identifiable net assets acquired	<u>4,036</u>
Goodwill	<u>2,646</u>
Total consideration	<u>\$ 6,682</u>

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.

Asset Acquisition

Effective as of August 9, 2023, the Company purchased an asset from a private entity. The asset consists of a licensing agreement with a university institution. See also Note 9.

The purchased asset did not meet the definition of a business under ASC Topic 805, *Business Combinations*, and therefore the Company accounted for the transaction as an asset acquisition. In an asset acquisition, goodwill is not recognized, but rather,

any excess consideration transferred over the fair value of the net assets acquired is allocated on a relative fair value basis to the identifiable assets acquired.

Acquisition costs relating to the asset acquired were \$2.6 million, comprised of base consideration of \$1.8 million, contingent consideration at fair value of \$0.5 million and associated transaction costs of \$0.3 million. There was only one asset acquired and the entire cost is assigned to the licensing agreement, which is recorded under Intangible assets, net, in the condensed consolidated balance sheets. The licensing agreement has an indefinite life and is presented in notes to the unaudited condensed consolidated financial statements under the intangible assets with indefinite lives category.

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 upon the occurrence of certain events or substantive changes in circumstances. There were no indicators of impairment in the three and six months ended June 30, 2024 and 2023. The balance of the Company's goodwill was \$40.3 million as of June 30, 2024 and December 31, 2023.

Intangible Assets

The following table presents details of the Company's intangible assets as of June 30, 2024 (\$ in thousands):

	June 30, 2024				
	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	\$ 37,367	\$ (19,935)	\$ (2,444)	\$ 14,988	6.9
Customer relationships	25,718	(9,936)	(2,191)	13,591	8.8
Commercialization rights	11,579	(5,128)	—	6,451	5.1
Trademarks and tradenames	5,220	(1,904)	(331)	2,985	8.9
Total intangible assets with finite lives	79,884	(36,903)	(4,966)	38,015	
Intangible assets with indefinite lives:					
Acquired in-process technology	1,250	—	—	1,250	
Favorable license agreement	2,631	—	—	2,631	
Total intangible assets with indefinite lives	3,881	—	—	3,881	
Total intangible assets	\$ 83,765	\$ (36,903)	\$ (4,966)	\$ 41,896	

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

	December 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	\$ 37,367	\$ (18,340)	\$ (2,269)	\$ 16,758	7.2
Customer relationships	25,718	(9,094)	(1,959)	14,665	9.2
Commercialization rights	11,579	(4,496)	—	7,083	5.6
Trademarks and tradenames	5,220	(1,713)	(288)	3,219	9.3
Total intangible assets with finite lives	79,884	(33,643)	(4,516)	41,725	
Intangible assets with indefinite lives:					
Acquired in-process technology	1,250	—	—	1,250	
Favorable license agreement	2,726	—	—	2,726	
Total intangible assets with indefinite lives	3,976	—	—	3,976	
Total intangible assets	\$ 83,860	\$ (33,643)	\$ (4,516)	\$ 45,701	

Acquisition of Intangible Assets

In January 2023 and July 2023, the Company acquired the intangible assets of HLA Data Systems and MediGO, respectively. The Acquired and developed technology, Customer relationships, and Trademarks and tradenames are recorded under Intangible assets, net, in the condensed consolidated balance sheets as of June 30, 2024 and December 31, 2023.

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of testing services	\$ 329	\$ 329	\$ 658	\$ 658
Cost of product	411	416	831	834
Cost of patient and digital solutions	238	255	509	503
Sales and marketing	628	606	1,261	1,201
Total	\$ 1,606	\$ 1,606	\$ 3,259	\$ 3,196

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of June 30, 2024 (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 2024	\$ 658	\$ 828	\$ 340	\$ 1,259	\$ 3,085
2025	1,316	1,656	681	2,517	6,170
2026	1,316	739	681	2,515	5,251
2027	1,316	739	681	2,501	5,237
2028	1,316	739	681	2,501	5,237
Thereafter	1,509	2,543	1,462	7,521	13,035
Total future amortization expense	\$ 7,431	\$ 7,244	\$ 4,526	\$ 18,814	\$ 38,015

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Finished goods	\$ 4,803	\$ 3,658
Work in progress	4,014	5,191
Raw materials	10,417	10,622
Total inventory	<u>\$ 19,234</u>	<u>\$ 19,471</u>

Accrued and Other Liabilities

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

	June 30, 2024	December 31, 2023
Clinical studies	\$ 16,766	\$ 15,744
Professional fees	6,091	5,911
Short-term lease liability	6,062	5,943
Deferred revenue	5,852	4,748
Contingent consideration	4,743	5,469
Laboratory processing fees and materials	3,431	2,890
Deferred payments for intangible assets	818	920
Travel and expenses	767	—
Accrued shipping expenses	487	335
Capital expenditures	235	151
Accrued royalty	222	348
License and other collaboration fees	—	250
Other accrued expenses	1,979	2,788
Total accrued and other liabilities	<u>\$ 47,453</u>	<u>\$ 45,497</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; Omaha, Nebraska; 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 June 30, 2024, the carrying value of the ROU asset was \$27.2 million. The related current and non-current liabilities as of June 30, 2024 were \$6.1 million and \$25.4 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.

Effective March 2024, the Company entered into a sublease agreement with a sub-lessee (a third-party) for office space with a six-year term, commencing on May 1, 2024, for a total of \$2.6 million base rent for the duration of the contract.

The following table summarizes the lease cost for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating lease cost	\$ 1,965	\$ 1,972	\$ 3,936	\$ 3,955
Total lease cost	<u>\$ 1,965</u>	<u>\$ 1,972</u>	<u>\$ 3,936</u>	<u>\$ 3,955</u>

	June 30, 2024	December 31, 2023
Other information:		
Weighted-average remaining lease term - Operating leases (in years)	5.01	5.43
Weighted-average discount rate - Operating leases (%)	7.1 %	7.1 %

Maturities of operating lease liabilities as of June 30, 2024 are as follows (in thousands):

Years Ending December 31,	Operating Leases
Remainder of 2024	\$ 4,010
2025	7,929
2026	7,164
2027	7,274
2028	6,599
Thereafter	4,115
Total lease payments	37,091
Less imputed interest	5,643
Present value of future minimum lease payments	31,448
Less operating lease liability, current portion	6,062
Operating lease liability, less current portion	\$ 25,386

The following table summarizes the supplemental cash flow information related to leases for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cash paid for amounts included in the measurement of lease liabilities				
Operating cash flows used for operating leases	\$ 1,468	\$ 1,366	\$ 2,829	\$ 2,699

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 reduced the maximum royalty rate to a lower rate at which the Company may be liable to Stanford effective from April 2022 and also provided that the Company would seek a review from the U.S. Supreme Court (the “Review”). During the pendency of the Review, certain of the Company’s licensing payment and reporting obligations to Stanford with respect to licensed products sold in the U.S. were suspended. As a result, the Company reversed the excess liability in March 2023.

