

**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, 2025

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

CAREDIX, INC.

(Exact name of registrant as specified in its charter)

Delaware

**(State or other jurisdiction of
incorporation or organization)**

94-3316839

**(I.R.S. Employer
Identification Number)**

**8000 Marina Boulevard, 4th Floor
Brisbane, California 94005**

(Address of principal executive offices and zip code)

(415) 287-2300

(Registrant's telephone number, including area code)

N/A

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

Securities registered pursuant to Section 12(b) of the Act

Title of Each Class

Trading Symbol

Name of Each Exchange on Which Registered

Common Stock, par value \$0.001 per share

CDNA

The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

There were 51,432,639 shares of the registrant's Common Stock issued and outstanding as of October 30, 2025.

CareDx, Inc.
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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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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,” “predict,” “expect” and the negative and plural forms of these words and similar expressions are intended to identify forward-looking statements.

“CareDx” or the “Company” or “we” or “us” or “our” as used in the Quarterly Report on Form 10-Q refer to CareDx, Inc. and its subsidiaries.

These forward-looking statements may include, but are not limited to, statements concerning the following:

- our ability to generate revenue and increase the commercial success of our current and future testing services, products and patient and digital solutions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for our current and other future testing services, if any;
- our plans and ability to continue updating our testing services, products and patient and digital solutions to maintain our leading position in transplantation;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us;
- our ability to successfully assert, defend against or settle any litigation brought by or against us or other legal matters or disputes; and
- our ability to remediate the material weakness that was identified in our internal control over financial reporting and which was not remediated as of September 30, 2025.

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, in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025, filed with the SEC on April 30, 2025, in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2025, filed with the SEC on August 6, 2025, and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 28, 2025. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover,

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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.

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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 91,435	\$ 114,689
Marketable securities	102,782	145,964
Accounts receivable	47,844	64,605
Inventory	28,328	19,503
Prepaid and other current assets	29,891	7,071
Total current assets	300,280	351,832
Property and equipment, net	30,845	33,552
Operating leases right-of-use assets	24,047	24,340
Intangible assets, net	33,446	38,184
Goodwill	40,336	40,336
Restricted cash	551	585
Other assets	2,802	2,221
Total assets	<u><u>\$ 432,307</u></u>	<u><u>\$ 491,050</u></u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 11,597	\$ 7,686
Accrued compensation	23,237	38,333
Accrued litigation settlement expense	20,250	—
Accrued and other liabilities	43,960	43,352
Total current liabilities	99,044	89,371
Deferred tax liability	117	164
Contingent consideration	160	174
Operating lease liability, less current portion	21,212	22,263
Other liabilities	634	645
Total liabilities	<u><u>121,167</u></u>	<u><u>112,617</u></u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock: \$0.001 par value; 100,000,000 shares authorized at September 30, 2025 and December 31, 2024; 51,407,335 and 54,771,203 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	51	51
Additional paid-in capital	1,036,091	1,013,193
Accumulated other comprehensive loss	(5,955)	(8,569)
Accumulated deficit	(719,047)	(626,242)
Total stockholders' equity	<u><u>311,140</u></u>	<u><u>378,433</u></u>
Total liabilities and stockholders' equity	<u><u>\$ 432,307</u></u>	<u><u>\$ 491,050</u></u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Testing services revenue	\$ 72,168	\$ 60,807	\$ 196,122	\$ 185,562
Product revenue	12,478	10,212	35,121	29,416
Patient and digital solutions revenue	15,409	11,864	40,176	32,228
Total revenue	100,055	82,883	271,419	247,206
Operating expenses:				
Cost of testing services	14,705	13,447	45,224	41,387
Cost of product	5,629	6,212	16,196	17,854
Cost of patient and digital solutions	10,320	7,913	26,307	22,264
Research and development	16,769	17,486	52,123	55,890
Sales and marketing	24,449	19,802	71,719	60,634
General and administrative	28,429	31,744	78,881	92,791
Litigation settlement expense	—	—	5,710	—
Total operating expenses	100,301	96,604	296,160	290,820
Loss from operations	(246)	(13,721)	(24,741)	(43,614)
Other income:				
Interest income, net	2,013	3,001	7,161	8,712
Other (expense) income, net	(107)	283	260	(107)
Total other income	1,906	3,284	7,421	8,605
Income (loss) before income taxes	1,660	(10,437)	(17,320)	(35,009)
Income tax benefit (expense)	15	(200)	74	(139)
Net income (loss)	\$ 1,675	\$ (10,637)	\$ (17,246)	\$ (35,148)
Net income (loss) per share (Note 3):				
Basic	\$ 0.03	\$ (0.20)	\$ (0.32)	\$ (0.67)
Diluted	\$ 0.03	\$ (0.20)	\$ (0.32)	\$ (0.67)
Weighted-average shares used to compute net income (loss) per share:				
Basic	52,507,582	52,903,338	54,016,446	52,266,106
Diluted	53,736,790	52,903,338	54,016,446	52,266,106

