REFINITIV

DELTA REPORT

10-Q

CDNA - CAREDX, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	2030
CHANGES	265
DELETIONS	1213
ADDITIONS	552

REFINITIV

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023 March 31, 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	**94-3316839**
(State or other jurisdiction of incorporation or organization)	**(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 54,098,378 52,083,792 shares of the registrant's Common Stock issued and outstanding as of November 6, 2023 May 7, 2024.

Table of Contents

CareDx, Inc.
TABLE OF CONTENTS

	Page No.
PART I. FINANCIAL INFORMATION	3
Item 1. Unaudited Condensed Consolidated Financial Statements	3
Condensed Consolidated Balance Sheets as of September 30, 2023 March 31, 2024 and December 31, 2022 2023	3
Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2023 March 31, 2024 and 2022 2023	4
Condensed Consolidated Statements of Comprehensive Loss for the Three and Nine Months Ended September 30, 2023 March 31, 2024 and 2022 2023	5
Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2023 March 31, 2024 and 2022 2023	6
Condensed Consolidated Statements of Cash Flows for the Nine Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023	8
Notes to Unaudited Condensed Consolidated Financial Statements	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	35 33
Item 3. Quantitative and Qualitative Disclosures About Market Risk	55 47
Item 4. Controls and Procedures	55 47
PART II. OTHER INFORMATION	57 49
Item 1. Legal Proceedings	57 49
Item 1A. Risk Factors	57 49
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	73 57
Item 3. Defaults Upon Senior Securities	74 58
Item 4. Mine Safety Disclosures	74 58
Item 5. Other Information	74 58
Item 6. Exhibits	75 59
Signatures	77 61

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

		September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Assets	**Assets**				
Current assets:	Current assets:				
Current assets:					
Current assets:					
Cash and cash equivalents					
Cash and cash equivalents					
Cash and cash equivalents	Cash and cash equivalents	$ 75,980	$ 89,921		
Marketable securities	Marketable securities	192,204	203,168		
Accounts receivable	Accounts receivable	51,694	66,312		
Inventory	Inventory	17,978	19,232		

Prepaid and other current assets	Prepaid and other current assets	7,310	9,216
Total current assets	Total current assets	345,166	387,849
Property and equipment, net	Property and equipment, net	35,355	35,529
Operating leases right-of-use assets	Operating leases right-of-use assets	30,973	34,689
Intangible assets, net	Intangible assets, net	46,455	43,051
Goodwill	Goodwill	40,208	37,523
Restricted cash	Restricted cash	582	522
Other assets	Other assets	2,441	3,828
Total assets	Total assets	$501,180	$542,991
Liabilities and stockholders' equity	**Liabilities and stockholders' equity**		
Current liabilities:	Current liabilities:		
Current liabilities:			
Current liabilities:			
Accounts payable			
Accounts payable			
Accounts payable	Accounts payable	$ 8,972	$ 9,942
Accrued compensation	Accrued compensation	16,664	16,902
Accrued and other liabilities	Accrued and other liabilities	47,038	49,131
Total current liabilities	Total current liabilities	72,674	75,975
Total current liabilities			
Total current liabilities			
Deferred tax liability	Deferred tax liability	140	—
Common stock warrant liability		—	32
Deferred payments for intangible assets			
Deferred payments for intangible assets			
Deferred payments for intangible assets	Deferred payments for intangible assets	4,735	2,418
Operating lease liability, less current portion	Operating lease liability, less current portion	29,252	33,406
Other liabilities	Other liabilities	245	249
Total liabilities	Total liabilities	107,046	112,080
Commitments and contingencies (Note 9)	Commitments and contingencies (Note 9)		Commitments and contingencies (Note 9)
Stockholders' equity:	Stockholders' equity:		

Preferred stock: $0.001 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022		—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at September 30, 2023 and December 31, 2022; 54,153,496 shares issued and outstanding at September 30, 2023; 53,583,301 shares issued and 53,533,250 shares outstanding at December 31, 2022		52	52
Preferred stock: $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023			
Preferred stock: $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023			
Preferred stock: $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023			
Common stock: $0.001 par value; 100,000,000 shares authorized at March 31, 2024 and December 31, 2023; 51,782,612 and 51,503,377 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			
Additional paid-in capital	Additional paid-in capital	936,954	898,806
Accumulated other comprehensive loss	Accumulated other comprehensive loss	(8,670)	(7,503)
Accumulated deficit	Accumulated deficit	(534,202)	(460,444)

Total stockholders' equity	Total stockholders' equity	394,134	430,911
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity	$501,180	$542,991

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

Table of Contents

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Revenue:					
Revenue:					
Revenue:	Revenue:				
Testing services revenue	Testing services revenue	$ 47,784	$ 64,751	$ 162,982	$ 198,330
Testing services revenue					
Testing services revenue					
Product revenue					
Product revenue					
Product revenue	Product revenue	9,536	7,194	24,273	20,696
Patient and digital solutions revenue	Patient and digital solutions revenue	9,872	7,414	27,500	20,383
Patient and digital solutions revenue					
Patient and digital solutions revenue					
Total revenue					
Total revenue					
Total revenue	Total revenue	67,192	79,359	214,755	239,409
Operating expenses:	Operating expenses:				
Operating expenses:					
Operating expenses:					
Cost of testing services					
Cost of testing services					
Cost of testing services	Cost of testing services	13,217	17,771	43,837	53,629
Cost of product	Cost of product	4,750	4,736	12,742	13,022
Cost of product					
Cost of product					
Cost of patient and digital solutions					
Cost of patient and digital solutions					

Cost of patient and digital solutions	Cost of patient and digital solutions	6,566	5,794	19,807	16,071
Research and development	Research and development	19,000	22,306	63,590	66,818
Research and development					
Research and development					
Sales and marketing					
Sales and marketing					
Sales and marketing	Sales and marketing	18,474	22,261	63,335	72,359
General and administrative	General and administrative	33,968	23,830	91,327	75,621
Restructuring costs		—	—	848	—
General and administrative					
General and administrative					
Total operating expenses					
Total operating expenses					
Total operating expenses	Total operating expenses	95,975	96,698	295,486	297,520
Loss from operations	Loss from operations	(28,783)	(17,339)	(80,731)	(58,111)
Other income (expense):					
Loss from operations					
Loss from operations					
Other income:					
Other income:					
Other income:					
Interest income, net					
Interest income, net					
Interest income, net	Interest income, net	3,171	1,225	8,708	1,892
Change in estimated fair value of common stock warrant liability	Change in estimated fair value of common stock warrant liability	—	14	10	89
Other income (expense), net		2,047	(572)	(198)	(1,948)
Change in estimated fair value of common stock warrant liability					
Change in estimated fair value of common stock warrant liability					
Other expense, net					
Other expense, net					
Other expense, net					
Total other income					
Total other income					
Total other income	Total other income	5,218	667	8,520	33
Loss before income taxes	Loss before income taxes	(23,565)	(16,672)	(72,211)	(58,078)
Loss before income taxes					
Loss before income taxes					
Income tax benefit (expense)					
Income tax benefit (expense)					
Income tax benefit (expense)	Income tax benefit (expense)	80	(267)	24	(206)

Net loss	Net loss	$ (23,485)	$ (16,939)	$ (72,187)	$ (58,284)
Net loss					
Net loss					
Net loss per share (Note 3):					
Net loss per share (Note 3):					
Net loss per share (Note 3):	Net loss per share (Note 3):				
Basic	Basic	$ (0.43)	$ (0.32)	$ (1.34)	$ (1.09)
Basic					
Basic					
Diluted					
Diluted					
Diluted	Diluted	$ (0.43)	$ (0.32)	$ (1.34)	$ (1.09)
Weighted-average shares used to compute net loss per share:	Weighted-average shares used to compute net loss per share:				
Weighted-average shares used to compute net loss per share:					
Weighted-average shares used to compute net loss per share:					
Basic					
Basic					
Basic	Basic	54,178,759	53,489,418	53,891,374	53,253,210
Diluted	Diluted	54,178,759	53,489,418	53,891,374	53,253,210
Diluted					
Diluted					

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

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (23,485)	$ (16,939)	$ (72,187)	$ (58,284)
Other comprehensive loss:				
Foreign currency translation adjustments, net of tax	(220)	(1,627)	(1,167)	(4,139)
Net comprehensive loss	$ (23,705)	$ (18,566)	$ (73,354)	$ (62,423)

	Three Months Ended March 31,	
	2024	2023
Net loss	$ (16,659)	$ (23,749)
Other comprehensive (loss) gain:		
Foreign currency translation adjustment, net of tax	(1,145)	64
Comprehensive loss	$ (17,804)	$ (23,685)

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						
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						
Employee stock-based compensation expense	—	—	13,719	—	—	13,719
Foreign currency translation adjustment	—	—	—	64	—	64

Employee stock-based compensation expense							
Foreign currency translation adjustment, net of tax							
Net loss	Net loss	—	—	—	—	(23,749)	(23,749)
Balance at March 31, 2023		53,653,182	52	912,291	(7,439)	(484,883)	420,021
Balance at March 31, 2024							
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 for cash upon exercise of warrants		3,132	—	26	—	—	26
Employee stock-based compensation expense		—	—	12,663	—	—	12,663
Foreign currency translation adjustment		—	—	—	(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
Issuance of common stock under employee stock purchase plan		143,816	—	1,039	—	—	1,039
Repurchase and retirement of common stock		(92,766)	—	—	—	(814)	(814)
RSU settlements, net of shares withheld		64,879	—	(355)	—	—	(355)
Issuance of common stock for services		4,513	—	37	—	—	37
Issuance of common stock for cash upon exercise of stock options		19,453	—	99	—	—	99
Employee stock-based compensation expense		—	—	12,620	—	—	12,620
Foreign currency translation adjustment		—	—	—	(220)	—	(220)
Net loss		—	—	—	—	(23,485)	(23,485)
Balance at September 30, 2023		54,153,496	$ 52	$936,954	$ (8,670)	$ (534,202)	$ 394,134

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

Table of Contents

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				

Balance at December 31, 2021		52,923,360	$ 52	$ 853,683	$ (4,670)	$ (383,189)	$ 465,876

	Common Stock			Common Stock	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares							
Balance at December 31, 2022								
Balance at December 31, 2022								
Balance at December 31, 2022								
Issuance of common stock under employee stock purchase plan	Issuance of common stock under employee stock purchase plan	25,852	—	999	—	—	999
Repurchase and retirement of common stock								
RSU settlements, net of shares withheld	RSU settlements, net of shares withheld	64,819	—	(1,482)	—	—	(1,482)
Issuance of common stock for services	Issuance of common stock for services	1,249	—	58	—	—	58
Issuance of common stock for cash upon exercise of stock options	Issuance of common stock for cash upon exercise of stock options	69,993	—	1,598	—	—	1,598
Employee stock-based compensation expense	Employee stock-based compensation expense	—	—	10,563	—	—	10,563
Foreign currency translation adjustment		—	—	—	(420)	—	(420)
Employee stock-based compensation expense								
Employee stock-based compensation expense								
Foreign currency translation adjustment, net of tax								
Net loss	Net loss	—	—	—	—	(19,648)	(19,648)
Balance at March 31, 2022		53,085,273	52	865,419	(5,090)	(402,837)	457,544
Balance at March 31, 2023								
RSU settlements, net of shares withheld		216,950	—	(3,211)	—	—	(3,211)
Issuance of common stock for services		2,156	—	79	—	—	79
Issuance of common stock for cash upon exercise of stock options		19,333	—	413	—	—	413
Employee stock-based compensation expense		—	—	12,513	—	—	12,513

Foreign currency translation adjustment	—	—	—	(2,092)	—	(2,092)
Net loss	—	—	—	—	(21,697)	(21,697)
Balance at June 30, 2022	53,323,712	52	875,213	(7,182)	(424,534)	443,549
Issuance of common stock under employee stock purchase plan	67,570	—	1,231	—	—	1,231
RSU settlements, net of shares withheld	119,429	—	(850)	—	—	(850)
Issuance of common stock for services	3,545	—	79	—	—	79
Issuance of common stock for cash upon exercise of stock options	9,197	—	139	—	—	139
Employee stock-based compensation expense	—	—	11,097	—	—	11,097
Foreign currency translation adjustment	—	—	—	(1,627)	—	(1,627)
Net loss	—	—	—	—	(16,939)	(16,939)
Balance at September 30, 2022	53,523,453	$ 52	$886,909	$ (8,809)	$ (441,473)	$ 436,679

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

Table of Contents

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

		Nine Months Ended September 30,	
		2023	2022
Three Months Ended March 31,			
2024			
Operating activities:	**Operating activities:**		
Net loss			
Net loss			
Net loss	Net loss	$(72,187)	$(58,284)
Adjustments to reconcile net loss to net cash used in operating activities:	Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	Stock-based compensation	39,125	34,427
Stock-based compensation			
Stock-based compensation			
Revaluation of common stock warrant liability to estimated fair value			
Depreciation and amortization	Depreciation and amortization	10,755	8,389

Three Months Ended March 31,	
2024	2023

Asset impairments and write-downs	Asset impairments and write-downs	1,000	840
Amortization of right-of-use assets	Amortization of right-of-use assets	4,020	3,120
Unrealized loss on long-term marketable equity securities	Unrealized loss on long-term marketable equity securities	1,185	215
Revaluation of contingent consideration to estimated fair value	Revaluation of contingent consideration to estimated fair value	1,731	830
Loss on disposal of asset		37	—
Gain on settlement of obligation and recovery of written-off investment		(2,109)	—
Accretion of discount and amortization of premium on short-term marketable securities, net		(3,410)	993
Revaluation of common stock warrant liability to estimated fair value		(10)	(89)
Amortization of premium and accretion of discount on short-term marketable securities, net			
Amortization of premium and accretion of discount on short-term marketable securities, net			
Amortization of premium and accretion of discount on short-term marketable securities, net			
Changes in operating assets and liabilities:	Changes in operating assets and liabilities:		
Accounts receivable			
Accounts receivable			
Accounts receivable	Accounts receivable	15,351	(10,838)
Inventory	Inventory	758	(2,258)
Prepaid and other assets	Prepaid and other assets	2,542	(397)
Operating leases liabilities, net	Operating leases liabilities, net	(4,088)	(2,390)
Accounts payable	Accounts payable	(990)	(1,697)
Accrued compensation	Accrued compensation	(336)	(11,610)
Accrued and other liabilities	Accrued and other liabilities	(3,462)	6,482
Change in deferred taxes	Change in deferred taxes	81	(157)
Net cash used in operating activities		(10,007)	(32,424)

Net cash (used in) provided by operating activities			
Investing activities:	**Investing activities:**		
Acquisitions of business, net of cash acquired	Acquisitions of business, net of cash acquired	(6,682)	(610)
Acquisitions of intangible assets		(896)	(3,100)
Acquisitions of business, net of cash acquired			
Acquisitions of business, net of cash acquired			
Purchases of short-term marketable securities			
Purchases of short-term marketable securities			
Purchases of short-term marketable securities	Purchases of short-term marketable securities	(192,131)	(283,442)
Maturities of short-term marketable securities	Maturities of short-term marketable securities	206,503	74,132
Purchase of corporate equity securities	Purchase of corporate equity securities	(965)	—
Additions of capital expenditures	Additions of capital expenditures	(6,750)	(17,957)
Net cash used in investing activities		(921)	(230,977)
Net cash provided by (used in) investing activities			
Financing activities:	**Financing activities:**		
Proceeds from issuance of common stock under employee stock purchase plan	Proceeds from issuance of common stock under employee stock purchase plan	1,495	2,231
Proceeds from issuance of common stock under employee stock purchase plan			
Proceeds from issuance of common stock under employee stock purchase plan			
Taxes paid related to net share settlement of restricted stock units	Taxes paid related to net share settlement of restricted stock units	(2,514)	(5,543)
Proceeds from exercise of warrants		4	—
Proceeds from exercise of stock options			
Proceeds from exercise of stock options			

Proceeds from exercise of stock options	Proceeds from exercise of stock options	107	2,149
Payment of contingent consideration			
Payment of contingent consideration			
Payment of contingent consideration	Payment of contingent consideration	(250)	(1,000)
Repurchase and retirement of common stock	Repurchase and retirement of common stock	(1,571)	—
Net cash used in financing activities	Net cash used in financing activities	(2,729)	(2,163)
Effect of exchange rate changes on cash and cash equivalents	Effect of exchange rate changes on cash and cash equivalents	(224)	25
Net decrease in cash, cash equivalents and restricted cash		(13,881)	(265,539)
Net increase (decrease) in cash, cash equivalents and restricted cash			
Cash, cash equivalents and restricted cash at beginning of period	Cash, cash equivalents and restricted cash at beginning of period	90,443	348,696
Cash, cash equivalents and restricted cash at end of period	Cash, cash equivalents and restricted cash at end of period	$ 76,562	$ 83,157

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

Table of Contents

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 common policy 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.

On March 2, 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection (the “Billing Article”). Prior to the Billing Article’s effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article would not be implemented until June 30, 2023. MolDX informed CareDx that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new billing article with an effective date of March 31, 2023 (the “Revised Billing Article” and together with the Billing Article, the “Billing Articles”). The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

Although the Company believes the Billing Articles are inconsistent with the LCDs, Noridian’s and MolDX’s responses to public comments explaining the intended scope of various LCDs, and medical necessity, the Company determined to pause its Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow the Company further time to evaluate the implications of the Billing Article and update its billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx’s test order forms to capture the new information required under the Billing Article. Accordingly, the Company did not submit claims for approximately 3,200 AlloSure Kidney tests for Medicare

Table of Contents

reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately $8.9 million (the “Impacted March Tests”).

On May 18, 2023, the Company submitted a letter to Noridian explaining, among other things, (i) the Company’s belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that the Company planned to submit claims for reimbursement for the Impacted March Tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, the Company submitted claims for reimbursement for the Impacted March Tests for which the Company subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023.

The Company has certain unbilled AlloSure Kidney claims with a service date after March 31, 2023, where the reason for testing is not specified by the ordering physician. The Company is in the process of supplementation for these tests. If these AlloSure Kidney tests are within the parameters of the Revised Billing Article, the Company will bill and would expect to recognize revenue in the quarter that the supplementation is completed.

CareDx continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, CareDx informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, CareDx would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart according to requirements of the Billing Article currently effective at Noridian. The Company also informed Noridian on May 18, 2023 that (i) until June 30, 2023, it planned to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article.

On August 28, 2023, the Company submitted a subsequent letter to Noridian regarding its AlloSure Heart and AlloMap Heart testing submissions, explaining, among other things, that (i) prior to August 17, 2023, the Company submitted claims as outlined in its prior communications, including submitting AlloSure Heart and AlloMap Heart claims that were in compliance with the billing article in effect for Noridian (but that were not necessarily in compliance with the Revised Billing Article that had not yet been adopted by Noridian); (ii) for claims with dates of service of August 17, 2023 or later, the Company is submitting AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant; and (iii) for AlloSure Heart and AlloMap Heart tests performed on or after August 17, 2023 that are outside the parameters of the Revised Billing Article, certain billing codes will be used to enable any additional review deemed appropriate by Noridian and potential appeal by the Company of the denied claims.