In May 2023, the Company submitted a petition of certiorari to the U.S. Supreme Court for consideration of the patent infringement suit and in October 2023, the U.S. Supreme Court declined to hear this patent infringement suit. As the Review is complete and the Company's petition for review was denied, the Stanford License automatically terminated, and in December 2023, the Company paid Stanford certain past royalties at a reduced rate that were previously suspended within 90 days of the termination. There was no outstanding obligation with Stanford as of June 30, 2024.

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.

Other Royalty Commitment

Effective as of August 2023, the Company entered into a license agreement with a university institution (the "University Agreement"). The University Agreement requires the Company to pay royalties in the low single digits on sales of products covered by the University Agreement.

Other Commitments

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

Effective as of July 2023, the Company entered into a license and collaboration agreement with a private entity pursuant to which the Company was granted an irrevocable, non-transferable right to commercialize its proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation for a period of four years with exclusive rights in the United States. The Company will share an agreed-upon percentage of revenue with the private entity, if and when revenues are generated from iBox.

Litigation and Indemnification Obligations

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.

Natera Inc.

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 finding that Natera violated the Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding the Company \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury, which the Company intends to appeal. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising. The case is now on appeal.

On July 19, 2022, the U.S. Court of Appeals for the Federal Circuit affirmed the Court's judgment dismissing the Company's patent infringement suit against Natera. In May 2023, the Company submitted a petition of certiorari to the U.S. Supreme Court for consideration of the patent infringement suit and in October 2023, the U.S. Supreme Court declined to hear the suit.

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. On December 11, 2023, the Court dismissed the case alleging infringement of Natera's U.S. Patent 10,597,724. Natera appealed that decision. On March 13, 2024, the Federal Circuit dismissed Natera's appeal after Natera failed to file its brief and other required papers. On May 30, 2024, Natera filed a second notice of appeal of the dismissal of U.S. Patent 10,597,724. On June 19, 2024, the Company moved to dismiss Natera's appeal.

On January 26, 2024, following a five-day trial, a jury concluded that the Company did not infringe Natera's U.S. Patent 10,655,180 but did infringe Natera's U.S. Patent 11,111,544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera's U.S. Patent 11,111,544 expires in September 2026. The Company anticipates continued litigation as to whether its current AlloSure process infringes the patent. Natera has moved for an injunction on the Company's prior AlloSure process. The Company is opposing the motion. Natera

may also move for injunctive relief over the Company's current AlloSure process if it is found to infringe. The Company is seeking judicial review of the verdict. The Company intends to contest any potential claims of ongoing infringement and any motion for injunctive relief. Natera is also seeking judicial review of the jury's finding that the Company did not infringe Natera's U.S. Patent 10,655,180. The Company intends to defend 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 recognized the damages of \$96.3 million as other liabilities on the condensed consolidated balance sheets as of June 30, 2024 and December 31, 2023.

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 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. By letter dated September 19, 2023, the Company was notified by the staff of the SEC that the SEC has concluded its investigation as to the Company and does not intend to recommend an enforcement action by the SEC against the Company. The notice was provided under the guidelines set out in the final paragraph of Securities Act Release No. 5310.

The Company may receive additional requests for information from the DOJ, the SEC, or other regulatory and governmental agencies regarding similar or related subject matters. The Company does not believe that the CID raises any issues regarding the safety or efficacy of any of the Company's products or services and is cooperating fully with the DOJ investigation. Although the Company remains committed to compliance with all applicable laws and regulations, it cannot predict the outcome of the DOJ investigation or any other requests or investigations that may arise in the future regarding these or other subject matters.

Olympbios Matter

On April 15, 2022, a complaint was filed by Michael Olympbios 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 alleged that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olympbios, and that the Company has defamed Dr. Olympbios. Dr. Olympbios also sought to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olympbios. 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, Dr. Olympbios filed a motion to withdraw from arbitration before Judicial Arbitration and Mediation Services, Inc., which was denied on August 18, 2022. Both the arbitration and the San Mateo County Court matter were settled in the fourth quarter of 2023 and have been resolved.

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 former 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 Company's Board of Directors 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.

On May 24, 2023, the court granted the Company's motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against the Company, Reginald Seeto, Ankur Dhingra, and Peter Maag. Under a briefing schedule ordered by the court on June 12, 2023, defendants' motion to dismiss and motion to strike the second amended complaint was filed on July 26, 2023, plaintiffs' opposition was filed on

August 30, 2023, and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 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 filed 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 asserting, among other things, alleged breaches of fiduciary duty against the Individual Defendants based on the factual allegations of the Securities Class Action (the "Edelman Derivative Action").

On December 8, 2022, the court entered an order staying the Edelman Derivative Action subject to certain terms and conditions.

On February 7, 2023, Jaysen Stevenson filed 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 asserting substantially similar claims (the "Stevenson Derivative Action").

On March 9, 2023, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action and stayed both actions pursuant to the terms of the stay order in the Edelman Derivative Action.

On February 8, 2024, Christian Jacobsen filed a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of the Company's Board of Directors asserting substantially similar claims as the prior-filed derivative actions (the "Jacobsen Derivative Action").

On March 19, 2024, the parties to the Jacobsen Derivative Action and the consolidated Edelman Derivative Action and Stevenson Derivative Action filed a stipulation and proposed order consolidating the Jacobsen Derivative Action with the consolidated Edelman Derivative Action and Stevenson Derivative Action and staying the Jacobsen Derivative Action pursuant to the terms of the stay order in the Edelman Derivative Action. On April 23, 2024, the court entered an order consolidating all three derivative actions (the "Consolidated Derivative Action"). The order provides that all previous orders in the Edelman Derivative Action and the Stevenson Derivative Action shall apply to the Jacobsen Derivative Action.

On May 16, 2024, the court lifted the stay in the Consolidated Derivative Action. Under a scheduling order entered by the court on May 14, 2024, plaintiffs filed an amended complaint in the Consolidated Derivative Action on July 1, 2024. Pursuant to a briefing notice entered by the court on June 17, 2024, defendants' deadline to file a motion to dismiss is August 30, 2024, plaintiffs' deadline to file an opposition brief is October 29, 2024, and defendants' deadline to file a reply brief is December 2, 2024. A motion hearing is scheduled for January 28, 2025.

On March 20, 2024, Edward W. Burns IRA filed a stockholder derivative action complaint in the Court of Chancery of the State of Delaware against the Company as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of the Board of Directors (the "Burns Derivative Action"). Prior to filing the complaint, the Company produced documents to the plaintiff in response to a books and records inspection demand made pursuant to Section 220 of the Delaware General Corporation Law. The plaintiff purports to incorporate those documents in the complaint. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, unjust enrichment, waste of corporate assets, and aiding and abetting breaches of fiduciary duty. The suit seeks declaratory relief, recovery of alleged damages sustained by the Company as a result of the alleged violations, equitable relief, restitution, and plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. On April 11, 2024, the court entered an order staying the Burns Derivative Action pursuant to a stipulation filed by the parties.