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net income (loss)	\$ 1,675	\$ (10,637)	\$ (17,246)	\$ (35,148)
Other comprehensive income (loss):				
Foreign currency translation adjustment, net of tax	158	785	2,614	(216)
Comprehensive income (loss)	<u><u>\$ 1,833</u></u>	<u><u>\$ (9,852)</u></u>	<u><u>\$ (14,632)</u></u>	<u><u>\$ (35,364)</u></u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	54,771,203	\$ 51	\$ 1,013,193	\$ (8,569)	\$ (626,242)	\$ 378,433
Issuance of common stock under employee stock purchase plan	66,747	—	873	—	—	873
RSU settlements, net of shares withheld	482,874	—	(3,065)	—	—	(3,065)
Issuance of common stock for services	856	—	21	—	—	21
Issuance of common stock for cash upon exercise of stock options	141,050	—	3,049	—	—	3,049
Employee stock-based compensation expense	—	—	8,911	—	—	8,911
Foreign currency translation adjustment, net of tax	—	—	—	1,480	—	1,480
Net loss	—	—	—	—	(10,353)	(10,353)
Balance at March 31, 2025	55,462,730	\$ 51	\$ 1,022,982	\$ (7,089)	\$ (636,595)	\$ 379,349
Issuance of common stock under employee stock purchase plan	84,234	1	1,398	—	—	1,399
Repurchase and retirement of common stock	(3,031,533)	(2)	—	—	(49,998)	(50,000)
RSU settlements, net of shares withheld	603,164	1	(6,240)	—	—	(6,239)
Issuance of common stock for services	967	1	20	—	—	21
Issuance of common stock for cash upon exercise of stock options	100,561	1	1,028	—	—	1,029
Employee stock-based compensation expense	—	—	9,403	—	—	9,403
Foreign currency translation adjustment, net of tax	—	—	—	976	—	976
Net loss	—	—	—	—	(8,568)	(8,568)
Balance at June 30, 2025	53,220,123	\$ 53	\$ 1,028,591	\$ (6,113)	\$ (695,161)	\$ 327,370
Repurchase and retirement of common stock	(1,986,563)	(2)	—	—	(25,561)	(25,563)
RSU settlements, net of shares withheld	143,421	—	(1,147)	—	—	(1,147)
Issuance of common stock for services	1,218	—	22	—	—	22
Issuance of common stock for cash upon exercise of stock options	29,136	—	232	—	—	232
Employee stock-based compensation expense	—	—	8,393	—	—	8,393
Foreign currency translation adjustment, net of tax	—	—	—	158	—	158
Net income	—	—	—	—	1,675	1,675
Balance at September 30, 2025	51,407,335	\$ 51	\$ 1,036,091	\$ (5,955)	\$ (719,047)	\$ 311,140