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.

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$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.

Table of ContentsIn 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 1,700 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.

Table of Contents

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, to perform HLA typing.

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

Patient and Digital Solutions

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

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

In January 2021, the Company acquired TransChart. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As part of the Company’s acquisition of TransChart in January 2021, the Company acquired TxAccess, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs 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 the first transplant-specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system. The Company has agreed to potential future milestone payments.

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

Table of Contents

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 $534.2 million $695.5 million at September 30, 2023 March 31, 2024. As of September 30, 2023 March 31, 2024, the Company had cash, cash equivalents and marketable securities of $268.2 million $215.9 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"), whereby and thereafter filed post-effective amendments thereto and expects to file another post-effective amendment thereto on or about May 9, 2024. Upon its effectiveness, 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 Securities and Exchange Commission (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 three and nine months ended September 30, 2023 March 31, 2024, the Company purchased an aggregate of 92,766 shares and 164,238 55,500 shares of its common stock, respectively, under the Repurchase Program for an aggregate purchase price of $0.8 million and $1.6 million, respectively. $0.5 million. As of September 30, 2023 March 31, 2024, $47.7 million $21.4 million remained available for future share repurchase 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, 2022 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, 2022 December 31, 2023, filed with the SEC on February 27, 2023 February 28, 2024. Material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 are reflected below.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"), and follow the requirements of the SEC for interim reporting. As permitted under those rules, certain notes and other financial information that are normally required by U.S. GAAP can be condensed or omitted. These unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments that are necessary for a fair statement of the Company's financial information. The condensed consolidated balance sheet as of December 31, 2022 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 nine months ended September 30, 2023 March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 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 issued common stock warrants and embedded derivatives; the fair value of assets and liabilities acquired in a business combination or an assets 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 September 30, 2023 March 31, 2024 and 2022, 2023, approximately 36% 33% and 53%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2023 and 2022, approximately 41% and 54% 42%, respectively, of total revenue was derived from Medicare.

As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, approximately 36% 37% and 27% 36%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either September 30, 2023 March 31, 2024 or December 31, 2022 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 September 30, 2023 March 31, 2024, the Company's short-term marketable securities consisted of corporate debt securities with maturities of greater than three months but less than twelve months at the time of purchase, which were classified as current assets on the condensed consolidated balance sheet.

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

The Company considers investments in securities with remaining maturities of over one year as long-term investments. As of September 30, 2023, the Company's long-term marketable securities consisted of corporate equity securities and corporate debt securities. These long-term marketable securities are classified as other assets on the condensed consolidated balance sheet.

The Company classifies its long-term marketable debt securities as available-for-sale and reevaluates such designation at each balance sheet date. Unrealized gains and losses from the reevaluation of the long-term marketable debt securities, if any, are included in other comprehensive gain (loss) in the condensed consolidated statement of comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary, if any, on long-term marketable securities are included in interest income (expense), net.

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

Leases

The Company adopted Accounting Standard Codification ("ASC") Topic 842, *Leases,* and determines if an arrangement is or contains a lease at contract inception. A right-of-use ("ROU") asset, representing the underlying asset during the lease term, and a lease liability, representing the payment obligation arising from the lease, are recognized on the condensed consolidated balance sheet at lease commencement based on the present value of the payment obligation. For operating leases, expense is recognized on a straight-line basis over the lease term. For finance leases, interest expense on the lease liability is recognized using the effective interest method and amortization of the ROU asset is recognized on a straight-line basis over the shorter of the estimated useful life of the asset or the lease term. The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's facility leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for leases with an initial term of 12 months or less.

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

Table of Contents

As of September 30, 2023, March 31, 2024, the Company's leases had remaining terms of 0.17 years to 9.35 8.84 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.

Table of Contents

Testing Services Revenue

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

InOn March 2, 2023, 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, Article") and together with an effective date of March 31, 2023. The Billing Article impacts the billing article issued in March 2023 (the "Billing Articles") impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, and AlloMap Heart and requires AlloSure Lung, and required certain companies, including the Company, to implement new processes to address the requirements related to Medicare claim submissions. *ASC 606-10-25-1* requires the Company to assess whether it is probable that it will collect substantially all of the consideration to which it will be entitled when determining if a contract with a customer exists. Based upon the Company's review of the Billing Article, it was determined to pause Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 that created uncertainty around the collection of the claims. Accordingly, the Company did not submit claims for approximately 3,200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately $8.9 million.

On May 18, 2023, the Company submitted a letter to Noridian explaining, among other things, (i) the Company's belief that the Billing Articles imposed new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that the Company planned to submit claims for reimbursement for the Impacted March Tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian, on May 18, 2023, the Company submitted claims for reimbursement for the Impacted March Tests, for which the Company subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023.

The Company has certain unbilled AlloSure Kidney claims with a service date after March 31, 2023, where the reason for testing is not specified by the ordering physician. The Company is in the process of supplementation for these tests. If these AlloSure Kidney tests are within the parameters of the Revised Billing Article, the Company will bill and would expect to recognize revenue in the quarter that the supplementation is completed.

Table of Contents

The Company continues its Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, the Company informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article the Company would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. The Company also informed Noridian on May 18, 2023 that (i) until June 30, 2023 August 17, 2023, it planned to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters retroactive effective date of the Revised Billing Article.

On August 28, 2023, the Company submitted a subsequent letter to Noridian regarding its AlloSure Heart and AlloMap Heart testing submissions, explaining, among other things, that (i) prior to August 17, 2023, the Company submitted claims as outlined in its prior communications, including submitting AlloSure Heart and AlloMap Heart claims that were in compliance with the billing article in effect for Noridian (but that were not necessarily in compliance with the Revised Billing Article that had not yet been adopted by Noridian); (ii) for claims with dates of service of August 17, 2023 or later, the Company is submitting AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant; and (iii) for AlloSure Heart and AlloMap Heart tests performed on or after August 17, 2023 that are outside the parameters of the Revised Billing Article, certain billing codes will be used to enable any additional review deemed appropriate by Noridian and potential appeal by the Company of the denied claims. 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.

Product Revenue

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

Patient and Digital Solutions Revenue

Patient and digital solutions revenue is mainly derived from a combination of software as a service ("SaaS") and perpetual software license agreements entered into with various transplant centers, which are the Company's customers for this class of revenue. The main performance obligations in connection with the Company's SaaS and perpetual software license 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.

Table of Contents

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

Table of Contents

There were no recently adopted accounting standards which would have a material effect on the Company's condensed consolidated financial statements and accompanying disclosures, and no recently issued accounting standards that are expected to have a material impact 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 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. We are currently evaluating the potential effect that the updated standard will have on our 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. We are currently evaluating the potential effect that the updated standard will have on our 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.

Table of Contents

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Numerator:					
Numerator:					
Numerator:	**Numerator:**				

Net loss used to compute basic and diluted net loss per share	Net loss used to compute basic and diluted net loss per share	$ (23,485)	$ (16,939)	$ (72,187)	$ (58,284)
Net loss used to compute basic and diluted net loss per share					
Net loss used to compute basic and diluted net loss per share					
Denominator:					
Denominator:					
Denominator:	**Denominator:**				
Weighted-average shares used to compute basic and diluted net loss per share	Weighted-average shares used to compute basic and diluted net loss per share	54,178,759	53,489,418	53,891,374	53,253,210
Weighted-average shares used to compute basic and diluted net loss per share					
Weighted-average shares used to compute basic and diluted net loss per share					
Net loss per share:					
Net loss per share:					
Net loss per share:	**Net loss per share:**				
Basic and diluted	Basic and diluted	$ (0.43)	$ (0.32)	$ (1.34)	$ (1.09)
Basic and diluted					
Basic and diluted					

The following potentially dilutive securities have been excluded from diluted net loss per share as of September 30, 2023 March 31, 2024 and 2022 2023 because their effect would be antidilutive:

		Three and Nine Months Ended September 30,	
		2023	2022
	Three Months Ended March 31,		
	2024		
Shares of common stock subject to outstanding options	Shares of common stock subject to outstanding options	3,167,977	3,116,421
Shares of common stock subject to outstanding common stock warrants	Shares of common stock subject to outstanding common stock warrants	—	3,132
Restricted stock units	Restricted stock units	4,977,616	3,077,633
Restricted stock units			
Restricted stock units			
Total common stock equivalents	Total common stock equivalents	8,145,593	6,197,186

	Three Months Ended March 31,	
	2024	2023

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.

Table of Contents

The following tables set table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023 (in thousands):

	March 31, 2024			
	Fair Value Measured Using			
	(Level 1)			
Assets				
Cash equivalents:				
Money market funds				
Money market funds				
Money market funds				
Total				

	September 30, 2023			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	$54,405	$ —	$ —	$54,405
Long-term marketable securities:				
Corporate equity securities	992	—	—	992
Total				
Total	$55,397	$ —	$ —	$55,397
Liabilities				
Short-term liabilities:				
Short-term liabilities:				
Short-term liabilities:				
Contingent consideration				
Contingent consideration				

	March 31, 2024			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Contingent consideration				
Contingent consideration	$ —	$ —	$2,083	$ 2,083
Long-term liabilities:				
Contingent consideration	—	—	4,735	4,735
Contingent consideration				
Contingent consideration				

Total	Total	$ —	$ —	$6,818	$ 6,818
Total					
Total					

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

Table of Contents

	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)
Common Stock Warrant Liability and Contingent Consideration	
Balance as of December 31, 2022 December 31, 2023	$ 3,475 7,930
Change in estimated fair value of contingent consideration on business combination	319 1,731
Addition of Change in estimated fair value of contingent consideration on asset acquisition	(226) 2,269
Payments related to contingent consideration	(625)
Balance as of September 30, 2023 March 31, 2024	$ 6,818 7,398

Table of Contents

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, to monitoring and/or to remote monitoring in the field of human organ allotrasplantation, 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 in Miromatrix and recorded as other income (expense), net at December 31, 2023. There was no outstanding investment with Miromatrix as of March 31, 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 September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *Long-term marketable equity and debt securities* – Investments in long-term marketable equity securities are classified within Level 1. The securities are recorded at fair value based on readily available quoted market prices in active markets. Investments in long-term marketable debt securities are classified within Level 2. The securities are recorded at fair value based on observable inputs for quoted prices for identical or similar assets in markets that are not active. Long-term marketable securities are located within other assets on the condensed consolidated balance sheets.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met based on management’s

Table of Contents

estimate of the probability of success and projected revenues for revenue-based considerations at discounted rates ranging from 7% to 12% at September 30, 2023 and 12% at December 31, 2022 March 31, 2024 and from 6% and 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 result 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.

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

Table of Contents

5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

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

		September 30, 2023	September 30, 2022
March 31, 2024		March 31, 2024	March 31, 2023
Cash and cash equivalents	Cash and cash equivalents	$75,980	$82,959
Restricted cash	Restricted cash	582	198

Total cash, cash equivalents and restricted cash at the end of the period	Total cash, cash equivalents and restricted cash at the end of the period	$76,562	$83,157

Marketable Securities

All short-term marketable securities were considered held-to-maturity at September 30, 2023 March 31, 2024. At September 30, 2023 March 31, 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, thus there 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 as of September 30, 2023 at March 31, 2024. All short-term marketable securities with unrealized losses as of the balance sheet date have been in a loss position for less than twelve months. Contractual maturities of the short-term marketable securities were within one year or less.

The long-term marketable equity securities were recorded at fair market value with changes in the fair value recognized in earnings at September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023. The long-term marketable debt securities were considered available-for-sale at September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023. The contractual maturities maturity of the long-term marketable debt securities are between one and less than three years.

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

	March 31, 2024			March 31, 2024
	Amortized Cost	Amortized Cost	Unrealized Holding Gains, Net	Fair Value
Short-term marketable securities:				
U.S. agency securities				
U.S. agency securities				
U.S. agency securities				
Corporate debt securities				
Total short-term marketable securities				

	September 30, 2023		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term marketable securities:			
U.S. agency securities	$ 100,306	$ 1,991	$102,297
Corporate debt securities	91,898	584	92,482

Total short-term marketable securities	192,204	2,575	194,779
Long-term marketable securities:			
Corporate equity securities	5,100	(4,108)	992
Total long-term marketable securities	5,100	(4,108)	992
Total	$ 197,304	$ (1,533)	$195,771

	December 31, 2023		
	Amortized Cost	Unrealized Holding Gains, Net	Fair Value
Short-term marketable securities:			
U.S. agency securities			
U.S. agency securities			
U.S. agency securities			
Corporate debt securities			
Total short-term marketable securities			

	December 31, 2022		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term marketable securities:			
U.S. agency securities	$ 79,347	$ 452	$ 79,799
Corporate debt securities	123,821	(220)	123,601
Total short-term marketable securities	203,168	232	203,400

Long-term marketable securities:			
Corporate equity securities	5,000	(2,924)	2,076
Total long-term marketable securities	5,000	(2,924)	2,076
Total	$ 208,168	$ (2,692)	$205,476

Table of Contents

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 statement of operations.

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

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

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

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

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

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

The pro forma impact of the HLA Data Systems acquisition is not material, and the results of operations of the acquisition have has been included in the Company's condensed consolidated statements of operations from the respective 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 statement 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

Table of Contents

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	$ 2,020	

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 and the provisional amounts (provisional amount) of the assets acquired and liabilities assumed recognized at their estimated fair value at the acquisition date (in thousands):

	Total
Consideration	
Cash	$ 6,682
Total consideration	$ 6,682
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	4,036
Goodwill	2,646
Total consideration	$ 6,682

The preliminary 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

Table of Contents

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.

Table of Contents

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 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. The Company identified an indicator There were no indicators of goodwill impairment in the three and nine months ended September 30, 2023 March 31, 2024. The balance of the Company's goodwill was $40.2 $40.3 million as of September 30, 2023 March 31, 2024 and $37.5 million as of December 31, 2022 December 31, 2023.

Goodwill Impairment

The Company assessed the current and future economic outlook as of September 30, 2023 for its single reporting unit and the Company experienced a sustained decrease in its share price, an indicator for impairment of goodwill. The evaluation began with a qualitative assessment to determine if it was more likely than not that the fair value of the reporting unit was less than its carrying value. The qualitative assessment did not indicate that it was more likely than not that the fair value exceeded the carrying value, which led to a quantitative assessment.

The Company estimated the fair value of its reporting unit using a combination of the income and market approaches. In performing the goodwill impairment test, the Company used an exit multiple given the development phase of the Company and a discount rate of 16.4% in its estimation of fair value. The evaluation performed resulted in no impairment as of September 30, 2023.

Intangible Assets

The following table presents details of the Company's intangible assets as of September 30, 2023 ($ in thousands):

	September 30, 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	$ (17,529)	$ (2,560)	$ 17,278	7.4
Customer relationships	25,718	(8,663)	(2,334)	14,721	9.5
Commercialization rights	11,578	(4,180)	—	7,398	5.8
Trademarks and tradenames	5,220	(1,617)	(356)	3,247	9.6
Total intangible assets with finite lives	79,883	(31,989)	(5,250)	42,644	
Intangible assets with indefinite lives:					
Acquired in-process technology	1,250	—	—	1,250	
Favorable license agreement	2,561	—	—	2,561	
Total intangible assets with indefinite lives	3,811	—	—	3,811	
Total intangible assets	$ 83,694	$ (31,989)	$ (5,250)	$ 46,455	

Table of Contents

The following table presents details of the Company's intangible assets as of December 31, 2022 March 31, 2024 ($ in thousands):

	December 31, 2022				
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
March 31, 2024					

	Gross Carrying Amount						Gross Carrying Amount		Accumulated Amortization		For Curr Trans		
Intangible assets with finite lives:	**Intangible assets with finite lives:**												
Acquired and developed technology													
Acquired and developed technology													
Acquired and developed technology	Acquired and developed technology	$35,747	$ (15,138)	$ (2,369)	$18,240	7.5	$ 37,367	$	$ (19,158)	$	$ (2,459)	$	$
Customer relationships	Customer relationships	21,898	(7,459)	(2,104)	12,335	9.0	Customer relationships	25,718	(9,518)	(9,518)	(2,213)	(2,213)	13
Commercialization rights	Commercialization rights	11,579	(3,233)	—	8,346	6.6	Commercialization rights	11,579	(4,812)	(4,812)	—	—	6
Trademarks and tradenames	Trademarks and tradenames	4,540	(1,345)	(315)	2,880	8.5	Trademarks and tradenames	5,220	(1,809)	(1,809)	(335)	(335)	3
Total intangible assets with finite lives	**Total intangible assets with finite lives**	73,764	(27,175)	(4,788)	41,801								
Total intangible assets with finite lives													
Total intangible assets with finite lives													
Intangible assets with indefinite lives:													
Intangible assets with indefinite lives:													
Intangible assets with indefinite lives:													
Acquired in-process technology	Acquired in-process technology	1,250	—	—	1,250								
Acquired in-process technology													
Acquired in-process technology													
Favorable license agreement													
Favorable license agreement													
Favorable license agreement													
Total intangible assets with indefinite lives													
Total intangible assets with indefinite lives													
Total intangible assets with indefinite lives													
Total intangible assets	**Total intangible assets**	$75,014	$ (27,175)	$ (4,788)	$43,051								
Total intangible assets													
Total intangible assets													

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

Table of Contents

	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 intangible assets are included in Acquired and developed technology, Customer relationships and Trademarks and tradenames as of September 30, 2023 March 31, 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 September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Cost of testing services					
Cost of testing services					
Cost of testing services	Cost of testing services	$ 329	$ 329	$ 987	$ 987
Cost of product	Cost of product	408	415	1,242	1,305
Cost of product					
Cost of product					
Cost of patient and digital solutions					
Cost of patient and digital solutions					
Cost of patient and digital solutions	Cost of patient and digital solutions	265	237	768	709
Sales and marketing	Sales and marketing	616	554	1,817	1,702
Sales and marketing					
Sales and marketing					
Total	Total	$ 1,618	$ 1,535	$ 4,814	$ 4,703
Total					
Total					

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2023 March 31, 2024 (in thousands):

Years Ending December 31,	Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Patient and Digital Solutions	Sales and Marketing	Total	Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Patient and Digital Solutions	Sales and Marketing	Total
Remainder of 2023		$ 329	$ 405	$ 271	$ 634	$ 1,639						
2024		1,316	1,621	850	2,494	6,281						
Remainder of 2024												
2025	2025	1,316	1,621	681	2,494	6,112						
2026	2026	1,316	732	681	2,492	5,221						
2027	2027	1,316	732	681	2,478	5,207						
2028												
Thereafter	Thereafter	2,825	3,260	2,142	9,957	18,184						
Total future amortization expense	Total future amortization expense	$8,418	$8,371	$ 5,306	$20,549	$42,644						

Table of Contents

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
March 31, 2024		
Finished goods	$ 3,173	$ 2,962
Work in progress	4,939	4,306
Raw materials	9,866	11,964
Total inventory	$17,978	$19,232

Accrued and Other Liabilities

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

	September 30, 2023	December 31, 2022
March 31, 2024		
Clinical studies	$14,677	$14,816
Short-term lease liability		
Contingent consideration		
Professional fees	11,134	6,115
Short-term lease liability	5,958	5,591
Deferred revenue	5,766	5,342

Laboratory processing fees and materials	Laboratory processing fees and materials	2,241	2,189
Contingent consideration		2,083	1,025
Deferred payments for intangible assets			
Travel and expenses			
Accrued shipping expenses			
Accrued royalty	Accrued royalty	1,793	4,633
Deferred payments for intangible assets		920	2,062
Accrued shipping expenses		370	489
License and other collaboration fees	License and other collaboration fees	212	1,000
Capital expenditures	Capital expenditures	—	1,316
Other accrued expenses	Other accrued expenses	1,884	4,553
Total accrued and other liabilities	Total accrued and other liabilities	$47,038	$49,131

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 September 30, 2023 March 31, 2024, the carrying value of the ROU asset was $31.0 million $28.6 million. The related current and non-current liabilities as of September 30, 2023 March 31, 2024 were $6.0 million $6.1 million and $29.3 million $26.9 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the condensed consolidated balance sheets.