On May 30, 2024, the parties to the Burns Derivative Action filed an amended stipulation and proposed order to continue the stay in that action, which was so-ordered by the court on May 31, 2024.

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.

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, and believes it has good and substantial support for its claims, but there is no guarantee that the Company will prevail in these claims.

On May 17, 2024, the Superior Court entered a decision finding against the Company. The Company is considering its appellate options.

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 \$0.5 million for each of the three months ended June 30, 2024 and 2023. The Company incurred expenses related to contributions to the 401(k) Plan of \$2.1 million and \$1.2 million for the six months ended June 30, 2024 and 2023, respectively.

11. WARRANTS

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

As of June 30, 2024 and December 31, 2023, no warrants to purchase common stock were outstanding.

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, 2019 Inducement Equity Incentive Plan and 2024 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, 2023	869,111	3,055,208	\$ 25.21	5,006,775	\$ 19.02
Additional shares authorized	6,748,645	—	—	—	—
Common stock awards for services	(11,748)	—	—	—	—
RSUs granted	(3,360,339)	—	—	3,360,339	9.32
RSUs vested	—	—	—	(1,456,490)	18.14
Options granted	(854,898)	854,898	9.29	—	—
Options exercised	—	(20,037)	6.54	—	—
Repurchase of common stock under employee incentive plans	391,535	—	—	—	—
RSUs forfeited	247,195	—	—	(247,195)	17.32
Options forfeited	21,809	(21,809)	27.94	—	—
Options expired	85,247	(85,247)	30.19	—	—
Balance—June 30, 2024	<u>4,136,557</u>	<u>3,783,013</u>	\$ 21.58	<u>6,663,429</u>	\$ 14.54

The total intrinsic value of options exercised was less than \$0.1 million for each of the three and six months ended June 30, 2024 and 2023.

As of June 30, 2024, the total intrinsic value of outstanding RSUs was approximately \$106.1 million and there were \$57.4 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.33 years.

The Company granted performance restricted stock units ("PSUs"), included in RSUs, under the 2014 Plan. The PSUs granted to employees consist of financial and operational metrics to be met over a performance period of 2 years. The number of shares outstanding was 412,843 and 449,983 as of June 30, 2024 and December 31, 2023, respectively. The weighted-average remaining recognition period was 0.59 years and 1.01 years as of June 30, 2024 and December 31, 2023, respectively.

Options outstanding that have vested and are expected to vest at June 30, 2024 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	2,122	\$ 25.06	6.34	\$ 3,836
Expected to vest	1,474	17.53	8.07	4,376
Total	3,596			\$ 8,212

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 June 30, 2024 for stock options that were in-the-money.

The total fair value of options that vested during the three and six months ended June 30, 2024 was \$2.7 million and \$6.4 million, respectively. As of June 30, 2024, there were approximately \$16.8 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.69 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 2024 that ended on June 30, 2024, 85,260 shares were purchased pursuant to the ESPP for aggregate proceeds of \$0.9 million from the issuance of such shares, which occurred on July 2, 2024.

During the offering period in 2023 that ended on December 31, 2023, 73,759 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, 2024.

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Employee stock options				
Expected term (in years)	5.8	5.0	5.8	5.6
Expected volatility	76.52%	76.63%	76.52%	77.86%
Risk-free interest rate	4.57%	3.99%	4.57%	3.67%
Expected dividend yield	—%	—%	—%	—%
Employee stock purchase plan				
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	91.99%	93.38%	91.99%	93.38%
Risk-free interest rate	5.24%	5.47%	5.24%	5.47%
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 and six months ended June 30, 2024 and 2023, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of testing services	\$ 357	\$ 492	\$ 814	\$ 971
Cost of product	225	274	542	634
Cost of patient and digital solutions	350	367	722	769
Research and development	1,628	1,704	3,388	3,666
Sales and marketing	2,927	2,779	5,971	6,516
General and administrative	7,683	7,084	15,077	13,898
Total	\$ 13,170	\$ 12,700	\$ 26,514	\$ 26,454

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 a change in valuation allowance, change in the mix of earnings in tax jurisdictions with different statutory rates, benefits related to tax credits, and the tax impact of non-deductible expenses and other permanent differences between income before income taxes and taxable income.

For the three and six months ended June 30, 2024, the Company recorded an income tax expense of \$22,000 and an income tax benefit of \$61,000, respectively. For the three and six months ended June 30, 2023, the Company recorded an income tax benefit of \$68,000 and an income tax expense of \$56,000, respectively. 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 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Testing services revenue				
United States	\$ 70,699	\$ 53,269	\$ 124,349	\$ 114,916
Rest of World	219	145	406	282
	<u>\$ 70,918</u>	<u>\$ 53,414</u>	<u>\$ 124,755</u>	<u>\$ 115,198</u>
Product revenue				
United States	\$ 6,575	\$ 4,320	\$ 11,851	\$ 8,047
Europe	2,822	2,532	5,104	4,993
Rest of World	1,213	1,024	2,249	1,697
	<u>\$ 10,610</u>	<u>\$ 7,876</u>	<u>\$ 19,204</u>	<u>\$ 14,737</u>
Patient and digital solutions revenue				
United States	\$ 10,694	\$ 8,889	\$ 20,278	\$ 17,395
Europe	39	121	66	205
Rest of World	13	1	20	28
	<u>\$ 10,746</u>	<u>\$ 9,011</u>	<u>\$ 20,364</u>	<u>\$ 17,628</u>
Total United States	<u>\$ 87,968</u>	<u>\$ 66,478</u>	<u>\$ 156,478</u>	<u>\$ 140,358</u>
Total Europe	<u>\$ 2,861</u>	<u>\$ 2,653</u>	<u>\$ 5,170</u>	<u>\$ 5,198</u>
Total Rest of World	<u>\$ 1,445</u>	<u>\$ 1,170</u>	<u>\$ 2,675</u>	<u>\$ 2,007</u>
Total	<u><u>\$ 92,274</u></u>	<u><u>\$ 70,301</u></u>	<u><u>\$ 164,323</u></u>	<u><u>\$ 147,563</u></u>

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

	June 30, 2024	December 31, 2023
Long-lived assets:		
United States	\$ 33,775	\$ 34,714
Europe	384	476
Rest of World	43	56
Total	<u><u>\$ 34,202</u></u>	<u><u>\$ 35,246</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 operations at one of its two locations in Fremantle, Australia. The affected location was closed as of June 2024. The Company incurred immaterial restructuring charges for the three and six months ended June 30, 2024.

In May and December 2023, the Company announced a reduction of its 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. The Company incurred \$0.8 million in restructuring charges for the three and six months ended June 30, 2023. The Company did not incur any restructuring charges related to this plan in the three and six months ended June 30, 2024.

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, 2023, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2024.