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	51,503,377	\$ 49	\$ 946,511	\$ (6,963)	\$ (678,269)	\$ 261,328
Issuance of common stock under employee stock purchase plan	73,759	—	532	—	—	532
Repurchase and retirement of common stock	(55,500)	—	—	—	(522)	(522)
RSU settlements, net of shares withheld	252,662	—	(668)	—	—	(668)
Issuance of common stock for services	6,813	—	56	—	—	56
Issuance of common stock for cash upon exercise of stock options	1,501	—	8	—	—	8
Employee stock-based compensation expense	—	—	16,524	—	—	16,524
Foreign currency translation adjustment, net of tax	—	—	—	(1,145)	—	(1,145)
Net loss	—	—	—	—	(19,888)	(19,888)
Balance at March 31, 2024	51,782,612	\$ 49	\$ 962,963	\$ (8,108)	\$ (698,679)	\$ 256,225
RSU settlements, net of shares withheld	811,360	1	(3,601)	—	—	(3,600)
Issuance of common stock for services	4,935	—	49	—	—	49
Issuance of common stock for cash upon exercise of stock options	18,536	—	123	—	—	123
Employee stock-based compensation expense	—	—	16,351	—	—	16,351
Foreign currency translation adjustment, net of tax	—	—	—	144	—	144
Net loss	—	—	—	—	(4,623)	(4,623)
Balance at June 30, 2024	52,617,443	\$ 50	\$ 975,885	\$ (7,964)	\$ (703,302)	\$ 264,669
Issuance of common stock under employee stock purchase plan	85,260	—	865	—	—	865
RSU settlements, net of shares withheld	208,508	—	(2,577)	—	—	(2,577)
Issuance of common stock for services	3,997	—	48	—	—	48
Issuance of common stock for cash upon exercise of stock options	191,663	—	3,191	—	—	3,191
Employee stock-based compensation expense	—	—	16,902	—	—	16,902
Foreign currency translation adjustment, net of tax	—	—	—	785	—	785
Net loss	—	—	—	—	(10,637)	(10,637)
Balance at September 30, 2024	53,106,871	\$ 50	\$ 994,314	\$ (7,179)	\$ (713,939)	\$ 273,246

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

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

	Nine Months Ended September 30,	
	2025	2024
Operating activities:		
Net loss	\$ (17,246)	\$ (35,148)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	26,773	49,895
Depreciation and amortization	11,136	10,833
Impairment of intangible asset and associated construction in progress	2,258	—
Amortization of right-of-use assets	4,020	4,236
Revaluation of contingent consideration to estimated fair value	547	761
Amortization of premium on short-term marketable securities, net	1,493	1,177
Other non-cash operating activities	48	—
Changes in operating assets and liabilities:		
Accounts receivable	17,215	(15,550)
Inventory	(6,993)	294
Prepaid and other assets	(8,359)	(315)
Operating leases liabilities, net	(4,455)	(4,425)
Accounts payable	3,186	(6,699)
Accrued compensation	(15,438)	10,239
Accrued and other liabilities	5,542	804
Change in deferred revenue	942	—
Change in deferred taxes	—	57
Net cash provided by operating activities	20,669	16,159
Investing activities:		
Acquisitions of intangible asset	(675)	—
Purchases of short-term marketable securities	(84,351)	(143,185)
Maturities of short-term marketable securities	126,039	149,775
Additions of capital expenditures	(3,942)	(4,962)
Net cash provided by investing activities	37,071	1,628
Financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	2,272	1,397
Taxes paid related to net share settlement of restricted stock units	(10,451)	(6,525)
Proceeds from exercise of stock options	4,310	3,322
Payment of contingent consideration	(1,500)	(2,375)
Repurchase and retirement of common stock	(75,563)	(522)
Net cash used in financing activities	(80,932)	(4,703)
Effect of exchange rate changes on cash and cash equivalents	(96)	125
Net (decrease) increase in cash, cash equivalents and restricted cash	(23,288)	13,209
Cash, cash equivalents and restricted cash at beginning of period	115,274	82,783
Cash, cash equivalents and restricted cash at end of period	\$ 91,986	\$ 95,992

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

CareDx, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. (“CareDx” or the “Company”), together with its subsidiaries, is a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. The Company offers testing services, products, and patient and digital solutions along the pre- and post- transplant patient journey, and it is a leading provider of genomics-based information for transplant patients. The Company’s headquarters are in Brisbane, California and it has other primary operations in Omaha, Nebraska and Stockholm, Sweden.

The Company’s commercially available post-transplant testing services consist of AlloSure® Kidney, a donor-derived cell-free DNA (“dd-cfDNA”) solution for kidney transplant patients, AlloMap® Heart, a gene expression profiling solution for heart transplant patients, AlloSure® Heart, a dd-cfDNA solution for heart transplant patients, HeartCare, the combined use of AlloMap Heart and AlloSure Heart, 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. The Company has signed multiple biopharma research partnerships for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. The Company also offers high-quality products in the pre-transplant space 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 transplant solutions and various offerings that help transplant centers with patient management, outcomes quality and operational support.