The following table summarizes the lease cost for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	2024			
	2024			
	2024			

Operating lease cost					
Operating lease cost					
Operating lease cost	Operating lease cost	$ 1,981	$ 1,955	$ 5,936	$ 4,740
Total lease cost	Total lease cost	$ 1,981	$ 1,955	$ 5,936	$ 4,740
Total lease cost					
Total lease cost					

Table of Contents

	September 30, 2023	December 31, 2022
Other information:		
Weighted-average remaining lease term (in years)	5.63	6.26
Weighted-average discount rate (%)	7.1 %	7.1 %

	March 31, 2024	December 31, 2023
Other information:		
Weighted-average remaining lease term - Operating leases (in years)	5.21	5.43
Weighted-average discount rate - Operating leases (%)	7.1 %	7.1 %

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

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

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

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

	September 30, 2023	December 31, 2022
ROU assets	$ 12,897	$ 14,321
Lease liabilities	$ 13,915	$ 15,302

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

	September 30, 2023	December 31, 2022
ROU assets	$ 5,465	$ 5,814
Lease liabilities	$ 5,732	$ 6,005

Maturities of operating lease liabilities as of September 30, 2023 March 31, 2024 are as follows (in thousands):

Years Ending December 31,	Years Ending December 31,	Operating Leases
Remainder of 2023		$ 2,024
2024		7,955
Years Ending December 31,		
Years Ending December 31,		**Operating Leases**
Remainder of 2024		
2025	2025	7,706

2026	2026	7,019
2027	2027	7,166
2028		
Thereafter	Thereafter	10,604
Total lease payments	Total lease payments	42,474
Less imputed interest	Less imputed interest	7,264
Present value of future minimum lease payments	Present value of future minimum lease payments	35,210
Less operating lease liability, current portion	Less operating lease liability, current portion	5,958
Operating lease liability, long-term portion	Operating lease liability, long-term portion	$29,252

Table 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 Contents
$2.6 million base rent for the duration of the contract.

The following table summarizes the supplemental cash flow information related to leases for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Cash paid for amounts included in the measurement of lease liabilities					
Cash paid for amounts included in the measurement of lease liabilities					
Cash paid for amounts included in the measurement of lease liabilities	**Cash paid for amounts included in the measurement of lease liabilities**				
Operating cash flows used for operating leases	Operating cash flows used for operating leases	$ 1,172	$ 822	$ 3,871	$ 2,746

Operating cash flows used for operating leases	
Operating cash flows used for operating leases	

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 our the Company's petition for review was denied, the Stanford License automatically terminated, and in December 2023, the Company will be required to pay to 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 March 31, 2024.

Illumina

Table of Contents

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 low-double digits on sales of products covered by the Illumina Agreement.

Other Royalty Commitment

Effective as of August 9, 2023, 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.

Cibiltech Commitments

Pursuant to that certain license and commercialization agreement that the Company entered into with Cibiltech, effective April 30, 2019, the Company will share an agreed-upon percentage of revenue with Cibiltech, if and when revenues are generated from iBox.

In July 2023, the Company entered into a settlement agreement with Cibiltech (the "Settlement Agreement"), pursuant to which the Company agreed to pay a certain amount of its obligation owed to Cibiltech. A judicial court in Paris, France, granted the liquidation of Cibiltech, which filed for bankruptcy. In the Settlement Agreement, Cibiltech irrevocably waived and relinquished any and all claims, demands, grievances, proceeding, actions or other requests, whether judicial, administrative, arbitral or otherwise, against the Company. The outstanding obligation of the Company with Cibiltech was waived and relinquished, except for $0.4 million, which was paid in July 2023, and represented the amount that the Company agreed to per the Settlement Agreement. There is no outstanding obligation as of September 30, 2023.

Other Commitments

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

Table Effective as of Contents

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

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 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 case 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 may also move for injunctive relief. The Company is ongoing. 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 CareDx did not infringe Natera's U.S. Patent 10,655,180. The Company intends to defend both of these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company has not recorded any recognized the damages of $96.3 million as other liabilities for these suits. on the consolidated balance sheets as of March 31, 2024 and December 31, 2023.

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

Table of Contents

As previously disclosed, in 2021, the Company received a civil investigative demand ("CID") from the United States Department of Justice ("DOJ") requesting that the Company produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to the Company's kidney testing and phlebotomy services, and a subpoena from the United States Securities and Exchange Commission (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 are 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.

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.

Olymbios Matter

On April 15, 2022, a complaint was filed by Michael Olymbios against the Company in the Superior Court of the State of California for the County of San Mateo (the "San Mateo County Court"). The complaint alleges alleged that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olymbios, and that the Company has defamed

Table of Contents

Dr. Olymbios. Dr. Olymbios also seeks sought to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olymbios. 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. Olymbios filed a motion to withdraw from arbitration before Judicial Arbitration and Mediation Services, Inc., which was denied on August 18, 2022. The Both the arbitration and the San Mateo County Court matter is currently proceeding in arbitration. The Company intends to vigorously pursue its arbitration proceeding against Dr. Olymbios and to vigorously defend itself against Dr. Olymbios' claims. The Company believes it has good and substantial support for its claims and good and substantial defenses to the claims alleged were settled in the suit by Dr. Olymbios, but there is no guarantee that the Company will prevail if the case continues. The fourth quarter of 2023 and have been resolvedCompany has not recorded any liabilities for this suit. .

Securities Class Action

On May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action in the U.S. District Court for the Northern District of California against the Company, Reginald Seeto, its 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,

Table of Contents

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

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

On February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra and other current and former members of the Company's Board of Directors (the "Stevenson Derivative Action"). The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff

Table of Contents

alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by the Company as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

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 the Company as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of the Company's Board of Directors (the "Jacobsen Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company, violated Section 14(a) of the Exchange Act, are liable for contribution under Sections 10(b) and 21(D) of the Exchange Act, engaged in unjust enrichment, waste of corporate assets, aiding and abetting, insider trading, and misappropriation of information, and/or are liable for indemnification. The suit seeks declaratory relief, disgorgement, and to recover alleged damages sustained by the Company as a result of the alleged violations, along with plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. On March 20, 2024, the court determined that the Jacobsen Derivative Action is related to the consolidated derivative action.

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

On March 20, 2024, Edward W. Burns IRA filed a joint status statement with stockholder derivative action complaint in the Court of Chancery of the State of Delaware against us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of our 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 on September 6, 2023 entered an order staying the Burns Derivative Action pursuant to a stipulation filed by the parties.

Table of Contents

On May 2, 2024, the court in the consolidated derivative action ordered that the stay of the consolidated derivative action will be lifted as of May 16, 2024.

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

Insurance Matter

In December 2022, the Company filed a lawsuit against its Directors directors and Officers 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. The parties have completed briefing on the Company's entitlement to coverage under the policies and are awaiting a decision from the Court.

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 $0.2 million $1.6 million and $0.3 million $0.7 million for the three months ended September 30, 2023 March 31, 2024 and 2022, respectively. The Company incurred expenses related to contributions to the 401(k) Plan of $1.4 million and $1.5 million for the nine months ended September 30, 2023 and 2022, 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 paid-in capital and not remeasured.

In the three months ended September 30, 2023, no warrants to purchase shares of common stock were exercised. In the nine months ended September 30, 2023, warrants to purchase approximately 3,000 shares of common stock were exercised for cash proceeds of $4,000.

In the three and nine months ended September 30, 2022, no warrants to purchase shares of common stock were exercised.

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

Table of Contents

12. STOCK INCENTIVE PLANS

Stock Options and Restricted Stock Units ("RSU")

The following table summarizes option and RSU activity under the Company's 2014 Equity Incentive Plan, 2016 Inducement Equity Incentive Plan and 2019 Inducement Equity Incentive Plan, and related information:

	Shares Available for Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Number of RSU Shares	Weighted-Average Grant Date Fair Value
Balance—December 31, 2022	1,490,462	2,921,925	$ 28.13	3,094,396	$ 37.39

	Shares Available for Grant	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						
Additional shares authorized	Additional shares authorized	2,141,330	—	—	—	—
Common stock awards for services	Common stock awards for services	(15,809)	—	—	—	—
RSUs granted	RSUs granted	(3,461,674)	—	—	3,461,674	11.11

RSUs vested	RSUs vested	—	—	—	(815,374)	35.90
Options granted	Options granted	(680,788)	680,788	12.60	—	—
Options exercised	Options exercised	—	(23,203)	4.59	—	—
Repurchase of common stock under employee incentive plans	Repurchase of common stock under employee incentive plans	265,953	—	—	—	—
RSUs forfeited	RSUs forfeited	761,771	—	—	(761,771)	24.67
Options forfeited	Options forfeited	178,830	(178,830)	27.61	—	—
Options expired	Options expired	236,645	(236,645)	26.93	—	—
Balance—September 30, 2023		916,720	3,164,035	$ 25.18	4,978,925	$ 21.24
Balance—March 31, 2024						

The total intrinsic value of options exercised was $74,000 and $0.1 million less than $0.1 million for each of the three and nine months ended September 30, 2023, respectively. The total intrinsic value of options exercised was $0.1 million March 31, 2024 and $1.3 million for the three and nine months ended September 30, 2022, respectively. 2023.

As of September 30, 2023 March 31, 2024, the total intrinsic value of outstanding RSUs was approximately $35.8 million $78.5 million and there were $63.6 million $63.9 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.51 2.28 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 472,116 as of March 31, 2024 and 2023, respectively. The weighted-average remaining recognition period was 0.84 years and 1.74 years for the three months ended March 31, 2024 and 2023, respectively.

Options outstanding that have vested and are expected to vest at September 30, 2023 March 31, 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)
	Number of Shares Issued (In thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	Vested 1,620	$ 26.60	6.48	$ 399
Expected to vest	Expected to vest 1,378	23.50	8.84	—
Total	Total 2,998			$ 399

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at September 30, 2023 March 31, 2024 for stock options that were in-the-money.

The total fair value of options that vested during the three and nine months ended September 30, 2023 March 31, 2024 was $3.2 million and $15.6 million, respectively. $3.7 million. As of September 30, 2023 March 31, 2024, there were approximately $20.4 million $14.7 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.40 2.11 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 2023 that ended on June 30, 2023, 143,817 shares were purchased pursuant to the ESPP for aggregate proceeds of $1.0 million from the issuance of such shares, which occurred on July 6, 2023.

Table of Contents

During the offering period in 2022 2023 that ended on December 31, 2022 December 31, 2023, 47,025 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, 2023 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 September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Employee stock options					
Employee stock options					
Employee stock options	**Employee stock options**				
Expected term (in years)	Expected term (in years)	N/A	6.0	5.6	6.0
Expected term (in years)					
Expected term (in years)					
Expected volatility					
Expected volatility					
Expected volatility	Expected volatility	N/A	78.29%	77.86%	77.58%
Risk-free interest rate	Risk-free interest rate	N/A	2.99%	3.67%	2.69%
Risk-free interest rate					
Risk-free interest rate					
Expected dividend yield					
Expected dividend yield					
Expected dividend yield	Expected dividend yield	N/A	—%	—%	—%
Employee stock purchase plan	**Employee stock purchase plan**				
Employee stock purchase plan					
Employee stock purchase plan					
Expected term (in years)					
Expected term (in years)					
Expected term (in years)	Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	Expected volatility	93.38%	91.16%	93.38%	74.66%
Expected volatility					
Expected volatility					
Risk-free interest rate					
Risk-free interest rate					
Risk-free interest rate	Risk-free interest rate	5.53%	3.92%	5.49%	2.92%
Expected dividend yield	Expected dividend yield	—%	—%	—%	—%

Expected dividend yield

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

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense relating to employee and non-employee stock-based awards for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, included in the condensed consolidated statements of operations as follows (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Cost of testing services					
Cost of testing services					
Cost of testing services	Cost of testing services	$ 496	$ 470	$ 1,467	$ 1,055
Cost of product	Cost of product	301	321	935	851
Cost of product					
Cost of product					
Cost of patient and digital solutions					
Cost of patient and digital solutions					
Cost of patient and digital solutions	Cost of patient and digital solutions	297	299	1,066	882
Research and development	Research and development	1,491	2,058	5,157	6,571
Research and development					
Research and development					
Sales and marketing					
Sales and marketing					
Sales and marketing	Sales and marketing	3,041	2,672	9,557	9,702
General and administrative	General and administrative	7,045	5,380	20,943	15,366
General and administrative					
General and administrative					
Total	Total	$ 12,671	$ 11,200	$ 39,125	$ 34,427
Total					
Total					

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.

Table of Contents

For the three months ended March 31, 2024 and 2023, the Company recorded an income tax benefit of $0.1 million and an income tax expense of $0.1 million, respectively. The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative,

Table of Contents

including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income, and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. consolidated net deferred tax assets. The Company has also placed a valuation allowance on the net deferred tax assets of its Sweden operations. Accordingly, the U.S. and Sweden net deferred tax assets have been offset by a full valuation allowance.

For the three and nine months ended September 30, 2023, the Company recorded an income tax benefit of $80,000 and $24,000, respectively. For the three and nine months ended September 30, 2022, the Company recorded an income tax expense of $0.3 million and $0.2 million, respectively. The income tax benefit of $80,000 and $24,000 for the three and nine months ended September 30, 2023, respectively, is primarily attributable to the U.S. current tax benefit resulting from the recently filed 2022 income tax returns and a U.S. deferred tax benefit resulting from the acquisition of MediGO in July 2023.

Table of Contents

14. SEGMENT REPORTING

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

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

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
Testing services revenue					
Testing services revenue					
Testing services revenue	**Testing services revenue**				
United States	United States	$ 47,644	$ 64,547	$ 162,560	$ 197,675
United States					
United States					
Rest of World	Rest of World	140	204	422	655
		$ 47,784	$ 64,751	$ 162,982	$ 198,330
Rest of World					
Rest of World					
		$			
		$			
		$			
Product revenue					

Product revenue					
Product revenue	**Product revenue**				
United States	United States	$ 5,810	$ 4,245	$ 13,857	$ 11,435
United States					
United States					
Europe					
Europe					
Europe	Europe	2,437	2,262	7,430	6,887
Rest of World	Rest of World	1,289	687	2,986	2,374
		$ 9,536	$ 7,194	$ 24,273	$ 20,696
Rest of World					
Rest of World					
		$			
		$			
		$			
Patient and digital solutions revenue					
Patient and digital solutions revenue					
Patient and digital solutions revenue	**Patient and digital solutions revenue**				
United States	United States	$ 9,735	$ 7,187	$ 27,130	$ 19,865
United States					
United States					
Europe					
Europe					
Europe	Europe	34	209	239	429
Rest of World	Rest of World	103	18	131	89
Rest of World					
Rest of World					
		$			
		$			
		$			
		$ 9,872	$ 7,414	$ 27,500	$ 20,383
Total United States					
Total United States					
Total United States	Total United States	$ 63,189	$ 75,979	$ 203,547	$ 228,975
Total Europe	Total Europe	$ 2,471	$ 2,471	$ 7,669	$ 7,316
Total Europe					
Total Europe					
Total Rest of World					
Total Rest of World					
Total Rest of World	Total Rest of World	$ 1,532	$ 909	$ 3,539	$ 3,118
Total	Total	$ 67,192	$ 79,359	$ 214,755	$ 239,409
Total					
Total					

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

		September 30, 2023	December 31, 2022
March 31, 2024			
March 31, 2024			December 31, 2023
Long-lived assets:	Long-lived assets:		
United States	United States		
United States	United States	$34,815	$35,020
Europe	Europe	471	405
Rest of World	Rest of World	69	104
Total	Total	$35,355	$35,529

Table of Contents

15. RESTRUCTURING

In January 2023, the Company announced a restructuring plan that is intended to optimize costs and simplify its organizational and corporate structure. The restructuring plan includes the discontinuation of the Company's operations at one of its two locations in Fremantle, Australia, terminating its employees in that location and vacating its facilities there. The Company incurred immaterial restructuring charges for each of the three and nine months ended September 30, 2023. Australia. The Company expects to complete the closure of its Australia the affected location in June 2024. The Company incurred immaterial restructuring charges for the three months ended March 31, 2024.

In May and December 2023, the Company announced a reduction of its U.S. workforce to simplify and streamline its organization and strengthen the overall effectiveness of its operations. The restructuring charges are primarily related to employee severance pay and related costs. As a result of this plan, the Company incurred $0.8 $2.2 million in restructuring charges for the three months year ended June 30, 2023 December 31, 2023. The Company did not incur any restructuring charges related to this plan in the three months ended September 30, 2023 March 31, 2024.

Table of Contents

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included elsewhere in Item 1 of Part I of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023, filed with the Securities and Exchange Commission, or the SEC, on February 27, 2023 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 continue and expand reimbursement coverage from payers for our current and other future testing services, if any, including with respect to AlloSure Kidney; 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, including Kidney Allograft Outcomes AlloSure Registry, or K-OAR, the Outcomes of KidneyCare™ on Renal Allografts registry study, or OKRA, and the Surveillance HeartCare Outcomes Registry, or SHORE; 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 plans with respect to certain future Medicare reimbursement submissions;
- our ability to remediate the material weaknesses in our internal control over financial reporting as of December 31, 2022 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

Table of Contents

year ended December 31, 2022 December 31, 2023, filed with the SEC on February 27, 2023 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

Table of Contents

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 healthcare solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients.