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 and expand reimbursement coverage from payers for our current and other future testing services, if any;
- our plans and ability to continue updating our testing services, products and patient and digital solutions to maintain our leading position in transplantations;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us;
- our ability to successfully assert, defend against or settle any litigation brought by or against us or other legal matters or disputes;
- our ability to remediate the material weaknesses in our internal control over financial reporting as of December 31, 2023; 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, 2023, filed with the SEC on February 28, 2024. 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, together with our 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. We offer testing services, products, and patient and digital 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 June 30, 2024

- Reported total revenue of \$92.3 million, an increase of 31% year-over-year.
- Grew Testing Services volume to 43,700 tests, an increase of 17% year-over-year.
- Reported GAAP net loss of \$1.4 million, a significant improvement from the second quarter 2023.
- Generated \$18.9 million cash from operations. Ended the quarter with cash, cash equivalents, and marketable securities of approximately \$228.9 million, with no debt.
- In the first half of 2024, expanded coverage by 27 million lives nationwide.
- Published SHORE study data demonstrating that HeartCare® outperforms dd-cfDNA alone in identifying allograft rejection.
- Nature Medicine publication validates CareDx AlloView™ AI-enabled risk prediction model and demonstrates AlloSure® Kidney detects subclinical rejection in stable patients.

Testing Services

We develop and provide diagnostic testing services, including for surveillance, for solid organ transplant recipients, hematopoietic stem cell transplant recipients and recipients of cell therapies.

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. In transplantation, there is well-established literature from studies around the world demonstrating 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 in the DNA with an approach specifically designed for transplantation 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 then adopted by Noridian Healthcare Solutions, our Medicare Administrative Contractor, or Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841.

In March and May 2023, MolDX issued new billing articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection. The billing article issued in May 2023, or the Revised Billing Article, and together with the billing article issued in March 2023, the Billing Articles, impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, AlloMap Heart and AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 14, 2023, MolDX released a draft billing article (DA58019) to accompany the proposed draft LCD, which generally reflected the changes in coverage included in the Revised Billing Article. The comment period end date for this proposed LCD was September 23, 2023. We presented at public meetings regarding the proposed draft LCD held on September 18, 2023 and September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on the proposed draft LCD.

On February 29, 2024, MolDX and Noridian released a revised version of the Revised Billing Article.

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 enables more frequent, quantitative and safer assessment of allograft rejection and injury status. 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, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. In June 2024, a publication in the high-impact journal Nature Medicine described the ability of AlloSure to predict rejection in numerous scenarios including subclinical rejection in stable patients. This same publication demonstrated the correlation with severity of rejection and also showed the value of use in surveillance for rejection in patients with multiple AlloSure tests.

The prospective multicenter trial, or the K-OAR study, completed with over 1,900 patients enrolled, monitors patients with AlloSure Kidney for 3 years with the objective of providing further evidence of clinical utility of AlloSure Kidney in the surveillance of kidney transplant recipients. Preliminary results from the K-OAR study were presented at the CareDx Symposium at the American Transplant Congress held in June 2021. Data from the study are being analyzed and data for contemporary control patients are being collected to enable robust final analyses.

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 yet to submit 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 the K-OAR study, more than 3,000 patients have been enrolled.

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 in heart transplant recipients who have stable graft function at the time of testing, to aid in the identification of those 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. 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. In 2021, Palmetto and Noridian issued coverage policies written by MolDX

to replace the former product-specific policies. The common policy LCD is titled “MoIDX: Molecular Testing for Solid Organ Allograft Rejection” and the associated LCD numbers are L38568 (MoIDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

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

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.

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

Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance is covered for Medicare beneficiaries through the MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993. In May 2024, the first publication from the SHORE registry appeared in The Journal of Heart and Lung Transplantation, demonstrating the validity and utility of HeartCare to inform on the risk of rejection and reduce the use of invasive biopsies.

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test was undergoing further studies. One of these studies, launched in April 2020, was the ALARM study, or AlloSure Lung Allograft Remote Monitoring, with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC was measured. AlloSure Lung applies proprietary next generation sequencing, or NGS, technology to measure dd-cfDNA from the donor lung in the recipient bloodstream to monitor graft injury. In October 2021, we launched AlloSure Lung. We have gained early coverage with some commercial payers. Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753.

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 study, or the 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 product portfolio includes AlloSeq Tx, QTYPE, Olerup SSP, AlloSeq HCT, and AlloSeq cfDNA. QTYPE enables Human Leukocyte Antigen, or HLA, typing at a low to intermediate resolution for samples that require a fast turnaround 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.

Our 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, an NGS solution for chimerism testing for stem cell transplant recipients.

We received CE mark authorization for AlloSeq cfDNA in January 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.

In September 2019, we 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 17 received CE mark authorization in May 2020.

In June 2020, we launched AlloSeq HCT, an 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 May 2022, we commercially launched AlloSeq Tx9, a high throughput version of AlloSeq Tx17 for HLA typing in high volume laboratories. AlloSeqTx9 received CE mark authorization in August 2022.

In 2023, we continued to improve and progress our NGS product lines and software through exclusive and non-exclusive collaborations. Also in 2023, we notified our SSP customers of the future 'end of life' production phase out schedule.

Patient and Digital Solutions

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

In May 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.

In August 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. Our XynCare offering 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. 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 and 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 with large transplant databases. This partnership delivers the next level of innovation by incorporating a variety of clinical inputs to create a universal composite scoring system.

In November 2021, we 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, we 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.

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.

In July 2023, we acquired MediGO, an organ transplant supply chain and logistics company. MediGO provides access to donated organs by digitally transforming donation and transplantation workflows to increase organ utilization.

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 primarily derived from AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung tests, which represented 77% and 76% of our total revenue for the three and six months ended June 30, 2024, respectively, and 76% and 78% of our total revenue for the three and six months ended June 30, 2023, 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.

Product Revenue

Our product revenue is primarily derived from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 11% and 12% of our total revenue for the three and six months ended June 30, 2024, respectively, and 11% and 10% of our total revenue for the three and six months ended June 30, 2023. 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 in the contract. The 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 primarily derived from sales of our Ottr software, XynQAPI, MedActionPlan, mTilda (HLA Data Systems), MediGO, 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 12% of total revenue for each of the three and six months ended June 30, 2024, and 13% and 12% of our total revenue for the three and six months ended June 30, 2023.

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 U.S. generally accepted accounting principles, or U.S. GAAP. 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 unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. We believe that the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our

financial statements. We believe the following critical accounting policies are affected by significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements:

- Revenue recognition;
- Business combinations;
- Acquired intangible assets;
- Impairment of goodwill, intangible assets and other long-lived assets; and
- Stock-based compensation.

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our unaudited condensed consolidated financial statements during the three and six months ended June 30, 2024, respectively, 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, 2023, filed with the SEC on February 28, 2024.