Highlights for the Three Months Ended September 30, 2023 March 31, 2024

- Reported first quarter revenue of $67.2 million $72.0 million.
- Revenue for Testing Services of $53.8 million, an increase of 7% over 15% as compared to the second fourth quarter of 2023, excluding approximately $7.8 million related to Medicare claims billing that were held over from the first quarter of 2023 and recognized in second quarter 2023 revenue. 2023.
- Grew Testing Services patient testing services patients results for the third consecutive quarter to 38,400, approximately 42,000, an increase of 2% 6% as compared to the second fourth quarter of 2023.
- Achieved Over 30 oral presentations, posters and two symposia highlighting CareDx's scientific advancements in heart and lung transplantation presented at the International Society for Heart and Lung Transplantation (ISHLT).
- SHORE data presented at ISHLT demonstrated that HeartCare® multimodal testing outperforms donor-derived cell-free DNA (dd-cfDNA) testing alone in identifying allograft rejection.
- Expanded payer coverage by 14 million lives nationwide.
- Reported first quarter revenue of $9.9 million $9.6 million for Patient and Digital Solutions and $9.5 million $8.6 million for Products, representing year-over-year growth of 33% for both businesses. 12% and 25%, respectively.

- Achieved Ended the fourth consecutive quarter of collections at over 100% of revenue for Testing Services; collected over $22 million in incremental with cash, in the past four quarters.
- Maintained a strong balance sheet, with $268.2 million in cash and cash equivalents, and marketable securities of approximately $216 million, with no debt.
- Received Medicare coverage for HeartCare™ and AlloSure® Lung.
- Raised revenue guidance to $274 to $278 million for the full year 2023.
- SEC has concluded its inquiry and does not intend to recommend an enforcement action against the Company.

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 built on a next generation sequencing, or NGS, platform. offering. In transplantation, more than 100 papers there is well-established literature from over 50studies globally have shown 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 between donor and recipient. This single nucleotide polymorphism, or SNP, in the DNA with an approach across all the somatic chromosomes is specifically designed for transplantation allowing a scalable, high-quality test to differentiate dd-cfDNA.

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

Table of Contents

On March 2, 2023, In March and May 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Article. Prior to the Billing Article's effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article would not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new Rejection. The billing article with an effective date of March 31, 2023, issued in May 2023, or the Revised Billing Article, and together with the Billing Article, billing article issued in March 2023, the Billing Articles. The Revised Billing Article impacts Articles, impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, and AlloMap Heart and requires AlloSure Lung, and required certain companies, including CareDx, us, to implement new processes to address the requirements

Table of Contents

related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts. MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

Although we believeOn August 10, 2023, MolDX and Noridian released a draft proposed revision to the Billing Articles are inconsistent with LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the LCDs, Noridian's existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and MolDX's responses L38629).On August 14, 2023, MolDX released a draft billing article (DA58019) to public comments explaining accompany the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate proposed draft LCD, which generally reflected the implications of changes in coverage included in the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update CareDx's test order forms to capture the new information required under the Revised Billing Article. Accordingly, we did not submit claims The comment period end date for approximately 3,200 AlloSure Kidney tests for Medicare reimbursement for this proposed LCD was September 23, 2023. We presented at public meetings regarding the period from March 7, 2023 through March 31, 2023 proposed draft LCD held on September 18, 2023 and did not recognize revenue September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on these claims in the first quarter of 2023 aggregating to approximately $8.9 million, or the Impacted March Tests. proposed draft LCD.

On May 18, 2023 February 29, 2024, we submitted MolDX and Noridian released a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles imposed new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we planned to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters revised version of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023.

We have certain unbilled AlloSure Kidney claims with a service date after March 31, 2023, where the reason for testing is not specified by the ordering physician. We are in the process of supplementation for these tests. If these AlloSure Kidney tests are within the parameters of the Revised Billing Article, we will bill and would expect to recognize revenue in the quarter that the supplementation is completed.

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

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long-term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated. AlloSure Kidney provides a non-invasive test, assessing allograft injury that enables more frequent, quantitative and safer assessment of allograft rejection and injury status. Beyond allograft rejection, the assessment of molecular inflammation has shown further utility in the assessment of proteinuria, the formation of De Novo donor specific antibodies, or DSAs, and as a surrogate predictive measure of estimated glomerular filtration rate, or eGFR, decline. Monitoring of graft injury through AlloSure Kidney allows clinicians to optimize allograft biopsies, identify allograft injury and guide immunosuppression management more accurately.

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016, before the commercial launch of AlloSure Kidney, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Bloom et al. evaluated 102 kidney recipients and demonstrated that dd-cfDNA levels could discriminate accurately and non-invasively distinguish rejection from other types of graft injury. In contrast, serum creatinine has area under the curve of 50%, showing no significant difference between patients with and without rejection. Multiple publications and abstracts have shown AlloSure Kidney's value in the management of BK viremia, as well as numerous pathologies that cause molecular inflammation and injury such as DSAs and eGFR decline. Most recently, its utility in the

Table of Contents

assessment of T-cell mediated rejection, or TCMR, 1A clinical and borderline sub-clinical rejection, was published evaluated in the American Journal of Transplant, or the AJT, and the outcomes of over 1,000 patients were and published in Kidney International.

The prospective multicenter trial, or the K-OAR study, has enrolled completed with over 1,700 1,900 patients with plans to survey enrolled, monitors patients with AlloSure Kidney for 3 years and provide 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 not yet made 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 into the study. 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 heart transplant recipients, 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. The Revised Billing Article impacts Medicare coverage for AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, though acknowledged that the Billing Article is a change as to its previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. As previously discussed, Noridian has not adopted the Billing Articles. We continued the Medicare reimbursement submissions for AlloMap Heart following the issuance of the new Billing Articles. In addition, we informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, we would continue to submit AlloMap Heart tests for reimbursement only when used in conjunction with AlloSure Heart. We also informed Noridian on May 18, 2023 that (i) until June 30, 2023, we planned to submit claims for reimbursement for AlloMap Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers. On August 28, 2023, we informed Noridian that beginning on August 17, 2023 when they publicized the adoption of the Billing Article, we would submit Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant; and for Heart tests performed on or after August 17, 2023 that are outside the parameters of the Revised Billing Article, certain billing codes will be used to enable any additional review deemed appropriate by Noridian and potential appeal by us of the denied claims.

In October 2020, we received a final Palmetto MolDX Medicare coverage decision for AlloSure

Table of Contents

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 common policy LCD is titled “MolDX: Molecular Testing for Solid Organ Allograft Rejection” and

Table of Contents

the associated LCD numbers are L38568 (MolDX) and L38629 (Noridian).The Medicare reimbursement rate for AlloSure Heart is currently $2,753. $2,753The Revised Billing Article impacts Medicare. 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 and requires certain companies, including CareDx, to implement new processes to address requirements related to Medicare claim submissions. We continued the Medicare reimbursement submissions for dd-cfDNA in a routine, clinical surveillance setting with heart transplant recipients. The D-OAR study validated that plasma levels of AlloSure Heart following the issuance of the Billing Articles. In addition, we informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, we would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart. We also informed Noridian on May 18, 2023 that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloSure Heart tests for which we have not obtained additional information dd-cfDNA can discriminate acute rejection from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified no rejection, as determined by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without confirming whether they meet the Revised Billing Article’s parameters, there is a risk that any reimbursement of such claims are subject to forfeiture. 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.

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

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, acute cellular rejection and antibody mediated rejection. In September 2018, we initiated the SHORE study. SHORE is 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 most recent ISHLT guidelines published online in 2022 reinforced their 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 subject to certain limitations, for Medicare beneficiaries through the MolDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is $5,993.

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is was undergoing further studies. One of these studies, launched in April 2020, is was the ALARM study, or AlloSure Lung Allograft Remote Monitoring, with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC is being 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 as part of the CHEST 2021 Annual Meeting. Lung. We have gained early adoption coverage with some commercial payers. 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.

Table of Contents

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

Table of Contents

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

Our historical product portfolio includes AlloSeq Tx, QTYPE, Olerup SSP, AlloSeq HCT, and Olerup SSP. 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.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, Inc., or Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS products and technologies for use in transplantation diagnostic testing.

On June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA was discontinued in December 2021 and we have progressively converted existing customers to AlloSeq. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These Our NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, solution; AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, recipients; and AlloSeq HCT, a an NGS solution for chimerism testing for stem cell transplant recipients.

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we We received CE mark authorization on January 10, 2020. 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.

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

In June 2020, we commercially launched AlloSeq HCT, a 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 March 2021, we acquired certain assets of BFS Molecular S.R.L., or BFS Molecular, a software company focused on NGS-based patient testing solutions. BFS Molecular brings extensive software and algorithm development capabilities for NGS transplant surveillance products.

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

In 2023, we continue continued to develop 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 Inc., or Ottr, and XynManagement, Inc., or XynManagement.

On May 7, 2019, 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

Table of Contents

transplant patient management. The Ottr software enables integration with electronic medical records, or EMR, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

On August 26, 2019, 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, LLC, or TransChart. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Access, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs 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 the first transplant-specific dd-cfDNA assay, with large transplant databases to provide clinical

data solutions. databases. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

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

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

Table of Contents

In January 2023, we acquired HLA Data Systems LLC, or 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, Inc., or 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, product products sales, and patient and digital solutions revenues. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

Our testing services revenue is derived from AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung tests, which represented 71% and 76% 75% of our total revenue for the three and nine months ended September 30, 2023, respectively, March 31, 2024 and 82% and 83% 80% of our total revenue for the three and nine months ended September 30, 2022, respectively. March 31, 2023. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; and (v) how quickly we can successfully commercialize new product offerings.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a LCD first issued by MolDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and adopted by Noridian. The Medicare reimbursement rate for AlloSure Kidney is currently $2,841. AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently

Table of Contents

$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.

On March 2, 2023, MolDX issued the Billing Article, with an effective date of March 31, 2023. Prior to the Billing Article’s effective date, MolDX informed the affected parties, including CareDx, that enforcement of the revised billing practices outlined in the Billing Article would not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued the Revised Billing Article. The Revised Billing Article impacts Medicare coverage for AlloSure Kidney, AlloSure Heart and AlloMap Heart and requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, though acknowledged that the Billing Article is a change as to our previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

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

On May 18, 2023, we submitted a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles imposed new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we planned to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions

contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023.

We have certain unbilled AlloSure Kidney claims with a service date after March 31, 2023, where the reason for testing is not specified by the ordering physician. We are in the process of supplementation for these tests. If these AlloSure Kidney tests are within the parameters of the Revised Billing Article, we will bill and would expect to recognize revenue in the quarter that the supplementation is completed.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, we would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart according to requirements of the Billing Article currently effective at Noridian. We also informed Noridian on May 18, 2023 that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without

Table of Contents

confirming whether they meet the Revised Billing Article's parameters, there is a risk that any reimbursement of such claims are subject to forfeiture.

On August 28, 2023, we submitted a subsequent letter to Noridian regarding our AlloSure Heart and AlloMap Heart testing submissions, explaining, among other things, that (i) prior to August 17, 2023, we submitted claims as outlined in its prior communications, including submitting AlloSure Heart and AlloMap Heart claims that were in compliance with the billing article in effect for Noridian (but that were not necessarily in compliance with the Revised Billing Article that had not yet been adopted by Noridian); (ii) for claims with dates of service of August 17, 2023 or later, we are submitting AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant; and (iii) for AlloSure Heart and AlloMap Heart tests performed on or after August 17, 2023 that are outside the parameters of the Revised Billing Article, certain billing codes will be used to enable any additional review deemed appropriate by Noridian and potential appeal by CareDx of the denied claims. On June 9, 2023, Noridian retired the LCD entitled MolDX: AlloSure or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (L38380) that had been adopted and remained in effect since December 6, 2020. Noridian left in place the foundational LCD, entitled MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38629).

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 the 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.

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

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 14% and 11% 12% of our total revenue for the three and nine months ended September 30, 2023, respectively, March 31, 2024 and 9% of our total revenue for each of the three and nine months ended September 30, 2022 March 31, 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 and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of delivery consistent with the terms of the contract or purchase order.

Patient and Digital Solutions Revenue

Our patient and digital solutions revenue is mainly derived from sales of our Ottr software, XynQAPI, MedActionPlan, 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 15% and 13% of total revenue for the three and nine months ended September 30, 2023, respectively, March 31, 2024 and 9% 11% of our total revenue for each of the three and nine months ended September 30, 2022 March 31, 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

Table of Contents

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;

Table of Contents

- 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 nine months ended September 30, 2023 March 31, 2024 as compared to those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, filed with the SEC on February 27, 2023 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.

Table of Contents

Results of Operations

Comparison of the Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

(In thousands)

		Three Months Ended September 30,		
		2023	2022	Change
Three Months Ended March 31,				
2024				
2024				
2024			2023	Change
Revenue:	Revenue:			
Testing services revenue				
Testing services revenue				
Testing services revenue	Testing services revenue	$ 47,784	$ 64,751	$(16,967)
Product revenue	Product revenue	9,536	7,194	2,342
Patient and digital solutions revenue	Patient and digital solutions revenue	9,872	7,414	2,458
Total revenue	Total revenue	67,192	79,359	(12,167)
Operating expenses:	Operating expenses:			
Cost of testing services				
Cost of testing services				
Cost of testing services	Cost of testing services	13,217	17,771	(4,554)

Cost of product	Cost of product	4,750	4,736	14
Cost of patient and digital solutions	Cost of patient and digital solutions	6,566	5,794	772
Research and development	Research and development	19,000	22,306	(3,306)
Sales and marketing	Sales and marketing	18,474	22,261	(3,787)
General and administrative	General and administrative	33,968	23,830	10,138
Total operating expenses	Total operating expenses	95,975	96,698	(723)
Total operating expenses				
Total operating expenses				
Loss from operations	Loss from operations	(28,783)	(17,339)	(11,444)
Other income (expense):				
Other income:				
Interest income, net				
Interest income, net				
Interest income, net	Interest income, net	3,171	1,225	1,946
Change in estimated fair value of common stock warrant liability	Change in estimated fair value of common stock warrant liability	—	14	(14)
Other income (expense), net		2,047	(572)	2,619
Other expense, net				
Other expense, net				
Other expense, net				
Total other income	Total other income	5,218	667	4,551
Loss before income taxes	Loss before income taxes	(23,565)	(16,672)	(6,893)
Income tax benefit (expense)	Income tax benefit (expense)	80	(267)	347
Net loss	Net loss	$(23,485)	$(16,939)	$ (6,546)

Testing Services Revenue

Testing services revenue decreased by $17.0 $7.9 million, or (26) (13)%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The decrease is primarily driven by the reduction in the Medicare volume across in AlloMap and AlloSure testing services due to the implementation of the revised billing practices to address the requirements related to Medicare claim submissions outlined in the Billing Article. This decrease was partially offset by an increase in AlloSure Lung Medicare revenue due to reimbursement coverage starting in the third quarter of 2023.

Product Revenue

Product revenue increased by $2.3 $1.7 million, or 33% 25%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 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 $2.5 $1.0 million, or 33% 12%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022, primarily due to organic growth related to our digital offerings and pharmacy revenue of $1.1 million with the remaining 2023. The increase was mainly driven by revenue generated from the acquisitions acquired businesses of HLA Data Systems and MediGO.

Cost of Testing Services

Cost of testing services decreased by $4.6 $1.7 million, or (26) (11)%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The decrease is attributed to lower overall volume reduction across AlloMap and AlloSure tests, primarily due to the implementation of the revised billing practices to address the requirements related to Medicare claim submissions outlined in the Billing Article. Articles. The total decrease in the cost of testing services is in line with the reduction in revenue for testing services for the three months ended September 30, 2023 March 31, 2024 and was also due to lower royalty expense and cost saving measures.

Table of Contents

Cost of Product

Cost of product increased by $0.01 $1.3 million, or 0.3% 31%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The increase is primarily due to increased sales of our commercial NGS-based kitted solutions, which was partially offset by certain costs cost reduction effort to help improve margin. efforts.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by $0.8 million $0.4 million, or 13% 5%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The increase is primarily due to an increase in cost of goods from sales in the pharmacy digital solution business.

Research and Development

Research and development expenses decreased by $3.3 $5.6 million, or (15) (23)%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The decrease is primarily due to cost saving measures initiated by us a decrease in the second quarter, resulting in clinical trials expense of $3.2 million, a decrease in personnel-related costs of $2.8 million $0.7 million, a decrease in consulting expense of $0.6 million, a decrease in software cost of $0.4 million, a decrease in reagent and consumables expense of $0.4 million, and a decrease in partnership milestone stock-based compensation expense of $0.4 million $0.2 million.

Sales and Marketing

Sales and marketing expenses decreased by $3.8 $3.4 million, or (17) (15)%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The decrease is primarily due to a decrease in personnel-related costs of $2.5 million $2.1 million, a decrease in stock-based compensation expense of $0.7 million, and a decrease in marketing programs and tradeshows travel expense of $1.4 million $0.5 million.

General and Administrative

General and administrative expenses increased decreased by $10.1 $1.1 million, or 43% (4)%, for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The increase decrease is primarily due to an increase a decrease in legal expense of $5.2 million $2.2 million and a decrease in consulting expense of $0.6 million, offset by an increase in personnel-related costs of $2.7 million $0.9 million, and an increase in other expenses stock-based compensation expense of $2.1 million $0.6 million.

Interest income, net

Interest income, net increased by $1.9 $0.2 million for the three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The increase is primarily due to interest income earned on U.S. agency securities and corporate debt securities as a result of rising interest rates.

Other income (expense), net

Other income (expense), net increased by $2.6 million for the three months ended September 30, 2023, compared to the same period in 2022, primarily due to a $1.0 million gain from settlement of an obligation, a $1.1 million gain from the recovery of an impaired loan that was already written-off and was included in the purchase price of an asset acquisition of a private entity, and an increase in state tax expense of $0.2 million.

Income tax benefit (expense)

Income tax benefit (expense) increased by $0.3 million for the three months ended September 30, 2023, compared to the same period in 2022. The increase is primarily attributable to the U.S. current tax benefit resulting from the recently filed 2022 income tax returns and a U.S. deferred tax benefit resulting from the acquisition of MediGO in July 2023.

Table of Contents

Comparison of the Nine Months Ended September 30, 2023 and 2022

(In thousands)

	Nine Months Ended September 30,		
	2023	2022	Change
Revenue:			
Testing services revenue	$ 162,982	$ 198,330	$ (35,348)
Product revenue	24,273	20,696	3,577
Patient and digital solutions revenue	27,500	20,383	7,117
Total revenue	214,755	239,409	(24,654)
Operating expenses:			

Cost of testing services	43,837	53,629	(9,792)
Cost of product	12,742	13,022	(280)
Cost of patient and digital solutions	19,807	16,071	3,736
Research and development	63,590	66,818	(3,228)
Sales and marketing	63,335	72,359	(9,024)
General and administrative	91,327	75,621	15,706
Restructuring costs	848	—	848
Total operating expenses	295,486	297,520	(2,034)
Loss from operations	(80,731)	(58,111)	(22,620)
Other income (expense):			
Interest income, net	8,708	1,892	6,816
Change in estimated fair value of common stock warrant liability	10	89	(79)
Other expense, net	(198)	(1,948)	1,750
Total other income	8,520	33	8,487
Loss before income taxes	(72,211)	(58,078)	(14,133)
Income tax benefit (expense)	24	(206)	230
Net loss	$ (72,187)	$ (58,284)	$ (13,903)

Testing Services Revenue

Testing services revenue decreased by $35.3 million, or (18)%, for the nine months ended September 30, 2023, compared to the same period in 2022. The decrease is primarily driven by the reduction in the Medicare volume across AlloMap and AlloSure testing services due to the implementation of the revised billing practices to address the requirements related to Medicare claim submissions outlined in the Billing Article. This decrease was partially offset by an increase in the average selling price on non-Medicare testing services, primarily due to improved collection efforts during the nine months ended September 30, 2023.