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 June 30, 2024 and 2023

(In thousands)

	Three Months Ended June 30,		
	2024	2023	Change
Revenue:			
Testing services revenue	\$ 70,918	\$ 53,414	\$ 17,504
Product revenue	10,610	7,876	2,734
Patient and digital solutions revenue	10,746	9,011	1,735
Total revenue	92,274	70,301	21,973
Operating expenses:			
Cost of testing services	14,308	15,324	(1,016)
Cost of product	6,245	3,926	2,319
Cost of patient and digital solutions	7,393	6,637	756
Research and development	19,678	20,233	(555)
Sales and marketing	21,002	21,630	(628)
General and administrative	27,678	29,327	(1,649)
Restructuring costs	68	848	(780)
Total operating expenses	96,372	97,925	(1,553)
Loss from operations	(4,098)	(27,624)	23,526
Other income:			
Interest income, net	2,826	2,871	(45)
Change in estimated fair value of common stock warrant liability	—	3	(3)
Other expense, net	(100)	(271)	171
Total other income	2,726	2,603	123
Loss before income taxes	(1,372)	(25,021)	23,649
Income tax (expense) benefit	(22)	68	(90)
Net loss	\$ (1,394)	\$ (24,953)	\$ 23,559

Testing Services Revenue

Testing services revenue increased by \$17.5 million, or 33%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase is primarily driven by testing services volume growth of 17%. The difference between revenue and volume growth is primarily driven by increased collections related to tests performed in prior periods and revenue recognition for specific tests performed in prior periods as per ASC 606.

Product Revenue

Product revenue increased by \$2.7 million, or 35%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase is primarily due to higher sales of our commercial NGS-based kitted solutions.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue increased by \$1.7 million, or 19%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase was mainly driven by revenue generated from the acquired businesses of HLA Data Systems and MediGO.

Cost of Testing Services

Cost of testing services decreased by \$1.0 million, or (7)%, for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily driven by efficiency measures to lower laboratory expenses.

Cost of Product

Cost of product increased by \$2.3 million, or 59%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase is primarily due to increased sales of our commercial NGS-based kitted solutions.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by \$0.8 million, or 11%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase is primarily associated with the revenue growth in the patient and digital solution business.

Research and Development

Research and development expenses decreased by \$0.6 million, or (3)%, for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in equipment maintenance expenses of \$0.3 million and software costs of \$0.2 million.

Sales and Marketing

Sales and marketing expenses decreased by \$0.6 million, or (3)%, for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in marketing and tradeshow expenses.

General and Administrative

General and administrative expenses decreased by \$1.6 million, or (6)%, for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in legal expenses of \$5.8 million and a decrease in consulting expenses of \$0.2 million, offset by an increase in personnel-related costs of \$4.1 million and an increase in stock-based compensation expense of \$0.6 million.

Restructuring costs

The restructuring costs decreased by \$0.8 million for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is due to the \$0.8 million restructuring charges during the three months ended June 30, 2023, which related to employee severance pay and related costs.

Other expense, net

Other expense, net decreased by \$0.2 million for the three months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a reduction of foreign exchange loss of \$0.2 million.

Comparison of the Six Months Ended June 30, 2024 and 2023

(In thousands)

	Six Months Ended June 30,		Change
	2024	2023	
Revenue:			
Testing services revenue	\$ 124,755	\$ 115,198	\$ 9,557
Product revenue	19,204	14,737	4,467
Patient and digital solutions revenue	20,364	17,628	2,736
Total revenue	164,323	147,563	16,760
Operating expenses:			
Cost of testing services	27,940	30,620	(2,680)
Cost of product	11,589	7,992	3,597
Cost of patient and digital solutions	14,351	13,241	1,110
Research and development	38,389	44,590	(6,201)
Sales and marketing	40,832	44,861	(4,029)
General and administrative	54,589	57,359	(2,770)
Restructuring costs	68	848	(780)
Total operating expenses	187,758	199,511	(11,753)
Loss from operations	(23,435)	(51,948)	28,513
Other income:			
Interest income, net	5,711	5,537	174
Change in estimated fair value of common stock warrant liability	—	10	(10)
Other expense, net	(390)	(2,245)	1,855
Total other income	5,321	3,302	2,019
Loss before income taxes	(18,114)	(48,646)	30,532
Income tax benefit (expense)	61	(56)	117
Net loss	\$ (18,053)	\$ (48,702)	\$ 30,649

Testing Services Revenue

Testing services revenue increased by \$9.6 million, or 8%, for the six months ended June 30, 2024, compared to the same period in 2023. Revenue increase is primarily driven by increased collections related to tests performed in prior periods and revenue recognition for specific tests performed in prior periods as per ASC 606.

Product Revenue

Product revenue increased by \$4.5 million, or 30%, for the six months ended June 30, 2024, compared to the same period in 2023. The increase is primarily due to higher sales of our commercial NGS-based kitted solutions.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue increased by \$2.7 million, or 16%, for the six months ended June 30, 2024, compared to the same period in 2023. The increase was mainly driven by revenue generated from the acquired businesses of HLA Data Systems and MediGO.

Cost of Testing Services

Cost of testing services decreased by \$2.7 million, or (9)%, for the six months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily driven by efficiency measures to lower laboratory expenses.

Cost of Product

Cost of product increased by \$3.6 million, or 45%, for the six months ended June 30, 2024, compared to the same period in 2023. The increase is primarily due to increased sales of our commercial NGS-based kitted solutions.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by \$1.1 million, or 8%, for the six months ended June 30, 2024, compared to the same period in 2023. The increase is primarily associated with the revenue growth in the patient and digital solution business.

Research and Development

Research and development expenses decreased by \$6.2 million, or (14)%, for the six months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in clinical trials expenses of \$2.9 million, a decrease in personnel-related costs of \$1.9 million, a decrease in consulting expenses of \$0.8 million and a decrease in software costs of \$0.6 million.

Sales and Marketing

Sales and marketing expenses decreased by \$4.0 million, or (9)%, for the six months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in personnel-related costs of \$1.7 million, a decrease in stock-based compensation expense of \$0.5 million, a decrease in marketing and tradeshow expenses of \$1.0 million and a decrease in sponsorship expenses of \$0.8 million.

General and Administrative

General and administrative expenses decreased by \$2.8 million, or (5)%, for the six months ended June 30, 2024, compared to the same period in 2023. The decrease is primarily due to a decrease in legal expenses of \$8.0 million, a decrease in consulting expenses of \$0.8 million and a decrease in office and corporate related expenses of \$1.0 million, offset by an increase in personnel-related costs of \$4.9 million, an increase in software expenses of \$0.9 million and an increase in stock-based compensation expense of \$1.2 million.

Restructuring costs

The restructuring costs decreased by \$0.8 million for the six months ended June 30, 2024, compared to the same period in 2023. The decrease is due to the \$0.8 million restructuring charges during the six months ended June 30, 2023, which related to employee severance pay and related costs.

Interest income, net

Interest income, net increased by \$0.2 million for the six months ended June 30, 2024, compared to the same period in 2023. The increase is primarily due to interest income earned on U.S. agency securities and corporate debt securities.

Other expense, net

Other expense, net decreased by \$1.9 million for the six months ended June 30, 2024, compared to the same period in 2023, primarily due to \$1.0 million in investment write-off and \$0.9 million in unrealized loss on the investment in Miromatrix in the six months ended June 30, 2023.

Income tax benefit (expense)

Income tax benefit (expense) increased by \$0.1 million for the six months ended June 30, 2024, compared to the same period in 2023. The increase is primarily attributable to a change in mixed profit (loss) across jurisdictions.

Cash Flows for the Six Months Ended June 30, 2024 and 2023

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

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ 3,637	\$ 172
Investing activities	16,034	577
Financing activities	(6,125)	(2,704)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	41	(118)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 13,587	\$ (2,073)

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 six months ended June 30, 2024 was \$3.6 million. Net operating assets decreased by \$16.4 million. Our noncash items included \$26.5 million in stock-based compensation expense, \$7.4 million of depreciation and amortization expense, \$2.8 million of amortization of right-of-use assets, \$0.5 million of revaluation of contingent consideration to estimated fair value, and \$0.8 million of amortization of premium on short-term marketable securities, net.

Cash provided by operating activities for the six months ended June 30, 2023 was \$0.2 million. Net operating assets increased \$12.4 million. Our noncash items included \$26.5 million in stock-based compensation expense, \$7.1 million of depreciation and amortization expense, \$2.7 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, \$0.5 million of revaluation of contingent consideration to estimated fair value and \$2.1 million of amortization of premium on short-term marketable securities, net.

Investing Activities

For the six months ended June 30, 2024, net cash provided by investing activities of \$16.0 million was primarily related to proceeds from maturities of marketable securities of \$112.5 million, offset by purchases of marketable securities of \$93.2 million, and \$3.3 million related to additions of capital expenditures, net.

For the six months ended June 30, 2023, net cash provided by investing activities of \$0.6 million was primarily related to maturities of marketable securities of \$145.6 million, offset by the purchases of marketable securities of \$135.3 million, \$5.1 million related to additions of capital expenditures, net and \$4.6 million acquisition of business, net of cash acquired.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2024 of \$6.1 million was primarily due to taxes paid related to net share settlements of restricted stock units of \$4.3 million, repurchase and retirement of common stock of \$0.5 million and payments of contingent consideration of \$2.0 million. These payments were offset by proceeds from issuances of common stock under our employee stock purchase plan of \$0.5 million.

Net cash used in financing activities for the six months ended June 30, 2023 of \$2.7 million was primarily due to taxes paid related to net share settlements of restricted stock units of \$2.2 million, repurchase and retirement of common stock of \$0.8 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.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$696.8 million at June 30, 2024. As of June 30, 2024, we had cash, cash equivalents and marketable securities of \$228.9 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.

Shelf Registration Statement

On May 10, 2023, we filed a universal shelf registration statement (File No. 333-271814), or the Registration Statement, and we thereafter filed post-effective amendments on May 9, 2024 and May 23, 2024. The SEC declared the Registration Statement effective on May 23, 2024, and as a result, we can sell from time to time up to \$250.0 million of shares of our common stock, preferred stock, debt securities, warrants, units or rights comprised of any combination of these securities, for our own account in one or more offerings under the Registration Statement. The terms of any offering under the Registration Statement will be established at the time of such offering and will be described in a prospectus supplement to the Registration Statement filed with the SEC prior to the completion of any such offering.

Stock Repurchase Program

On December 3, 2022, our Board of Directors approved a stock repurchase program (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 and block trades and in privately negotiated transactions. During the six months ended June 30, 2024, we purchased an aggregate of 55,500 shares of our common stock, under the Repurchase Program for an aggregate purchase price of \$0.5 million. There were no repurchases during the three months ended June 30, 2024. As of June 30, 2024, \$21.4 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 then 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. In November 2020, Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MolDX to replace the former product-specific policies. The foundational LCD is titled “MolDX: Molecular Testing for Solid Organ Allograft Rejection” and the associated LCD numbers are L38568 (MolDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the same MolDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753. Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance, is covered, subject to certain limitations, for Medicare beneficiaries through the same MolDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993.

In March and May 2023, MolDX issued new billing articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Articles. The Revised Billing Article impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, AlloMap Heart and AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 14, 2023, MolDX released a draft billing article (DA58019) to accompany the proposed draft LCD, which generally reflected the changes in coverage included in the Revised Billing Article. The comment period end date for this proposed LCD was September 23, 2023. We presented at public meetings regarding the proposed draft LCD held on September 18, 2023 and September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on the proposed draft LCD.

On February 29, 2024, MolDX and Noridian released a revised version of the Revised Billing Article.

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

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 its guidelines and 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 on 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 is 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*”.

Reimbursement for HeartCare

Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance is covered for Medicare beneficiaries through the MolDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993.

Reimbursement for AlloSure Lung

Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the MolDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$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 turnaround 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 Tx. 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, an NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we 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 launched AlloSeq HCT, an 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. With the addition of MediGO, we are now serving the organ procurement market for organ logistical needs.

Development of Additional Services and Products

Our development pipeline includes other 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 services and products. Our success in developing new services and products will be important in our efforts to grow our business by expanding our potential market opportunity 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 June 30, 2024 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, refer to Note 9 of the unaudited 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, government regulations or 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 \$228.9 million at June 30, 2024, which consisted of bank deposits, money market funds and corporate debt securities, and we had cash and cash equivalents and marketable securities of \$235.4 million at December 31, 2023, which consisted of bank deposits, money market funds and corporate debt securities. 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 \$2.3 million on our unaudited 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 June 30, 2024, would have negatively impacted our financial results for the six months ended June 30, 2024 by \$0.8 million and our product revenue by \$0.7 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, including our principal executive officer and principal 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 June 30, 2024. 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 principal executive officer and principal financial officer concluded that, as of June 30, 2024, in light of the material weaknesses identified in our internal control over financial reporting, 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 principal executive officer and principal 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, 2023, which was filed with the SEC on February 28, 2024, the following material weaknesses were identified as of December 31, 2023:

General Information Technology Controls. We did not design and maintain effective general information technology controls, or 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, or 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 its 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 unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q were prepared in accordance with 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 is committed to maintaining a strong internal control environment. In response to the material weaknesses described above, our management is continuing to take actions to remediate the material weaknesses in internal control over financial reporting, which include but are not limited to the following:

- Continuing to enhance the design and control procedures of the GITCs to ensure that the control activities related to GITCs are functioning appropriately.
- Continuing to implement training to ensure a clear understanding of risk assessment, control execution, and monitoring activities related to financial reporting and continue driving accountability of Sarbanes-Oxley Act of 2002 control activities.
- Continuing to focus on controls execution and monitoring activities of internal controls related to the procure-to-pay process.
- Continuing to expand the available resources at the Company with experience designing and implementing control activities, including GITCs, through hiring and use of third-party consultants and specialists.