Product Revenue

Product revenue increased by $3.6 million, or 17%, for the nine months ended September 30, 2023, compared to the same period in 2022. 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 $7.1 million, or 35%, for the nine months ended September 30, 2023, compared to the same period in 2022, primarily due to organic growth related to our digital offerings and pharmacy revenue of $5.0 million with the remaining increase driven by the acquisitions of HLA Data Systems and MediGO.

Cost of Testing Services

Cost of testing services decreased by $9.8 million, or (18)%, for the nine months ended September 30, 2023, compared to the same period in 2022. The decrease is attributed to lower overall volume reduction across AlloMap and AlloSure tests, primarily due to the implementation of the revised billing practices to address the requirements related to Medicare claim submissions

Table of Contents

outlined in the Billing Article. The total decrease in the cost of testing services is in line with the reduction in revenue for testing services for the period and was also due to lower royalty expense and cost saving measures.

Cost of Product

Cost of product decreased by $0.3 million, or (2)%, for the nine months ended September 30, 2023, compared to the same period in 2022. The decrease is primarily due to a decrease in scrap and obsolescence of $0.3 million. Our cost saving actions related to the consolidation of our manufacturing sites helped offset cost increases associated with increased sales.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by $3.7 million, or 23%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increase is primarily due to an increase in cost of goods from sales in the pharmacy business and our digital offerings.

Research and Development

Research and development expenses decreased by $3.2 million, or (5)%, for the nine months ended September 30, 2023, compared to the same period in 2022. The decrease is primarily due to cost saving measures initiated by us in the second quarter, resulting in a decrease in personnel-related costs of $4.2 million and a decrease in partnership milestone expense of $1.5 million, partially offset by an increase in clinical trials expense of $1.7 million and an increase in depreciation expense of $1.3 million.

Sales and Marketing

Sales and marketing expenses decreased by $9.0 million, or (12)%, for the nine months ended September 30, 2023, compared to the same period in 2022. The decrease is primarily due to cost saving measures, leading to a decrease in personnel-related costs of $3.4 million, a decrease in tradeshows expense of $2.3 million, a decrease in travel related expenses of $0.9 million, a decrease in advertising and marketing related costs of $0.8 million and a decrease in speakers' events expense of $0.6 million.

General and Administrative

General and administrative expenses increased by $15.7 million, or 21%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increase is primarily due to an increase in legal expense of $6.2 million, an increase in stock-based compensation expense of $5.7 million, an increase in rent and utilities expense of $1.3 million and an increase in computer hardware and software expenses of $0.7 million.

Restructuring costs

Restructuring costs were incurred for the nine months ended September 30, 2023, which relate to employee severance pay and related costs.

Interest income, net

Interest income, net increased by $6.8 million for the nine months ended September 30, 2023, compared to the same period in 2022. The increase is primarily due to interest income earned on U.S. agency securities and corporate debt securities as a result of rising interest rates. securities.

Other expense, net

Other expense, net decreased by $1.8 $1.7 million for the nine three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022, 2023, primarily due to a $1.0 million gain from settlement of an obligation and a $1.1 million gain from the recovery of an impaired loan that was already written-off and was included in investment write-off in the purchase price of an asset acquisition of a private entity, partially three months ended March 31, 2023 and $0.9 million in unrealized loss on the investment in Miromatrix in the three months ended March 31, 2023, offset by an increase in exchange losses and other expenses. expenses of $0.3 million.

Income tax benefit (expense)

Income tax benefit (expense) increased by $0.2 million for the nine three months ended September 30, 2023 March 31, 2024, compared to the same period in 2022. 2023. The increase is primarily attributable to the U.S. current tax benefit resulting from the recently filed 2022 income tax returns, the release of valuation allowance at Australia and a U.S. deferred tax benefit resulting from the acquisition of MediGO change in July 2023. mixed profit (loss) across jurisdictions.

Table of Contents

Cash Flows for the Nine Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

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

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in:		

	Three Months Ended March 31,		Three Months Ended March 31,	
	2024		2024	2023
	(in thousands)			(in thousands)
Net cash (used in) provided by:				
Operating activities				
Operating activities				
Operating activities	Operating activities	$(10,007)	$ (32,424)	
Investing activities	Investing activities	(921)	(230,977)	
Financing activities	Financing activities	(2,729)	(2,163)	
Effect of exchange rate changes on cash, cash equivalents and restricted cash	Effect of exchange rate changes on cash, cash equivalents and restricted cash	(224)	25	
Net decrease in cash, cash equivalents and restricted cash		$(13,881)	$(265,539)	

Net increase (decrease) in cash, cash equivalents and restricted cash

Table of Contents

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 used in operating activities for the nine three months ended September 30, 2023 March 31, 2024 was $10.0 $15.3 million. Net operating assets increased $9.9 decreased by $19.0 million. Our noncash items included $39.1 $13.3 million in stock-based compensation expense, $10.8 $3.8 million of depreciation and amortization expense, $4.0 $1.4 million of amortization of right-of-use assets, $1.2 $0.3 million of revaluation of contingent consideration to estimated fair value, and $1.5 million of amortization of premium on short-term marketable securities, net.

Cash provided by operating activities for the three months ended March 31, 2023 was $0.7 million. Net operating assets increased $4.4 million. Our noncash items included $13.8 million in stock-based compensation expense, $3.4 million of depreciation and amortization expense, $1.3 million of amortization of right-of-use assets, $0.9 million of unrealized loss on long-term marketable equity securities, $1.0 million of asset impairment and write-downs $1.7 million of revaluation of contingent consideration to estimated fair value, $3.4 and $0.8 million of amortization of premium on short-term marketable securities, net, and $2.1 million of other gains. net.

Cash used in operating activities for the nine months ended September 30, 2022 was $32.4 million. Our net loss of $58.3 million was our primary use of cash in operating activities that included a number of noncash items. Our noncash items included $34.4 million in stock-based compensation expense, $8.4 million of depreciation and amortization expense and $3.1 million of amortization of right-of-use assets. Net operating assets decreased $22.9 million.

Investing Activities

For the nine three months ended September 30, 2023 March 31, 2024, net cash provided by investing activities of $27.7 million was primarily related to proceeds from maturities of marketable securities of $86.9 million, offset by purchases of marketable securities of $57.7 million, and $1.5 million related to additions of capital expenditures, net.

For the three months ended March 31, 2023, net cash used in investing activities of $0.9 $14.8 million was primarily related to the purchases of marketable securities of $192.1 $86.3 million $6.8 and $2.8 million related to additions of capital expenditures, net and $6.7 million related to acquisition of business, net of cash acquired, net. These payments were offset by proceeds from maturities of marketable securities of $206.5 million.

For the nine months ended September 30, 2022, net cash used in investing activities of $231.0 million was primarily related to purchases of marketable securities of $283.4 million and $18.0 million related to additions of capital expenditures, net, partially offset by proceeds from maturities of marketable securities of $74.1 $79.0 million.

Financing Activities

Net cash used in financing activities for the nine three months ended September 30, 2023 March 31, 2024 of $2.7 $1.3 million was primarily due to taxes paid related to net share settlements of restricted stock units of $2.5 $0.7 million, repurchase and retirement of common stock of $1.6 $0.5 million and payments of contingent consideration of $0.2 $0.6 million. These payments were offset by proceeds from issuances of common stock under our employee stock purchase plan of $1.5 million and proceeds from exercises of stock options of $0.1 $0.5 million.

Net cash used in financing activities for the nine three months ended September 30, 2022 March 31, 2023 of $2.2 $1.1 million was primarily due to taxes paid related to net share settlements of restricted stock units of $5.5 $0.7 million, repurchase and retirement of common stock of $0.7 million and payments of contingent consideration of $1.0 $0.3 million. These payments were partially offset by proceeds from exercises of stock options of $2.1 million and proceeds from issuances of common stock under our employee stock purchase plan of $2.2 $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 $534.2 $695.5 million at September 30, 2023 March 31, 2024. As of September 30, 2023 March 31, 2024, we had cash, cash equivalents and marketable securities of $268.2 $215.9 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

Table of Contents

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, whereby and we thereafter filed post-effective amendments thereto and expect to file another post-effective amendment thereto on or about May 9, 2024. Upon its effectiveness, 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 our Stock Repurchase Program, or the Repurchase Program, a stock repurchase program (the "Repurchase Program"), whereby we may purchase up to $50 million of in shares of our common stock over a period of up to two years, commencing on December 8, 2022. December 8,

Table of Contents

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 three and nine months ended September 30, 2023 March 31, 2024, we purchased an aggregate of 92,766 shares and 164,238 55,500 shares of our common stock, respectively, under the Repurchase Program for an aggregate purchase price of $0.8 million and $1.6 million, respectively. $0.5 million. As of September 30, 2023 March 31, 2024, $47.7 million $21.4 million remained available for future share repurchase repurchases under the Repurchase Program.

Table of Contents

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.

On In March 2, and May 2023, MolDX issued new billing articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Article. Prior to the Billing Article's effective date, MolDX informed the affected parties, including us, that enforcement of the revised billing practices outlined in the Billing Article would not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued the Revised Billing Article. Articles. The Revised Billing Article impacts impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, and AlloMap Heart and requires AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts.MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

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

On May 18, 2023, we submitted a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles imposed new restrictions on Medicare coverage for our tests from those contained in the existing LCDs, (ii) that we planned to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, we would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap

Heart according to requirements of the Billing Article currently effective at Noridian. We also informed Noridian on May 18, 2023 that (i) until June 30, 2023, we plan to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not

Table of Contents

obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Additionally, although we have submitted to Medicare AlloMap Heart and AlloSure Heart tests for March 2023 without confirming whether they meet the Revised Billing Article's parameters, there is a risk that any reimbursement of such claims are subject to forfeiture.

On August 28, 2023, we submitted a subsequent letter to Noridian regarding our AlloSure Heart and AlloMap Heart testing submissions, explaining, among other things, that (i) prior to August 17, 2023, we submitted claims as outlined in its prior communications, including submitting AlloSure Heart and AlloMap Heart claims that were in compliance with the billing article in effect for Noridian (but that were not necessarily in compliance with the Revised Billing Article that had not yet been adopted by Noridian); (ii) for claims with dates of service of August 17, 2023 or later, we are submitting AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant; and (iii) for AlloSure Heart and AlloMap Heart tests performed on or after August 17, 2023 that are outside the parameters of the Revised Billing Article, certain billing codes will be used to enable any additional review deemed appropriate by Noridian and potential appeal by us of the denied claims. On June 9, 2023, Noridian retired the LCD entitled MolDX: AlloSure or Equivalent Cell-Free DNA Testing for Kidney and Heart Allografts (L38380) that had been adopted and remained in effect since December 6, 2020. Noridian left in place the foundational LCD, entitled MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38629).

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 the 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.AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

Reimbursement for AlloMap Heart

AlloMap Heart test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap Heart, as the ISHLT included AlloMap in 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 will be 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.

Table of Contents

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,*

Table of Contents

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

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

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

In June 2020, we commercially launched AlloSeq HCT, a 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

Table of Contents

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.

Table of Contents

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 September 30, 2023 March 31, 2024 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, please refer to Note 9 of the 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.

Table of Contents

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 $268.2 $215.9 million at September 30, 2023 March 31, 2024, which consisted of bank deposits, money market funds and corporate debt securities, and we had cash and cash equivalents and marketable securities of $293.1 $235.4 million at December 31, 2022 December 31, 2023, which consisted of bank deposits, and money market funds. 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 $2.7 $2.2 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 September 30, 2023 March 31, 2024, would have negatively impacted our financial results for the nine three months ended September 30, 2023 March 31, 2024 by $0.4 million and our product revenue by $1.1 $0.3 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, including our 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 September 30, 2023 March 31, 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 September 30, 2023 March 31, 2024, in light of the material weaknesses identified in our internal control over financial reporting, described below, our disclosure controls and procedures were not effective at the reasonable assurance level and are not effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the 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, 2022 December 31, 2023, which was filed with the SEC on February 27, 2023 February 28, 2024, the following material weaknesses were identified as of December 31, 2022 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.

Table of Contents

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

COSO Framework. We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with

established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an adequate process in place to complete our 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 has been engaged in developing and implementing remediation plans is committed to address maintaining a strong internal control environment. In response to the material weaknesses described above. These remediation efforts above, our management is continuing to take actions to remediate the material weaknesses in internal control over financial reporting, which include but are ongoing and are expected not limited to include the following:

- Enhancing Continuing to enhance the design and control procedures of the GITCs to ensure that the control activities related to GITCs are functioning appropriately; appropriately.
- Improving the Continuing to implement training to ensure a clear understanding of risk assessment, control environment in relation execution, and monitoring activities related to personnel training financial reporting and continue driving accountability of Sarbanes-Oxley Act of 2002 or SOX, control activities; activities.
- Hiring additional personnel in the IT Continuing to focus on controls execution and Finance and Accounting departments with an appropriate level of knowledge and experience to effectively execute our processes and procedures; and
- Expanding controls and/or applying appropriate procedures to address the design and operation monitoring activities of internal controls related to the procure-to-pay process.

In 2023• Continuing to date, we have hired seven additional full-time and contractors expand the available resources in our IT and Finance and Accounting departments to support our remediation efforts. We expect, and are planning, to continue adding incremental staffing in these departments throughout at the year. We delivered SOX compliance training to control owners and are updating the design of our controls and controls procedures to ensure we address the root causes of the material weaknesses. We have also enhanced our communication by frequently holding meetings Company with key management personnel and members of the Audit Committee of our Board of Directors to discuss the SOX program. In regards to the procure-to-pay process, we are implementing new automated and manual controls for the purchase order approval workflow and we plan to implement a new accounts payable system next year. We are also investing in experience designing and implementing other systems that will assist us in monitoring the timely execution control activities, including GITCs, through hiring and use of controls, third-party consultants and we expect to continue to implement these throughout the remaining part of the year. specialists.

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

Changes in Internal Control over Financial Reporting

Other than the changes associated with the material weaknesses and remediation actions noted above, there have been no changes in our internal control over financial reporting during the quarter ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information set forth in Note 9, *Commitments and Contingencies*, under the caption "Litigation and Indemnification Obligations", to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, filed with the Securities and Exchange Commission, or the SEC, on February 27, 2023 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, 2022 December 31, 2023, filed with the SEC on February 27, 2023 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 September 30, 2023 March 31, 2024, our net loss was $23.5 $16.7 million. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of $534.2 $695.5 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.*"

Table of Contents

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 September 30, 2023 March 31, 2024, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 51% 44% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued on June 17, 2016 and the new market-based rates took effect on January 1, 2018. The Centers for Medicare & Medicaid Services, or CMS, uses the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. Under PAMA, the reimbursement rate for AlloMap Heart is currently $3,240 for Medicare beneficiaries.

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

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through an 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.AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240.

In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto March 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.

On March 2, 2023, May 2023, MolDX issued a new billing article, with an effective date of March 31, 2023, articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection, or the Billing Article. Prior to the Billing Article's effective date, MolDX informed the affected parties, including us, that enforcement of the revised billing practices outlined in the Billing Article would not be implemented until June 30, 2023. MolDX informed us that its automatic adjudication process would remain in place until June 30, 2023, though claims submitted prior to that date must comply with the applicable LCDs. On May 4, 2023, MolDX issued a revised new Rejection. The billing article with an effective date of March 31, 2023, issued in May 2023, or the Revised Billing Article, and together with the Billing Article, billing article issued in March 2023, the Billing Articles. The Revised Billing

Article impacts Articles, impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, and AlloMap Heart and requires AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has stated that it views the Billing Article as clarifying existing coverage, especially as it relates to when tests are covered in the for-cause and surveillance contexts.MolDX has acknowledged, however, that the Billing Article is a change as it relates to billing more than one test during a single patient encounter. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023.

Although we believeOn August 10, 2023, MolDX and Noridian released a draft proposed revision to the Billing Articles are inconsistent with LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the LCDs, Noridian's existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and MolDX's responses L38629).On August 14, 2023, MolDX released a draft billing article (DA58019) to public comments explaining accompany the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate proposed draft LCD, which generally reflected the implications of changes in coverage included in the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update our test order forms to capture the new information required under the Revised Billing Article. Accordingly, we did not submit claims The comment period end date for approximately 3,200 AlloSure Kidney tests for Medicare reimbursement for this proposed LCD was September 23, 2023. We presented at public meetings regarding the period from March 7, 2023 through March 31, 2023 proposed draft LCD held on September 18, 2023 and did not recognize revenue September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on these claims in the first quarter of 2023 aggregating to approximately $8.9 million, or the Impacted March Tests.

Table of Contentsproposed draft LCD.

On May 18, 2023 February 29, 2024, we submitted MolDX and Noridian released a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles imposed new restrictions on Medicare coverage for our tests from those contained in the existing LCDs, (ii) that we planned to submit claims for reimbursement for the Impacted March Tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters revised version of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately $7.8 million in the second quarter of 2023. Although we submitted claims for Medicare reimbursement for the Impacted March Tests in May 2023 and have received reimbursement for these tests, there is a risk that the reimbursement of such claims is subject to forfeiture.

We continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, we informed Noridian on May 18, 2023 that until Noridian adopted the Revised Billing Article, we would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart according to requirements of the Billing Article currently effective at Noridian. We also informed Noridian on May 18, 2023 that (i) until June 30, 2023, we planned to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. There is a risk that claims submitted for reimbursement through June 30, 2023 for AlloMap Heart and AlloSure Heart tests for which we have not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles subject to forfeiture.

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

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

On a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractors, or MAC, services. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U.S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloMap Heart, AlloSure Kidney, AlloSure Heart or AlloSure Heart 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 Heart 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.