Management is taking steps to enhance our internal control over financial reporting and remediate the material weaknesses identified during the year ended December 31, 2023. To assess our remediation progress, during the second quarter of 2024, we began the implementation and testing of our existing and redesigned processes. These controls will not be deemed effective until they are performed for a sufficient period and we test and conclude that the controls are operating effectively during the year. We believe the measures described above will remediate the material weaknesses identified during the year ending December 31, 2024. We cannot, however, provide any assurance that our remediation efforts will be successful or that our internal control over financial reporting will be effective because of these efforts. We are committed to continuing to improve our internal control processes and will continue to review, optimize, and enhance our control environment. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. The Company will monitor the effectiveness of its remediation plan and refine its remediation plan as appropriate.

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 June 30, 2024 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, 2023, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2024, 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, 2023, filed with the SEC on February 28, 2024, 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 June 30, 2024, our net loss was \$1.4 million. As of June 30, 2024, we had an accumulated deficit of \$696.8 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 SEC and The Nasdaq Stock Market LLC;
- ongoing litigation;
- 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 June 30, 2024, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 54% 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, the reimbursement rate for AlloMap Heart is currently \$3,240 for Medicare beneficiaries.

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 then adopted by Noridian Healthcare Solutions, our Medicare Administrative Contractor, or Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841.

In March and May 2023, MolDX issued new billing articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection. The billing article issued in May 2023, or the Revised Billing Article, and together with the billing article issued in March 2023, the Billing Articles, impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, AlloMap Heart and AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 14, 2023, MolDX released a draft billing article (DA58019) to accompany the proposed draft LCD, which generally reflected the changes in coverage included in the Revised Billing Article. The comment period end date for this proposed LCD was September 23, 2023. We presented at public meetings regarding the proposed draft LCD held on September 18, 2023 and September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on the proposed draft LCD.

On February 29, 2024, MolDX and Noridian released a revised version of the Revised Billing Article.

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, AlloSure Heart or AlloSure Lung 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, AlloSure Heart or AlloSure Lung 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 the Centers for Medicare and Medicaid Services, or 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.

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 trial concluded on March 14, 2022, with the jury finding that Natera violated the

Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding us \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury. Both parties have appealed and briefing is now complete. Our appeal may be unsuccessful or, if it is successful and the damages are upheld, we may be unable to collect any monetary damages. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising.

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 May 2023, we submitted a petition of certiorari to the U.S. Supreme Court for consideration of the patent infringement suit and in October 2023, the U.S. Supreme Court declined to hear our suit.

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 September 6, 2022, we withdrew our motion to dismiss. On December 11, 2023, the Court dismissed Natera's U.S. Patent 10,597,724. Natera appealed that decision. On March 13, 2024, the Federal Circuit dismissed Natera's appeal after Natera failed to file its brief and other required papers. On May 30, 2024, Natera filed a second notice of appeal of the dismissal of U.S. Patent 10,597,724. On June 19, 2024, we moved to dismiss Natera's appeal.

On January 26, 2024, following a five-day trial, a jury concluded that we did not infringe Natera's U.S. Patent 10,655,180 but did infringe Natera's U.S. Patent 11,111,544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera's U.S. Patent 11,111,544 expires in September 2026. We anticipate continued litigation as to whether our current AlloSure process infringes the patent. Natera has moved for an injunction on our prior AlloSure process. We are opposing the motion. Natera may also move for injunctive relief over our current AlloSure process if it is found to infringe. We are seeking judicial review of the verdict. Natera is also seeking judicial review of the jury's finding that we did not infringe Natera's U.S. Patent 10,655,180. We intend to contest any potential claims of ongoing infringement and any motion for injunctive relief. We intend to defend 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 former 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 our Board of Directors 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.

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. On May 24, 2023, the court granted our motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against us, Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; and Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors. Under a briefing schedule ordered by the court on June 12, 2023, defendants filed a motion to dismiss and motion to strike the second amended complaint on July 26, 2023, plaintiffs' opposition was filed on August 30, 2023 and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 2023. 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 September 21, 2022, Jeffrey Edelman filed 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 Drs. Seeto and Maag

and Mr. Dhingra, and other current and former members of our Board of Directors asserting, among other things, alleged breaches of fiduciary duty against the Individual Defendants based on the factual allegations of the Securities Class Action. On December 8, 2022, the court entered an order staying the Edelman Derivative Action subject to certain terms and conditions.

In addition, on February 7, 2023, Jaysen Stevenson filed 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 Drs. Seeto and Maag and Mr. Dhingra, and other current and former members of our Board of Directors asserting substantially similar claims. On March 9, 2023, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action and stayed both actions pursuant to the terms of the stay order in the Edelman Derivative Action.

On February 8, 2024, Christian Jacobsen filed a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Jacobsen Derivative Action, against us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of our Board of Directors asserting substantially similar claims as the prior-filed derivative actions.

On March 19, 2024, the parties to the Jacobsen Derivative Action and the consolidated Edelman Derivative Action and Stevenson Derivative Action filed a stipulation and proposed order consolidating the Jacobsen Derivative Action with the consolidated Edelman Derivative Action and Stevenson Derivative Action and staying the Jacobsen Derivative Action pursuant to the terms of the stay order in the Edelman Derivative Action. On April 23, 2024, the court entered an order consolidating all three derivative actions, or the Consolidated Derivative Action. The order provides that all previous orders in the Edelman Derivative Action and the Stevenson Derivative Action shall apply to the Jacobsen Derivative Action.

On May 16, 2024, the court lifted the stay in the Consolidated Derivative Action. Under a scheduling order entered by the court on May 14, 2024, plaintiffs filed an amended complaint in the Consolidated Derivative Action on July 1, 2024. Pursuant to a briefing notice entered by the court on June 17, 2024, defendants' deadline to file a motion to dismiss is August 30, 2024, plaintiffs' deadline to file an opposition brief is October 29, 2024, and defendants' deadline to file a reply brief is December 2, 2024. A motion hearing is scheduled for January 28, 2025.

On March 20, 2024, Edward W. Burns IRA filed a stockholder derivative action complaint in the Court of Chancery of the State of Delaware, or the Burns Derivative Action, against us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of our Board of Directors. Prior to filing the complaint, we produced documents to the plaintiff in response to a books and records inspection demand made pursuant to Section 220 of the Delaware General Corporation Law. The plaintiff purports to incorporate those documents in the complaint. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company and engaged in insider trading, unjust enrichment, waste of corporate assets, and aiding and abetting breaches of fiduciary duty. The suit seeks declaratory relief, recovery of alleged damages sustained by us as a result of the alleged violations, equitable relief, restitution, and plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses.

On May 30, 2024 the parties to the Burns Derivative Action filed an amended stipulation and proposed order to continue the stay in that action, which was so-ordered by the court on May 31, 2024.

We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail. We have not recorded any liabilities for this suit.

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

If we are unable to successfully compete with established players in the clinical surveillance of the transplantation field, we may be unable to increase or sustain our revenues or achieve profitability.