Table of Contents

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

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

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

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

For new diagnostic testing services, each private and government payer decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may not be likely to order a diagnostic test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic testing service, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

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

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

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

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

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

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

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

Reimbursement for AlloSure Kidney, AlloMap Heart and AlloSure Heart comes primarily from Medicare and private third-party payers such as insurance companies and managed care organizations. The reimbursement process can take six months or

Table of Contents

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

Coverage policies approving AlloMap Heart have been adopted by many of the largest private payers. Many of the payers with positive coverage policies have also entered into contracts with us to formalize pricing and payment terms. We continue to work with third-party payers to expand and seek such coverage and to appeal denial decisions based on existing and ongoing studies, peer reviewed publications, support from physician and patient groups and the growing number of AlloMap Heart tests that have been reimbursed by public and private payers. There are no assurances that the current policies will not be modified in the future. If our test is considered on a policy-wide level by major third-party payers, whether at our request or on their own initiative, and our test is determined to be ineligible for coverage and reimbursement by such payers, if we do not submit for Medicare reimbursement for AlloSure Kidney for certain prior or future periods or if the Billing Articles limit Medicare reimbursement for AlloSure Heart or AlloMap Heart commencing on June 30, 2023, our collection efforts and potential for revenue growth could be adversely impacted.

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

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

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

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

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

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

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18, 2020 in the U.S. District Court for the District of Delaware, or the Court, alleging we made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of the Court to amend its counterclaims to include additional allegations regarding purportedly false claims we made with respect to AlloSure, and the Court granted Natera’s request. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury finding that Natera violated the

Table of Contents

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

Table of Contents

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 we intend to appeal. jury. Both parties have appealed and briefing is ongoing. 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 July 6, 2022, we moved to dismiss the rest of Natera’s claims. On September 6, 2022, we withdrew the our motion to dismiss. Discovery 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 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 may also move for injunctive relief. We are seeking judicial review of the verdict. Natera is ongoing. also seeking judicial review of the jury's finding that CareDx 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 both of these matters vigorously, and believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

Furthermore, on May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action in the U.S. District Court for the Northern District of California against us; Reginald Seeto, our 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. 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. The parties filed a joint status statement with the court on February 15, 2024. 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.

Additionally, on September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Edelman Derivative Action, against us as nominal defendant and Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors, Directors; Ankur Dhingra, our former Chief Financial Officer, Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of

Table of Contents

Directors and current member of our Board of Directors, Directors; and the other members of our Board of Directors. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of our Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to us, violated Sections 14(a) and 20(a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

In addition, on February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Stevenson Derivative Action, against us as nominal defendant and Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors; and other current and former members of our Board of Directors. The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the

Table of Contents

individual defendants breached their fiduciary duties as our directors and/or officers and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

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. The consolidated derivative action remains stayed. The parties in the Stevenson Derivative Action filed a joint status statement with the Court court on September 6, 2023, and the parties in the consolidated derivative action filed a joint status statement and administrative motion with the court on February 13, 2024.

Additionally, 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 our Board of Directors (the "Jacobsen Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company, violated Section 14(a) of the Exchange Act, are liable for contribution under Sections 10(b) and 21(D) of the Exchange Act, engaged in unjust enrichment, waste of corporate assets, aiding and abetting, insider trading, and misappropriation of information, and/or are liable for indemnification. The suit seeks declaratory relief, disgorgement, and to recover alleged damages sustained by us as a result of the alleged violations, along with plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. On March 20, 2024, the court determined that the Jacobsen Derivative Action is related to the consolidated derivative action.

On March 19, 2024, the parties to the Jacobsen Derivative Action and the consolidated derivative action filed a stipulation and proposed order consolidating the Jacobsen Derivative Action with the consolidated 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 the Jacobsen Derivative Action with the consolidated derivative action. The order provides that all previous orders in the consolidated derivative action shall apply to the Jacobsen Derivative Action.

Additionally, 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 us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of our Board of Directors (the "Burns Derivative Action").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 2, 2024, the court in the consolidated derivative action ordered that the stay of the consolidated derivative action will be lifted as of May 16, 2024.

We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the consolidated derivative action, and the Burns Derivative Action, but there is no guarantee that we will prevail.

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

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

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

- our ability to successfully market and sell our testing services and products;
- our ability to successfully commercialize new diagnostic solutions;
- the amount of our research and development expenditures;
- the timing of cash collections from third-party payers;
- the extent to which our current and future solutions, if any, are eligible for coverage and reimbursement from third-party payers;
- the process of integrating new acquisitions, and the associated potential disruption to our business;
- changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business, including as a result of the Billing Articles;
- our decision to continue our Medicare reimbursement submissions for AlloSure Kidney;
- our decision to issue future financial guidance and the terms of such guidance;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved or that otherwise may affect our intellectual property position;
- announcements by our competitors of new or competitive products;
- regulatory or legal developments affecting our test or competing products;
- total operating expenses; and
- changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts.

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

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

Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute rejection in kidney and heart transplant recipients by utilizing biopsies. Many clinicians use AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloSure Kidney, AlloSure Lung, AlloMap Heart or AlloSure Heart as biopsy alternatives, per se, if treatment center administrators view our test as an alternative to a biopsy but believe they would derive more revenue from the performance of biopsies, such administrators may be motivated to reduce or avoid the use of our test. While biopsies

Table of Contents

If we are less common 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 monitoring kidney transplant patients, there 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, EuroBio, and Oncocyte.

Competition for our AlloMap Heart solution for heart transplant centers that manage patients with protocol recipients also comes from biopsies, which could impact AlloSure Kidney revenue. We cannot provide assurance that our efforts 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 increase need to continue to educate clinicians, transplant recipients and payers about the use various benefits of our test by new or existing customers. Our failure 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 frequency process of use 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 by new and existing customers would adversely affect impact our growth operating margins and revenues. 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 2021 2022 to 2022, 2023, our revenue grew declined from $296.4 $321.8 million to $321.8 $280.3 million, which represents annual growth a decrease of 9% 13%. From the nine three months ended September 30, 2022 March 31, 2023 to the nine three months ended September 30, 2023 March 31, 2024, our revenue declined from $239.4 $77.3 million to $214.8 million, $72.0 million, which represents a decrease of $24.6 million $5.2 million or (10) (7)%. 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;

Table of Contents

- 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 September 30, 2023 March 31, 2024, we had cash, cash equivalents and marketable securities of $268.2 million $215.9 million and an accumulated deficit of $534.2 million $695.5 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 other 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.

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

Many of the countries in which we operate, including the U.S. and several of the members of the European Union, or EU, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. On June 23, 2016, the United Kingdom, or the UK, held a referendum pursuant to which voters elected to leave the EU, commonly referred to as Brexit. The UK formally left the EU on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, and the UK is in the process of negotiating trade deals with other countries, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in the EU and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

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

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

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

Risks Related to Billing and Reimbursement

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

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

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

- disputes among payers regarding which party is responsible for payment;

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

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

Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. In addition, we are subject to and expect to continue to be subject to one or more audits under the CMS Recovery Audit Contractor, or RAC, program, the CMS Targeted Probe and Educate, or TPE, program, the Unified Program Integrity Contractors, or UPIC, program and other federal and state audits. Following two rounds of TPE audit in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us it was making a referral to CMS given disagreement as to the interpretation of the applicable LCDs. We appealed claims which had a basis for appeal and those claims were denied. We continue to pursue appeals of these claims consistent with our statutory rights. We have met with CMS to discuss the difference in interpretation and intend to continue this dialogue regarding our position that the Noridian interpretation is inconsistent with the LCD, MolDX's and Noridian's prior associated responses to public comments, and medical necessity.In addition, in the second quarter of 2023, we received a record request from UPIC. UPIC has the authority to implement Medicare payment suspensions during the pendency of an audit and the ability to refer billing matters to other regulatory agencies. In the third quarter of 2023, the UPIC provided us with notice that we had received Medicare payments in error, resulting in an overpayment of $38,975.02. The UPIC further stated that going forward it wished to support our efforts to remedy the billing issues and it would continue to monitor our Medicare claim submission patterns. We plan to appeal the denied claims consistent with our statutory rights. We expect further intensification of the regulatory environment surrounding the healthcare industry, as third-party firms engaged by CMS and others conduct extensive pre- and post-payment audits of claims data as well as medical and other records in order to identify improper payments to healthcare providers under the Medicare and Medicaid programs. We could be forced to expend considerable resources responding to these audits or other inquiries. These billing complexities, and the resulting uncertainty in obtaining payment for AlloSure Kidney, AlloMap Heart, AlloSure Heart and future solutions, as well as the results of Noridian's referral to CMS and any audits or inquiries evaluating our services create a risk of further regulatory or enforcement action from these or other regulatory agencies, or that our claims are denied or that any historical reimbursement of such claims is subject to forfeiture and could negatively affect our revenue, cash flows and profitability.

Risks Related to the Healthcare Regulatory Environment

In order to operate our laboratory, we have to comply with the CLIA and federal and state laws and regulations governing clinical laboratories and laboratory developed tests, including FDA regulations.

We are subject to the CLIA, a federal law that regulates clinical laboratories that perform testing on specimens taken from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. If our laboratory is out of compliance with the CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our

Table of Contents

CLIA certificate, as well as a direct plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain the CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found to be out of compliance with the CLIA program requirements and subjected to sanction, our business could be materially harmed.

Licensure is also required for our laboratory under California law in order to conduct testing. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. Moreover, several states, including New York, require that we hold licenses to test specimens from patients residing in those states. Other states have similar requirements or may adopt similar requirements in the future. In addition to our California certifications, we currently hold licenses in Florida, Maryland, New York, Pennsylvania and Rhode Island. The loss of any of these state certifications would impact our ability to provide services in those states, which could negatively affect our business.

Finally, we may be subject to regulation in foreign jurisdictions where we offer our test. Failure to maintain certification in those states or countries where it is required could prevent us from testing samples from those states or countries, could lead to the suspension or loss of licenses, certificates or authorizations, and could have an adverse effect on our business.
We were inspected as part of the customary College of American Pathologists audit and recertified in March 2022 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2024.

If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to perform AlloMap Heart, AlloSure Kidney or AlloSure Heart, which would limit our revenues and materially harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states, which could also have a material adverse effect on our business.

The FDA has traditionally chosen not to exercise its authority to regulate laboratory developed tests, or LDTs, because it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as "in vitro diagnostic multivariate index assays," or IVDMIAs. According to the draft guidance, IVDMIAs do not fall within the scope of LDTs over which the FDA has exercised enforcement discretion because such tests incorporate complex and unique interpretation functions, which require clinical validation. We believed that AlloMap Heart met the definition of IVDMIA set forth in the draft guidance document. As a result, we applied for, and obtained in August 2008, 510(k) clearance for AlloMap Heart for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

In October 2023, the FDA proposed a new policy under which the FDA intends to provide greater oversight of LDTs, through a phase-out of its general enforcement discretion approach to LDTs.In connection with this, the FDA proposed a rule that would amend its regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug and Cosmetic Act. There is no assurance whether, or when, this proposed policy and/or rule will be adopted or as to the content of any policies or rules eventually adopted. Any future rulemaking, guidance, or other oversight of LDTs and clinical laboratories that develop and perform them, if and when finalized, may affect the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws.

While we believe that we are currently in material compliance with applicable laws and regulations relating to our LDTs, we cannot be certain that the FDA or other regulatory agencies would agree with our determination. A determination that we have violated these laws, or a public announcement that we are being investigated for possible violation of these laws, could hurt our business and our reputation.

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

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

- federal and state laws and regulations regarding billing and claims payment applicable to clinical laboratories and/or regulatory agencies enforcing those laws and regulations;

Table of Contents

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

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. We previously received a civil investigative demand, or CID, from the United States Department of Justice, or DOJ, requesting that we produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the SEC in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. On September 25, 2023, we reported that by letter dated September 19, 2023, we were notified by the staff of the SEC that the SEC has concluded its investigation as to our company and does not intend to recommend an enforcement action by the SEC against us. We also previously received an information request from a state regulatory agency. The state regulatory agency recently advised us that it has completed its review of our business practices and determined that no further information or action is required. In late 2022, we received a request for information from a separate state regulatory agency. We may receive additional requests for information from the DOJ or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the prior SEC subpoena or the state regulatory agency information request raise or raised any issues regarding the safety or clinical utility of any of our products or services and are cooperating fully with the investigations and the request for information. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of the DOJ investigation, the state regulatory agency information request, or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and

Table of Contents

administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, if any governmental body, such as the DOJ or SEC, determines that we have not complied with applicable securities or other laws, such governmental body could initiate a proceeding against us, which may ultimately lead to significant penalties and other relief assessed against us, including monetary fines. We may expend significant financial and managerial resources in connection with responding to the CID and other information requests. Any of the foregoing consequences could seriously harm our business and our financial results.

In addition, we have implemented and strive to continuously develop, implement and improve compliance policies and procedures intended to train our sales, billing, marketing and other personnel regarding compliance with state and federal laws applicable to our business. Our efforts to implement appropriate monitoring of compliance with such policies and procedures are likewise ongoing. We may need to supplement and amend our current policies and procedures and implement additional policies and procedures in the future. In addition, despite our compliance policies and procedures, and related training and monitoring, we may experience situations in which employees may fail to fully adhere to our policies and procedures. Such failures may subject us to administrative, civil, and criminal actions, penalties, damages, fines, exclusion from participation in federal health care programs, refunding of payments received by us and curtailment of our operations.

Risks Related to Our Intellectual Property

Our competitive position depends on maintaining intellectual property protection.

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

Our patent position for AlloMap Heart is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and quiescent leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of October 15, 2023 March 31, 2024, we had 10 9 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have one issued U.S. patent covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart, which will expire in March 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or and autoimmune disease, which will expire between August April 2024 and September 2029. 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. On March 29, 2023, we entered into an agreement with Stanford whereby we agreed, among other things, to seek a review from the United States Supreme Court, or the Review. During the pendency of the Review, certain of In addition, our licensing payment and reporting obligations to Stanford with respect to licensed products sold in the United States, and our right to terminate the exclusive agreement upon 30 days' advance notice to Stanford, are suspended. In May 2023, we submitted a petition of certiorari to the U.S. Supreme Court for consideration of the patent infringement suit we filed against Natera and in October 2023, the U.S. Supreme Court declined to hear this patent infringement suit. As the Review is complete and our petition for review was denied, our license agreement with Stanford automatically that previously covered certain patents related to diagnostic and predictive technologies terminated and we will be required to pay to Stanford certain past royalties that were previously suspended within 90 days of the termination.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. In the Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015) case, a federal court recently determined that a cfDNA product for fetal testing was not eligible for patent protection. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself.

Table of Contents

What constitutes a "sufficient" additional feature for this purpose is uncertain. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

Changes in either the patent laws or interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. In particular, in September 2011, the United States Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This has not yet had a material impact on the operation of our business and the protection and enforcement of our intellectual property, but it may in the future. The AIA and its implementation could still increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patent applications in the United States and many foreign jurisdictions are not published until at least 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, as applicable, were the first to invent the technology (pre-AIA) or first to file (post-AIA). 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.

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

Risks Related to Our Common Stock

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

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. From January 3, 2023 January 2, 2024 to September 30, 2023 March 31, 2024, our closing stock price ranged from $7.00 $7.96 to $17.61 $12.37 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;

Table of Contents

- 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.

Table of Contents

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

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

Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 27, 2023, factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of life sciences stocks;
- changes in operating performance and stock market valuations of other life sciences companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- entering into financing or other arrangements with rights or terms senior to the interests of common stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;

- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- public health emergencies;
- our prior decision to withdraw our revenue guidance for fiscal 2023;
- our decision to issue future financial guidance and the terms of such guidance; and
- general economic conditions and slow or negative growth of our markets.

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

Our executive officers, directors and holders of 5% or more of our outstanding common stock (based on the most recent public filings), and entities affiliated with them, beneficially own in the aggregate approximately 63.7% 60.5% of our common stock as of November 6, 2023 March 31, 2024. These stockholders, acting together, will have the ability to exert substantial influence over all matters

Table of Contents

requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

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

During the three and nine months ended September 30, 2023, we purchased an aggregate of 92,766 shares and 164,238 shares of our common stock, respectively, under the Repurchase Program for an aggregate purchase price of $0.8 million and $1.6 million, respectively. As of September 30, 2023, $47.7 million remained available for future share repurchase under the Repurchase Program.

In the event we make any additional stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our board of directors may modify or amend the Repurchase Program, or adopt a new stock repurchase program, at any time at its discretion without stockholder approval.

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2022, 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. 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, 2022 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 adequate restriction of 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

Table of Contents

implemented appropriately with appropriate segregation of duties; and (iii) Computer computer and Network 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.

Table of Contents

- **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. As of September 30, 2023, there is a likelihood that we will not be able to remediate all of the previously identified material weaknesses by December 31, 2023, in which case our management will again have to conclude that our system of internal control over financial reporting is not effective when it conducts its assessment of our internal control over financial reporting as of the year ending December 31, 2023.

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.

General Risk Factors

The impact of the Russian invasion of Ukraineand the Israel-Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.

The short and long-term implications of Russia's invasion of Ukraine and the Israel-Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and customers. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs of raw materials. We will continue to monitor these fluid situations and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation, rising interest rates and a potential economic recession; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; our ability to maintain or increase our product prices; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

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

Issuer Purchases of Equity Securities

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award awards a number of shares of our common stock

Table of Contents

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

Table of Contents

certain tax withholding obligations during the three months ended September 30, 2023 March 31, 2024:

	Total Number of Shares Purchased		Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program (4)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)	
July 1, 2023 - July 31, 2023	28,751	(1)	$ 8.49	21,567	$ 48.4	(4)
August 1, 2023 - August 31, 2023	43,798	(2)	9.62	31,200	48.1	(4)
September 1, 2023 - September 30, 2023	52,814	(3)	8.11	39,999	47.7	(4)
Total	125,363			92,766		

	Total Number of Shares Purchased		Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program (4)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)	
January 1, 2024 - January 31, 2024	28,738	(1)	$ 10.66	18,000	$ 21.7	(4)
February 1, 2024 - February 29, 2024	85,738	(2)	8.74	37,000	21.4	(4)
March 1, 2024 - March 31, 2024	6,625	(3)	11.55	500	21.4	(4)
Total	121,101			55,500		

(1) Comprised of 7,184 of: (a) 10,738 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was $4.53, $11.28, which represents the average fair market value of common stock on the date of withholding, and (b) 21,567 18,000 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of $9.81. $10.28.

(2) Comprised of 12,598 of: (a) 48,738 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was $10.58, $8.86, which represents the average fair market value of common stock on the date of withholding, and (b) 31,200 37,000 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of $9.23. $8.58.

(3) Comprised of: (a) 12,815 6,125 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was $8.50, $11.52, which represents the average fair market value of common stock on the date of withholding, and (b) 39,999 500 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of $7.99. $11.99.

(4) On December 3, 2022, our board of directors approved our stock repurchase program, authorizing us to purchase up to $50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of our board of directors through open market purchases, one or more Rule 10b5-1 trading plans 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 September 30, 2023 March 31, 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.

Table of Contents

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#† 10.1 (11)#	Separation Agreement, Offer Letter, dated September 20, 2023 March 24, 2024, by and between CareDx, Inc. and Abraham Ronai. John Hanna
10.2#† 10.2 (12)#	Legal Consulting Change of Control and Severance Agreement, dated September 20, 2023 March 25, 2024, by and between CareDx, Inc. and Abraham Ronai. John Hanna
10.3 (13)#	Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated March, 24, 2024, between CareDx, Inc. and John Hanna
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 April 15, 2024.

Table of Contents

(12)	Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed with the SEC on April 15, 2024.
(13)	Incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed with the SEC on April 15, 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.

CAREDX, INC.
(Registrant)

Date: November 8, 2023 May 9, 2024

By: /s/ ALEXANDER L. JOHNSON JOHN W. HANNA
Alexander L. Johnson John W. Hanna
President of Patient and Testing Services Chief Executive Officer
(Principal Executive Officer)

By: /s/ ABHISHEK JAIN
Abhishek Jain
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 10.1

SEPARATION AGREEMENT

I, Abraham Ronai, have resigned from my employment with CareDx, Inc. ("Company"), effective September 30, 2023 ("Resignation Date"). The "Effective Date" of this Separation Agreement will be the eighth day following the date that I sign and return this Agreement to the Company, provided I do not rescind this Agreement in the seven days following the date that I sign it.

1. **Consideration**: In exchange for this Agreement and conditioned on the occurrence of the Effective Date, I shall be entitled to receive the payments and benefits set forth in this Section 1 (collectively, the "Consideration"), which payment and benefits I am not otherwise entitled to receive and which will not be taken into account when determining my rights or benefits under any employee benefit plan, program or policy, notwithstanding anything in it to the contrary.

(a) Separation Payment: The Company will pay me continuing payments of severance pay at a rate equal to $35,000 per month, less applicable federal, state and local withholdings, reported via Internal Revenue Service Form W-2, for fourteen (14) months from the date of my separation, and paid periodically in accordance with the Company's normal payroll policies. In addition, the Company will pay me my 2023 annual target bonus of Two Hundred Fifty-Two Thousand Dollars ($252,000.00), less applicable tax withholdings, reported via Internal Revenue Service Form W-2. This bonus payment will be paid in accordance with the Company's standard bonus payment schedule in February 2024. These payments will not be taken into account when determining my rights or benefits under any other program.

(b) COBRA Subsidy: In addition to the normal COBRA rights I have and in exchange for my signing this Agreement, the Company agrees to reimburse me COBRA coverage that I purchase until the earlier of eighteen (18) months or when I become eligible for group health insurance coverage through a new employer, provided that I timely elect continuation coverage. The reimbursement shall be in an amount equivalent to my current health plan costs.

2. **Other Compensation**: The Company shall pay all other normal compensation due and owing me under applicable law up to the Resignation Date which shall be payable in accordance with the Company's customary and normal payroll policies.

3. **Tax Reporting and Withholding**: The Company will report all payments due under this Agreement to tax authorities, and withhold taxes and other amounts from them, as it determines is consistent with applicable law. I agree not to make any claim against the Company or any other person based on how the Company reports amounts or withholds taxes from them, or if an adverse determination is made as to the tax treatment of any amounts payable under this Agreement. I agree that the Company has no duty to try to prevent such an adverse determination, except as specifically set forth in the Consulting Agreement.

4. **Releases**: I irrevocably, unconditionally, and forever release (i.e., give up) all known and unknown claims that I have as of the time I sign this Agreement against the Company, all current and former, direct and indirect parents, subsidiaries, brother-sister companies and all other affiliates and related partnerships, joint ventures, or other entities, and, with respect to each of them, their predecessors and successors; and, with respect to each such entity, all of its past, present and future employees, officers, directors, stockholders, owners, representatives, assigns, attorneys, agents, insurers, employee benefit programs (and the trustees, administrators, fiduciaries, and insurers of such programs) and any other persons acting by, through, under or in concert with any of the persons or entities listed in this section, and their successors (Released Parties and each a Released Party). For example, I am releasing all common law contract, tort or other claims I have or might have, as well as all claims I have or might have under the Age Discrimination in Employment Act

(ADEA), the Worker Adjustment & Retraining Notification Act (the WARN Act), the Family and Medical Leave Act (FMLA), Title VII of the Civil Rights Act of 1964, Sections 1981 and 1983 of the Civil Rights Act of 1866, the Americans With Disabilities Act (ADA), the Employee Retirement Income Security Act of 1974 (ERISA) and any similar domestic or foreign laws, such as the California Fair Employment and Housing Act, California Labor Code Section 200 *et seq.*, California Business and Professions Code Section 17200, *et seq.*, and any applicable California Industrial Welfare Commission order. In addition, I am releasing all claims arising from my employment agreements with the Company, my employment relationship with the Company, and the termination of that relationship, as well as all forms of relief, of any kind or nature, causes of action, obligations, duties, demands, actions, debts, sums of money, costs and expenses, including attorney's fees, promises, damages and liabilities of every nature and description, whether arising under federal, state, local, statutory, common law, or any other domestic or foreign law, rule, or regulation, or that otherwise concern, arise out of, refer, or relate in any way to, or are based upon allegations, facts, or transactions relating in any way to the Company. Further, I understand and agree that this release is a good-faith compromise of disputed wage claims. However, I am not releasing (i) any of the few claims that the law does not permit me to release by private agreement; (ii) vested benefits (except already-denied benefits) under any employee-benefit plan governed by ERISA; (iii) any right I have to be indemnified by the Company; or (iv) my right to enforce this Agreement.

I expressly waive the protection of Section 1542 of the Civil Code of the State of California and any analogous rule or principle of any other jurisdiction. Section 1542 provides:

> A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.

The Company irrevocably, unconditionally, and forever releases (i.e., gives up), all known claims that it has as of the time it signs this Agreement against me and all of my family members,
representatives, assigns, attorneys, agents, insurers, and any other person acting by, through, under or in concert with any of the persons or entities listed in this section and their successors arising out of my employment with, or separation from the Company. However, notwithstanding the forgoing, the Company is not releasing (a) any of the few claims that the law does not permit the company to release by private agreement; (b) claims, which for the sake of clarity, are not known or which reasonably could not be known at the time of this agreement, including without limitation, claims related to the improper acquisition, use or disclosure of the Company's confidential information or information protected by the attorney client privilege and the attorney work product doctrine. Neither I nor the Company is releasing any claims that I or it may have for enforcement of this Agreement.

5. **Ownership of Claims**: I have not assigned or given away any of the claims I am releasing.

6. **Consulting**: In conjunction with my resignation from employment, I have agreed to offer consulting services to the Company, pursuant to a separate Consulting Agreement, which will take effect on October 1, 2023.

7. **Compensation and Benefit Plans**: As of the Resignation Date, I will cease to be eligible to participate under any stock option, bonus, incentive compensation, commission, medical, dental, disability, life insurance, retirement or other compensation or benefit plans of the Company or any affiliate, except as provided in my Consulting Agreement.

8. **Applicable Law**: To the extent federal law does not apply, this Agreement is governed by the internal laws (and not the conflicts of law rules) of California.

9. **Covenants**: I acknowledge and agree that:

(a) Medicare: If amounts I receive under this Agreement could be for medical expenses paid for by Medicare, I promise to reimburse Medicare as the government may require. The Company must report all settlements with Medicare-eligible employees to the government. I promise to assist the Company in this regard, if requested, and I agree that the provision of such assistance, which may include giving the Company information needed for reporting, will be a condition precedent to receiving any amounts due under this Agreement. I hereby represent that (initial one):

__ I am not Medicare-eligible.
__ I am Medicare-eligible but I have never enrolled in Medicare.
__ I have enrolled in Medicare and my Medicare enrollment number is _____.

If I violate any promise in this section or if any of my representations in this section are false, I agree to hold the Company and all Released Parties harmless from any Medicare-related liability, reporting penalties and defense costs.

(b) Return of Company Property: I promise to return to the Company all files, memoranda, documents, records, copies of the foregoing, Company-provided credit cards, keys, building passes, security passes, access or identification cards, mobile devices, laptops, thumb drives and any other property of the Company or any Released Party in my possession or control by October 1, 2023. I promise to clear all expense accounts, repay all debts owed to the Company or any Released Party, pay all amounts owed on Company-provided credit cards or accounts (such as cell phone accounts) and cancel or personally assume any such credit cards or accounts. I agree not to incur any expenses, obligations, or liabilities on behalf of the Company.

(c) Announcement: To announce my resignation, both parties agree to issue the statements set forth on Schedule A attached hereto.

(d) Cooperation: I agree that, as requested by the Company, and at no additional cost, I will cooperate reasonably with the Company or any affiliate in effecting a smooth transition of my responsibilities to others and with respect to any current or future investigation or the defense or prosecution of any claims, proceedings, arbitrations or other actions. For example, upon reasonable notice, I will promptly and fully respond to all reasonable inquiries from the Company or any affiliate and its representatives relating to any lawsuit or arbitration and testify truthfully on behalf of the Company in connection with any such lawsuit or arbitration. I further agree that, as reasonably requested by the Company and at no additional cost, I will cooperate fully with the Company or its representatives in any investigation, proceeding, administrative review or litigation brought against the Company or any Released Party by any government agency or private party pertaining to matters occurring during my employment with the Company or any Released Party, provided, however, that after the term of my Consulting Agreement, the Company will request such cooperation with due regard to my personal and professional commitments and provide reasonable reimbursement for my time in the event that such cooperation is requested on more than an occasional basis. To the extent that I incur out-of-pocket expenses (such as postage costs or telephone charges) in assisting the Company or any affiliate at its request, the Company will mail me a reimbursement check for those expenses within 15 days following its receipt of my request for payment, which request shall include satisfactory written substantiation of the claimed expenses.

10. **Consideration of Agreement**: If initially I did not think any representation made in this Agreement was true or if initially I felt uncomfortable in making it, I have resolved all my doubts and concerns before signing this Agreement. I have carefully read this Agreement, I fully understand what it means, I am entering into it knowingly and voluntarily, and all my representations in it are true. The consideration period described in the box above my signature began when I first was given this Agreement, and I waive any right to have it restarted or extended by any changes made to this Agreement after my first being given a copy of it.

11. **Additional Representations**: When I decided to sign this Agreement, I was not relying on any representations that are not included in this Agreement. The Company would not have agreed to pay me payments or benefits in exchange for signing this Agreement but for the representations and covenants I made by signing it. I have properly reported all hours that I have worked and I have been paid all compensation, benefits and other amounts that the Company or any Released Party owed me. I have submitted a request for reimbursement for all amounts that I am entitled to receive reimbursement from any of the Released Parties. I understand that the Company in the future may improve employee benefits or pay. I understand that my former job may be refilled.

12. **Remedies**: Without excluding other remedies available to the Company, if, within three years after the Effective Date of this Agreement, I am convicted or plead guilty or no contest to any federal or state felony in connection with actions or activities in which I engaged related to the Company's business or products, I shall repay the Company the net amount of the Consideration I received, *i.e.*, the amount of the consideration after the tax withholdings shown on the accompanying wage statement, within thirty (30) days after the entry of the conviction or plea of guilty or no contest, and the Company shall be excused from making any of the remaining Consideration payments, if any, after that date. Further, within three years after the Effective Date of this Agreement, in the event that a federal enforcement authority levies a fine against the Company as a result of or in connection with factual findings sating that said fine resulted from misconduct by me individually or committed at my individual direction during my employment with the Company, may clawback part or all of the consideration paid to me in Section 1 to offset the amount of said fine(s), if any.

13. **Re-Execution Requirements**: Notwithstanding anything in this Agreement to the contrary, after the Effective Date, if I fail to re-execute this Agreement after my last day of employment, I will receive only ten percent of the Separation Payment. My re-execution of this Agreement will update this Agreement to waive any claims that might have accrued after I first executed this Agreement.

14. **Arbitration of Disputes**: I acknowledge that the Company and I have agreed to resolve on an individual basis any disputes we may have with each other through final and binding arbitration, as set forth in my CONFIDENTIAL INFORMATION, INVENTION ASSIGNMENT, NON-COMPETITION AND ARBITRATION AGREEMENT. The Federal Arbitration Act will govern this section, but if for any reason the FAA is held to be inapplicable, then the law of arbitrability of the state in which I last worked for the Company will apply.

15. **Fees and Costs**: In the event of litigation or arbitration relating to this Agreement or its subject matter, the prevailing party shall be entitled to recover its reasonable attorneys' fees and costs.

16. **Trade Secrets and Confidential Information/Company Property**: I acknowledge and reaffirm my obligations under that certain CONFIDENTIAL INFORMATION, INVENTION ASSIGNMENT, NON-COMPETITION AND ARBITRATION AGREEMENT entered into between the Company and me. I represent that I have never violated the

CONFIDENTIAL INFORMATION, INVENTION ASSIGNMENT, NON-COMPETITION AND ARBITRATION AGREEMENT. I agree to maintain the confidentiality of all communications and information I received or shared while employed by the Company that at the time were protected by the attorney-client privilege and the attorney work product doctrine. I agree that I will return all documents and other items provided to me by the Company, developed or obtained by me in connection with my employment with the Company, or otherwise belonging to the Company by October 1, 2023.

17. **Unlawful Acts, Government and Agency Communication, Testimony, Charges, etc.**: Nothing in this Agreement or in the Consulting Agreement prevents me from discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination or any other conduct that I have reason to believe is unlawful, or from giving truthful testimony or truthfully responding to a valid subpoena, or communicating, testifying before or filing a charge with government or regulatory entities (such as the U.S. Equal Employment Opportunity Commission (EEOC), National Labor Relations Board (NLRB), U.S. Department of Labor (DOL) or U.S. Securities and Exchange Commission (SEC)), subject to any obligation I may have to take steps to protect trade secrets and similar confidential information from public disclosure. However, I promise never to seek or accept any compensatory damages, back pay, front pay or reinstatement remedies for myself personally with respect to any claims released by this Agreement.

18. **Miscellaneous**:

(a) Complete Agreement: This Agreement (including any agreements referenced herein) is the entire agreement relating to any claims or future rights that I have or might have with respect to the Company and the Released Parties. Once in effect, this Agreement is a legally admissible and binding agreement. It will not be construed strictly for or against me, the Company, or any other Released Party. The headings contained in this Agreement are for convenience and shall not affect the meaning or interpretation of this Agreement.

(b) Counterparts: This Agreement may be signed in one or more counterparts or multiple originals, each of which shall be an original but all of which together shall constitute one and the same document. The parties agree that facsimile and electronic signatures have the same force and effect as original signatures.

(c) Waiver: No waiver of any provision of this Agreement shall be binding unless reduced to writing and signed by the waiving party. No such waiver of any provision of this Agreement shall waive of any other provision of this Agreement or constitute a continuing waiver.

(d) Amendments: This Agreement only may be amended by a written agreement that the Company and I both sign.

(e) Effect of Void Provision: If the Company or I successfully assert that any provision in this Agreement is void, the rest of the Agreement will remain valid and enforceable unless the other party to this Agreement elects to cancel it; provided, however, that if the Company asks me to sign a new document containing a legal and enforceable replacement provision in lieu of canceling the Agreement, I promise that I will do so. If this Agreement is canceled, I will repay any payments or benefits I received for signing it.

(f) No Wrongdoing: This Agreement is not an admission of wrongdoing by the Company, any other Released Party, or Consultant; neither it nor any drafts will be admissible evidence of wrongdoing.

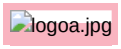
YOU MAY NOT MAKE ANY CHANGES TO THIS AGREEMENT. BEFORE SIGNING THIS AGREEMENT, READ IT CAREFULLY. YOU HAVE A RIGHT TO CONSULT AN ATTORNEY, AND THE COMPANY ADVISES YOU TO DISCUSS THIS AGREEMENT WITH YOUR ATTORNEY. YOU HAVE 21 DAYS FOLLOWING THE DATE ON WHICH YOU RECEIVED THIS AGREEMENT TO CONSIDER IT AND DELIVER A SIGNED COPY OF IT TO FRED COHEN AT FECOHEN@PACBELL.COM, ALTHOUGH YOU ARE FREE TO SIGN AND DELIVER IT ANYTIME WITHIN THAT PERIOD. BY SIGNING IT, YOU WILL BE WAIVING YOUR KNOWN AND UNKNOWN CLAIMS.

YOU MAY RESCIND THIS AGREEMENT. TO DO SO, YOU MUST DELIVER A WRITTEN NOTICE THAT YOU ARE RESCINDING THIS AGREEMENT TO FRED COHEN AT FECOHEN@PACBELL.COM BEFORE SEVEN DAYS EXPIRE FROM THE TIME YOU SIGNED IT. IF YOU RESCIND THIS AGREEMENT, IT WILL NOT GO INTO EFFECT AND YOU WILL NOT RECEIVE THE PAYMENTS OR BENEFITS DESCRIBED IN IT THAT ARE CONTINGENT ON YOUR ENTERING INTO AND NOT RESCINDING THIS AGREEMENT.

Date: 9/20/2023 /s/ Abraham Ronai
Abraham Ronai

Date: 9/20/2023 /s/ Michael Goldberg
CareDx, Inc.

Exhibit 10.2



LEGAL CONSULTING AGREEMENT

This Legal Consulting Agreement ("Agreement") is entered into on September 20, 2023 and is effective on October 1, 2023 ("Effective Date") and is between CareDx, Inc., with a business address at 8000 Marina Blvd, Brisbane, CA 94005 ("CareDx" or the "Company") and Abraham Ronai ("Consultant"), following Consultant's resignation of employment pursuant to the fully executed Separation Agreement between Consultant and CareDx. CareDx and Consultant may be referred to individually as a ("Party") and collectively as the ("Parties").

1. **Services**

a. Consultant will perform the legal services and/or participate in the event(s) described in Exhibit A ("Services"). CareDx will compensate Consultant as set forth in Exhibit A. Both Parties acknowledge that this compensation represents the fair market value of Consultant's Services.

b. Consultant shall not incur any expenses of any kind or nature without the prior written approval of the Chairperson. Upon prior written approval by the Chairperson, CareDx will reimburse Consultant for reasonable travel, lodging and incidental expenses incurred in the performance of the Services ("Reimbursable Expenses").

c. CareDx must comply with legal requirements to provide compliance and regulatory training to certain of its consultants. Consultant agrees to complete any appropriate training as may be assigned by CareDx.