Our AlloSure Kidney solution for kidney transplant recipients competes against existing diagnostic tests utilized by pathologists, which involves evaluating biopsy samples to determine the presence or absence of rejection. However, because of the risks and discomforts of the invasive kidney biopsy procedure, as well as the expense and relatively low rate of finding moderate to severe grade rejection, biopsy is not a standard practice for surveillance of transplanted kidneys. Additional competition for kidney surveillance diagnostics currently comes from general, non-specific clinical chemistry tests such as serum creatinine, urine protein, donor specific antibodies, complete blood count, lipid profile and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs. Our competitors also include companies that are focused on the development and commercialization of molecular diagnostic tests. In the field of post-transplant surveillance, Natera, Eurofins, and Oncocyte, have commercially available molecular diagnostics tests. Other entrants with kitted products have indicated they are entering the market for post-transplant surveillance, including Thermo Fisher, Devyser, Bio-Rad, EuroBio, and Oncocyte.

Competition for our AlloMap Heart solution for heart transplant recipients also comes from biopsies, which generally involve evaluating biopsy samples to determine the presence or absence of rejection. This practice has been the standard of care in the United States for many years, and we will need to continue to educate clinicians, transplant recipients and payers about the various benefits of our test in order to change clinical practice.

We expect the competition for pre-transplant typing and post-transplant surveillance to increase as there are numerous established and startup companies in the process of developing products and services for the transplant market which may directly or indirectly compete with our existing pre- and post-transplant solutions, or our development pipeline. Competition from other companies, especially those with an eye toward transitioning to more automated typing processes, could impact our ability to maintain market share and its current margins. For example, QTYPE competes with other quantitative polymerase chain reaction, or PCR, products including products offered by Thermo Fisher Scientific, Inc., as well as alternatives to PCR such as next generation sequencing, or NGS, typing products.

Competition for our patient and digital solutions include various companies that develop application software and operate in the healthcare field. Our competition for patient solutions includes hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. Our primary competitor for our patient management EMR solution is Phoenix, Epic's transplant application. In addition, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness.

The field of clinical surveillance of transplantation is evolving. New and well-established companies are devoting substantial resources to the application of molecular diagnostics to the treatment of medical conditions. Some of these companies may elect to develop and market diagnostic solutions in the post-transplant surveillance market.

Many of our potential competitors may have greater brand recognition or substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by clinicians and payers as functionally equivalent to our AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart tests, which could force us to lower the current list price of our test and impact our operating margins and our ability to achieve profitability. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our products and patient and digital solutions, which could prevent us from increasing or sustaining our revenues or achieving profitability and could cause the market price of our common stock to decline.

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

From 2022 to 2023, our revenue declined from \$321.8 million to \$280.3 million, which represents a decrease of 13%. From the three months ended June 30, 2023 to the three months ended June 30, 2024, our revenue grew from \$70.3 million to \$92.3 million, which represents an increase of \$22.0 million or 31%. In the future, our revenue may not grow at all and it may continue to 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 continue our 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 seek to and 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 June 30, 2024, we had cash, cash equivalents and marketable securities of \$228.9 million and an accumulated deficit of \$696.8 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. 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.

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.

As of June 30, 2024, we had 9 issued U.S. patents related to diagnosing transplant rejection and autoimmune disease, which will expire between April 2024 and May 2035.

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. In addition, our exclusive license agreement with Stanford that previously covered certain patents related to diagnostic and predictive technologies terminated in October 2023. 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 U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. 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 interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. Patent applications in the United States and many foreign jurisdictions are not published until at least 18 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, first to file. 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 U.S. Patent and Trademark Office or a court to determine priority of invention in the United States for pre-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 2, 2024 to June 28, 2024, our closing stock price ranged from \$7.56 to \$16.15 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;
- 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.

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 60.0% of our common stock as of June 30, 2024. 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 have identified material weaknesses in our internal control over financial reporting as of December 31, 2022, which were not remediated at December 31, 2023. 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, which were not remediated at December 31, 2023. 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, 2023:

- **General Information Technology Controls.** We did not design and maintain effective general information technology controls, or 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, or 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 our 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 awards 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 June 30, 2024:

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program (2)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
April 1, 2024 - April 30, 2024	148,472 (1)	\$ 9.45	—	\$ 21.4 (2)
May 1, 2024 - May 31, 2024	77,077 (1)	9.98	—	21.4 (2)
June 1, 2024 - June 30, 2024	100,385 (1)	14.74	—	21.4 (2)
Total	325,934		—	

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

(2) 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 and 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

During the fiscal quarter ended June 30, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

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)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, dated June 16, 2023.
3.4(4)	Amended and Restated Bylaws, effective as of March 24, 2023
4.1(5)	Form of Registrant’s common stock certificate.
4.2(6)#	2014 Equity Incentive Plan, as amended.
4.3(7)#	Form of Option Agreement under the 2014 Equity Incentive Plan for New Options.
4.4(8)#	2014 Employee Stock Purchase Plan and forms of agreements thereunder.
4.5(9)#	2016 Inducement Equity Incentive Plan.
4.6(10)#	CareDx, Inc. 2019 Inducement Equity Incentive Plan.
10.1 (11)#	CareDx, Inc. 2024 Equity Incentive Plan
31.1*	Certification of Periodic Report by Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Periodic Report by Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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 3.1 to the Registrant’s Form 8-K filed with the SEC on June 20, 2023.
(4)	Incorporated by reference to Exhibit 3.1 to the Registrant’s Form 8-K filed with the SEC on March 28, 2023.
(5)	Incorporated by reference to Exhibit 4.1 to the Registrant’s Form 10-K filed with the SEC on March 31, 2015.
(6)	Incorporated by reference to Exhibit 4.2 to the Registrant’s Form 10-Q filed with the SEC on July 29, 2021.
(7)	Incorporated by reference to Exhibit 99(d)(3) to the Registrant’s Form SC TO-I filed with the SEC on October 12, 2017.
(8)	Incorporated by reference to Exhibit 4.5 to the Registrant’s Form S-8 filed with the SEC on July 18, 2014.
(9)	Incorporated by reference to Exhibit 4.5 to the Registrant’s Form 10-Q filed with the SEC on July 29, 2021.
(10)	Incorporated by reference to Exhibit 4.7 to the Registrant’s Form 10-Q filed with the SEC on July 29, 2021.
(11)	Incorporated by reference to Exhibit 10.1 to the Registrant’s Form 8-K filed with the SEC on June 18, 2024.
#	Indicates management contract or compensatory plan or arrangement.
*	Filed herewith.

**

Furnished herewith.

†

Non-material schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules 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: July 31, 2024

CAREDX, INC.
(Registrant)

By: /s/ JOHN W. HANNA

John W. Hanna
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ ABHISHEK JAIN

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

**CERTIFICATION OF PRINCIPAL 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, John W. Hanna, 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: July 31, 2024

By: /s/ John W. Hanna

John W. Hanna
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL 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: July 31, 2024

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 June 30, 2024 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/ John W. Hanna
 John W. Hanna
 President and Chief Executive Officer
 (Principal Executive Officer)
 Date: July 31, 2024

By: /s/ Abhishek Jain
 Abhishek Jain
 Chief Financial Officer
 (Principal Accounting and Financial Officer)
 Date: July 31, 2024

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.