2. **Confidentiality**

a. Consultant understands that his consulting work for CareDx creates a relationship of confidence and trust with respect to any information of a confidential or secret nature that (i) relates to the business of CareDx or to the business of any parent, subsidiary, affiliate, customer or vendor of CareDx or any other party with whom CareDx agrees to hold information of such party in confidence; (ii) is not generally known to the public or to other persons in the industry; and (iii) CareDx has taken reasonable measures under the circumstances to protect from unauthorized use or disclosure ("Confidential Information"). Confidential Information means (a) trade secrets; (b) proprietary information that does not rise to the level of a statutorily protectable trade

secret that is made the property of CareDx through positive operation of law in the form of this mutual agreement of the parties; or (c) information that is otherwise legally protectable. Such Confidential Information includes, but is not limited to, Work Product (as defined below), information protected by the attorney/client privilege and attorney work product doctrine, and non-public knowledge, data, information and know-how, such as information relating to CareDx's products, services, and methods of operation, the identities and competencies of CareDx's employees, customers and suppliers, chemical formulae, computer software, financial information, operating and cost data, research databases, selling and pricing information, business and marketing plans, and information concerning potential acquisitions, dispositions or joint ventures, as well as all non-public intellectual property rights including unpublished or pending patent applications and all related patent rights, techniques, formulae, processes, discoveries, improvements, ideas, conceptions, compilations of data and developments, whether or not patentable and whether or not copyrightable. The foregoing are only examples of Confidential Information.

b. Consultant will, at all times, both during the term of this Agreement and for seven (7) years thereafter, hold all Confidential Information in the strictest confidence. Consultant will not attempt unauthorized access to Confidential Information, or use, disclose, copy, reverse-engineer or distribute any Confidential Information without the prior written consent of

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CareDx, except as may be necessary to perform Services. Despite Consultant's confidentiality obligations, Consultant understands that he is permitted to disclose Confidential Information that is required to be disclosed pursuant to judicial order or other legal mandate, provided that Consultant has given CareDx prompt notice of the disclosure requirement, and that Consultant fully cooperates with any efforts by CareDx to obtain and comply with any protective order imposed on such disclosure.

c. Confidential Information does not include information that Consultant can show: (i) was generally available to, or known by, the relevant public at the time of disclosure, or became generally available to, or known by the relevant public, after disclosure to Consultant; (ii) was lawfully received by Consultant from a third party without breach of any confidentiality obligation; (iii) was known to Consultant prior to receipt from CareDx; or (iv) was independently developed by Consultant or independent third parties without breach by Consultant or any third party of any obligation of confidentiality or non-use.

d. During the term of this Agreement, Consultant will not improperly use, disclose or induce CareDx to use any confidential information of any former or current employer (other than CareDx) or other person or entity with which Consultant has an agreement or duty to keep information in confidence.

e. Upon termination or expiration of this Agreement, or upon CareDx's earlier request, Consultant will deliver to CareDx, and will not keep in his possession, recreate or deliver to anyone else, any and all CareDx property, including, but not limited to, Confidential Information, as well as all devices and equipment belonging to CareDx (including computers, handheld electronic devices, telephone equipment and other electronic devices), CareDx credit cards, records, data, notes, notebooks, reports, files, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, photographs, charts, any other documents and property, and reproductions of any and all of the aforementioned items that were developed by Consultant as part of Consultant's Services for CareDx, obtained by Consultant in connection with Consultant's Services for CareDx, or otherwise belonging to CareDx. If, at the time of termination, Consultant has Confidential Information stored in Consultant's personal computer or any mobile, cloud or other storage medium, Consultant will so advise CareDx and not delete, cache or transfer it. Consultant will then work with CareDx to ensure that the location of all such information is fully disclosed to CareDx, retrieved and returned to CareDx in a forensically sound manner, and is permanently deleted.

3. **Intellectual Property**

a. Consultant hereby assigns and will assign all inventions, improvements, ideas, designs, original works of authorship, formulas, processes, compositions of matter, computer software programs and databases, that Consultant makes, creates, conceives, or first reduces to practice during the term of this Agreement that (i) are developed using equipment, supplies, facilities or trade secrets of CareDx, or (ii) are developed within the course and scope of Consultant's performance of Services hereunder ("Work Product").

b. Consultant recognizes and understands that this Agreement does not require assignment of any inventions that are developed either (i) during the course of and within the scope of Consultant's full-time employment with a subsequent employer, or (ii) entirely on Consultant's own time, and with respect to both the foregoing clauses (i) and (ii), without using any of CareDx's equipment, supplies, facilities or Confidential Information. Original works of authorship, inventions, developments and trade secrets that belong to Consultant are not assigned to CareDx ("Prior Inventions").

c. To the extent any future act is required, Consultant will assist CareDx, or its designee, at CareDx's expense, to secure CareDx's rights in the Work Product including copyrights, patents, mask work rights or other intellectual property rights relating thereto in any and all countries. Consultant will execute or cause to be executed any such instrument or papers during the term of this Agreement and after the term of this Agreement. If, at any time, a court or other tribunal rules that the assignment under this section is ineffective or unenforceable for any reason, Consultant agrees to perform all actions necessary to assign the Work Product to CareDx.

d. If Consultant incorporates any invention, improvement, development, concept, discovery, Prior Invention or other confidential information owned by Consultant or in which Consultant has an interest, into any Work Product, Consultant hereby grants and will grant, without any further action required by either Party, a nonexclusive, royalty-free, perpetual, irrevocable, with the right to grant and authorize sublicenses, worldwide license to use, make, have made, modify, use and sell such item as part of or in connection with such Work Product.

e. If CareDx is unable because of Consultant's unavailability, mental or physical incapacity, or any other reason, to secure Consultant's signature to pursue any application for any United States or foreign patents or mask work or copyright registrations covering the Work Product, then Consultant hereby irrevocably designates and appoints CareDx and its duly authorized officers and agents as Consultant's agent and attorney-in-fact, to act for and on Consultant's behalf to execute and file any such applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyright and mask work registrations thereon with the same legal force and effect as if executed by Consultant.

4. **No Conflicting Obligations**

Consultant warrants that entering into this Agreement does not violate any outstanding agreement, obligation or employment arrangement of Consultant. Consultant further warrants that during the term of this Agreement, he will not enter into any such conflicting agreement. Further, Consultant will not perform any services for CareDx that would conflict with any agreement or obligation of Consultant, or which would cause or result in any other person or entity having any ownership interest in any CareDx intellectual property, including Work Product (as defined below).

5. **Term and Termination**

The term of this Agreement will begin on the Effective Date and will continue in full force and effect for a period of 12 months from the Effective Date (the "Initial Term"). This Agreement may be extended or renewed for additional agreed upon periods (the "Renewal Term") upon the written agreement of the Parties at least ninety (90) days prior to the end of the Initial Term, or a Renewal Term, as the case may be (the Renewal Term, together with the Initial Term, the "Term") and shall otherwise terminate at the end of the Initial Term or any Renewal Term, as the case may be.

This Agreement will terminate automatically (i) upon Consultant's death or disability (if such disability substantially impairs his ability to provide consulting to the Company), provided, however, that upon such automatic termination, the Company shall not be entitled to any reimbursement of any amount actually paid to Consultant, or (ii) upon Consultant's valid revocation of the Separation Agreement (in either case, such a termination, an "Automatic Termination"). In the event of an Automatic Termination, notwithstanding anything in this Agreement to the contrary, the Company will only be obligated to pay for consulting actually rendered on or before the date of such automatic termination.

Further, CareDx may terminate this Agreement for "Good Cause," in which case Consultant shall not be entitled to any further compensation or benefits under this Agreement. For the purposes of this Agreement, "Good Cause" shall be defined as any act or omission by the Consultant that is materially

detrimental to the Company, including but not limited to, material acts of misconduct, material violation of CareDx policies, failure to fulfill the material terms of this Agreement, material breach of confidentiality, Consultant's material breach of his Separation Agreement, or any criminal or fraudulent activity. Notwithstanding the foregoing, a determination of Good Cause shall not be made unless and until there shall have been delivered to Consultant a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the members of the Company's Board of Directors (the "Board") at a meeting of the Board called and held for that purpose (after reasonable notice to Consultant and an opportunity for him, together with his counsel, to be heard before the Board), finding that in the good faith opinion of the Board, Consultant was guilty of conduct justifying termination for Good Cause and specifying the particulars thereof in detail.

In addition, Consultant may terminate this Agreement for "Good Reason" which, for purposes of this Agreement, shall be defined as any diminution in Consultant's title or any actual Change in Control as defined in the Indemnification Agreement or any material breach of this Agreement or the Separation Agreement by the Company.

6. **Independent Contractor**

Consultant is an independent contractor and nothing in this Agreement or the performance of the Parties under this Agreement will constitute (or be deemed to constitute in law or in equity) a partnership, agency, distributorship, fiduciary, employment, principal/agent relationship or joint venture relationship between the Parties. The Parties are not affiliated and neither has any right or authority to bind the other in any way. As such, Consultant will not be entitled to any benefits accorded to CareDx's employees, including workers' compensation, disability insurance, vacation or sick pay. Consultant will have sole control of and will determine the manner, method, details and means of performing the obligations under this Agreement, provided, however, that CareDx retains the right to control the overall objectives regarding the Services.

7. **DTSA Notification**

Despite Consultant's confidentiality obligations set forth in this Agreement, Consultant understands that, pursuant to the Defend Trade Secrets Act of 2016, Consultant will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. If Consultant files a lawsuit for retaliation by CareDx for reporting a suspected violation of law, Consultant may disclose the trade secret to Consultant's attorney and may use the trade secret information in the court proceeding, if Consultant (a) files any document containing the trade secret under seal, and (b) does not disclose the trade secret, except pursuant to court order.

8. **Restrictive Covenants**

Consultant will not, during the term of this Agreement and, to the fullest extent permissible under applicable law, for six (6) months thereafter, directly or indirectly, solicit or attempt to solicit employees or consultants of CareDx to terminate their relationship with CareDx. Despite the previous sentence, Consultant may hire CareDx employees or consultants that respond to a general solicitation for employment or other engagement. Consultant will not during the term of this Agreement directly or indirectly solicit or induce (or attempt to solicit or induce) vendors of CareDx to terminate their relationship with CareDx.

Consultant acknowledges that he is in possession of and will have continuing access to the Company's Confidential Information (as defined in Section 2 above) while Consultant provides services under this Agreement, and accordingly Consultant shall have a fiduciary duty and an undivided duty of loyalty to

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the Company such that Consultant shall not, while providing services to the Company, (i) accept employment with or render managerial, advisory or consulting services to any third party directly competitive with the Company; or (ii) perform services for himself or any third party, if doing so threatens to or actually requires him to reveal or utilize the Company's Confidential Information.

9. **Indemnification**

The Company will indemnify, defend (with counsel reasonably acceptable to Consultant) and hold harmless Consultant against any claim by the IRS or other taxing authority that the relationship created by this Consulting Agreement is actually an employment relationship, including any tax assessments, fines, penalties and legal or accounting expenses related to any such claim.

The terms of the Parties' September 20, 2021, Indemnification Agreement shall be unaffected by this Agreement and the Separation Agreement, except insofar as to recognize that Consultant is no longer a director or officer of the Company.

10. **Limitation of Liability**

Except for a willful breach of this Agreement or a breach by Consultant of Sections 2, 3, or 8, in no event will either Party be liable to the other for any special, incidental, punitive or consequential damages of any kind in connection with this Agreement, even if such party has been informed in advance of the possibility of such damages. Moreover, in no event shall either Party's aggregate liability under this Agreement, including under Section 9 above but excluding the Company's obligations under Section 4 of Exhibit A hereto, exceed an amount equal to the aggregate cash compensation (not including cash proceeds of equity compensation) paid to Consultant under this Agreement.

11. **Compliance with Laws**

Consultant warrants to CareDx that during the term of this Agreement, Consultant: (a) is not currently excluded, debarred, or otherwise ineligible to participate in any federal health care program as defined in 42 U.S.C. Section 1320a-7b(f) or any state healthcare program (collective, the "Healthcare Programs"); (b) has not been convicted of a criminal offense related to the provision of health care items or services and not yet been excluded, debarred or otherwise declared ineligible to participate in the Healthcare Programs; and (c) is not under investigation or otherwise aware of any circumstances which may result in Consultant being excluded from participation in Healthcare Programs. Consultant will immediately notify CareDx of any change in the status of the representations and warranties set forth in this section.

12. **Miscellaneous**

a. *Severability*. If any provision of this Agreement is determined to be illegal or unenforceable, that provision will be limited or eliminated to the minimum extent necessary so that this Agreement will otherwise remain enforceable and in full force and effect.

b. *Survival*. Sections 2 (Confidentiality), 3 (Intellectual Property), 8 (Restrictive Covenants), 9 (Indemnification), 10 (Limitation of Liability), and 12 (Miscellaneous) will survive such termination or expiration of this Agreement.

c. *Governing Law*. This Agreement will be governed by and construed under the laws of the State of California without regard to the conflict of law provisions thereof. Each Party consents to venue exclusively in San Mateo County, California, for any dispute or controversy arising out of or relating to any interpretation, construction, performance, or breach of this Agreement.

d. *Equitable Remedies*. In the event of a breach or a threatened breach of this Agreement by a Party, the other Party may seek judicial relief in any forum with jurisdiction over the Parties. In such case, each Party agrees that the other Party may suffer irreparable harm and will therefore be entitled to request injunctive relief to enforce this Agreement, without any requirement to obtain bonds or other security. Each Party also acknowledges that, in the event of breach of this Agreement by such Party, the other Party may pursue any and all available legal remedies, including monetary damages.

e. *No Assignment*. Consultant may not assign this Agreement to any third party.

f. *Waiver*. Waiver by either Party of a breach of any provision of this Agreement will not operate as a waiver of any other or subsequent breach.

g. *Entire Agreement.* This Agreement is the entire agreement of the Parties and supersedes any prior agreements, understandings, or arrangement between them with respect to the subject matter hereof, except to the extent such prior agreements are referenced herein.

h. *Modifications*. This Agreement may be modified only by a subsequent written agreement signed by both Parties.

i. *Execution*. This Agreement may be executed via facsimile, electronic signature via recognized provider (e.g., DocuSign or Adobe), or ".pdf" file, and in two counterparts, each of which will be deemed an original, but both of which together will constitute one and the same instrument and will have the same legal force and effect as the exchange of original signatures.

CareDx, Inc. **Abraham Ronai**

By: /s/ Michael Goldberg By: /s/ Abraham Ronai
Name: Michael D. Goldberg Date: September 20, 2023
Title: Chairperson of the Board of Directors
Date: September 20, 2023

EXHIBIT A

1. **Contact**

Consultant's Contact information is as follows:

Name: Abraham Ronai

Address:
United States

Phone:

Email:

2. **Services**

Consultant shall report directly to CareDx, Inc.'s Chairperson of the Board, Michael Goldberg or Mr. Goldberg's successor as Chairperson of the Board, as Senior Legal Advisor to the Chairperson. Consultant acknowledges and warrants that he is a licensed attorney in good standing, and hereby agrees to provide legal services in connection with threatened or pending legal matters and to offer legal advice to the Company, including in connection with the pending SEC and DOJ investigations. All communications, documents, and work product generated by the Consultant during the course of his service, including but not limited to written advice, reports, memoranda, emails, and other materials (collectively referred to as "Communications and Work Product"), shall be deemed attorney-client privileged communications and/or attorney work product, treated with the utmost confidentiality, and shall not be disclosed to any third party except as authorized by the Company or required by law. The Parties further understand and acknowledge that the attorney-client privilege and attorney work product doctrine may apply to protect the Communications and Work Product from disclosure in legal proceedings, with no waiver of such privileges intended. This Agreement is governed by the laws of the state of California. The Services may be performed, at Consultant's discretion, remotely via Zoom or similar teleconferencing technology.

3. **Time Commitment**

The Consultant shall provide services for a maximum of forty (40) hours in any given month, beginning on the Effective Date. Company shall reasonably accommodate Consultant's personal and other professional obligations and shall provide reasonable advance notice of the time-frame associated with any specific requested Services.

4. **Compensation and Expense Reimbursement**

From October 1, 2023, to December 31, 2023, CareDx shall remunerate the Consultant with a fixed fee of One Hundred Fifteen Thousand Dollars ($115,000.00), to be paid in January 2024. In addition, for each subsequent month during the Term of this Agreement, including any Renewal Term, CareDx shall compensate the Consultant with a fixed fee of Twenty-Five Thousand Dollars ($25,000). Payment to the Consultant will occur on a quarterly basis promptly after the end of the quarter. In the event that the Company terminates the Consulting Agreement during the Initial Term, other than for Good Cause, Consultant shall be entitled to the continued payment of the monthly consulting fees for the remainder of the Initial Term.

Furthermore, the Consultant shall retain the entitlement to continue vesting according to the original vesting schedules for the Grants and Awards set forth in **Schedule A** below ("Existing Equity Grants"), which the Consultant would have otherwise received had he remained employed after his separation date. The vesting rate shall remain unaffected and shall not be reduced, deferred, or canceled, regardless of the number of hours required to work during the term of the Consulting Agreement, except that the Existing Equity Grants shall vest upon (i) termination of this Consulting Agreement by the Company (other than

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for Good Cause), (ii) termination of this Consulting Agreement by Consultant for Good Reason, or (iii) the expiration of the Initial Term or any Additional Term in the event of non-renewal.

The Company agrees to grant the Consultant 360,000 restricted stock units ("RSU Consultancy Grant") upon execution of this Agreement. Fifty percent of the RSU Consultancy Grant and all remaining unvested Existing Equity Grants shall vest upon the termination of this Agreement, other than a termination by the Consultant (unless for Good Reason) or a termination by the Company for Good Cause. The remaining fifty percent of the RSU Consultancy Grant shall vest on the earlier of (a) October 1, 2024, and (b) the termination of this Agreement other than (i) a termination by the Consultant (unless for Good Reason) or (ii) a termination by the Company for Good Cause.

In the event of an Automatic Termination (other than a revocation of the Agreement), the Company will only be obligated to pay for consulting actually rendered on or before the date of such Automatic Termination, however, Consultant's RSU Consultancy Grant and all Existing Equity Grants will automatically vest and the Company shall not be entitled to recoup any amount actually paid to Consultant other than as otherwise authorized by this Agreement.

In the event of a termination for Good Cause, the Company will only be obligated to pay for consulting actually rendered on or before the date of such termination, and Consultant's unvested stock units will automatically expire.

In the event of a termination for Good Reason, Consultant shall be entitled to immediate vesting of the RSU Consultancy Grant and any unvested Existing Equity Grants and any unpaid cash consideration that would otherwise have been payable to Consultant for the Initial Term to the extent not yet paid in the event that no termination had occurred until the conclusion of the Initial Term, and the Company shall not be entitled to recoup any amount actually paid to Consultant other than as otherwise authorized by this Agreement.

CareDx will reimburse Consultant all pre-authorized Reimbursable Expenses upon presentation of an invoice, including original receipts.

Exhibit 31.1

**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, Alexander L. Johnson, 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: November 8, 2023 May 9, 2024

By: /s/ Alexander L. Johnson John W. Hanna

Alexander L. Johnson John W. Hanna

President of Patient and Testing Services Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

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: November 8, 2023 May 9, 2024

By: /s/ Abhishek Jain
Abhishek Jain
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the "Company") for the period ended September 30, 2023 March 31, 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/ Alexander L. Johnson John W. Hanna
Alexander L. Johnson John W. Hanna
President of Patient and Testing Services Chief Executive Officer
(Principal Executive Officer)
Date: November 8, 2023 May 9, 2024

By: /s/ Abhishek Jain
Abhishek Jain
Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: November 8, 2023 May 9, 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.

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

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