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, 2024, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the United States Securities and Exchange Commission (the “SEC”) on February 28, 2025.

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, 2024 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.

Certain reclassifications have been made to prior period amounts to conform to current period presentations. Operating results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025.

Immaterial Correction

As noted in Item 9-B of the Company’s Form 10-K for the fiscal year ending December 31, 2024, as filed with the SEC on February 28, 2025, the Company corrected certain misstatements (which the Company determined were not material to the Company’s consolidated financial statements, individually or in the aggregate) in the comparative financial statements including the Condensed Consolidated Statement of Operations, Condensed Consolidated Statement of Comprehensive Loss, Condensed Consolidated Statement of Stockholders’ Equity and Condensed Consolidated Statement of Cash Flows for the three and nine months ended September 30, 2024 and applicable footnotes.

The following tables present a summary of the effects of the correction of the Company’s previously issued condensed consolidated financial statements for the three and nine months ended September 30, 2024:

Condensed Consolidated Statements of Operations (unaudited)

(in thousands)	Three Months Ended September 30, 2024			Nine Months Ended September 30, 2024		
	As Previously Reported	Adjustments	As Corrected	As Previously Reported	Adjustments	As Corrected
General and administrative	\$ 28,515	\$ 3,229	\$ 31,744	\$ 83,104	\$ 9,687	\$ 92,791
Total operating expenses	93,375	3,229	96,604	281,133	9,687	290,820
Loss from operations	(10,492)	(3,229)	(13,721)	(33,927)	(9,687)	(43,614)
Loss before income taxes	(7,208)	(3,229)	(10,437)	(25,322)	(9,687)	(35,009)
Net loss	\$ (7,408)	\$ (3,229)	\$ (10,637)	\$ (25,461)	\$ (9,687)	\$ (35,148)
Net loss per share						
Basic	\$ (0.14)	\$ (0.06)	\$ (0.20)	\$ (0.49)	\$ (0.18)	\$ (0.67)
Diluted	\$ (0.14)	\$ (0.06)	\$ (0.20)	\$ (0.49)	\$ (0.18)	\$ (0.67)

Condensed Consolidated Statements of Comprehensive Loss (unaudited)

(in thousands)	Three Months Ended September 30, 2024			Nine Months Ended September 30, 2024		
	As Previously Reported	Adjustments	As Corrected	As Previously Reported	Adjustments	As Corrected
Net loss	\$ (7,408)	\$ (3,229)	\$ (10,637)	\$ (25,461)	\$ (9,687)	\$ (35,148)
Comprehensive loss	(6,623)	(3,229)	(9,852)	(25,677)	(9,687)	(35,364)

Condensed Consolidated Statement of Stockholders' Equity (unaudited)

(in thousands)	Nine Months Ended September 30, 2024		
	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
<u>As Previously Reported</u>			
Balance at December 31, 2023	\$ 946,511	\$ (678,269)	\$ 261,328
Employee stock-based compensation expense	40,090	—	40,090
Net loss	—	(25,461)	(25,461)
Balance at September 30, 2024	984,627	(704,252)	273,246
<u>Adjustments</u>			
Employee stock-based compensation expense	9,687	—	9,687
Net loss	—	(9,687)	(9,687)
<u>As Corrected</u>			
Balance at December 31, 2023	946,511	(678,269)	261,328
Employee stock-based compensation expense	49,777	—	49,777
Net loss	—	(35,148)	(35,148)
Balance at September 30, 2024	\$ 994,314	\$ (713,939)	\$ 273,246

Condensed Consolidated Statement of Cash Flows (unaudited)

(in thousands)	Nine Months Ended September 30, 2024		
	As Previously Reported	Adjustments	As Corrected
Net loss	\$ (25,461)	\$ (9,687)	\$ (35,148)
Stock-based compensation	\$ 40,208	\$ 9,687	\$ 49,895

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; accrued expenses for clinical studies; inventory valuation; 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.

For the three and nine months ended September 30, 2025, the Company recognized \$5.9 million and \$1.0 million, respectively, in revenue for tests performed in prior periods, as all performance obligations were satisfied at the time the contract was established.

For the three and nine months ended September 30, 2024, the Company recognized \$1.2 million and \$18.2 million, respectively, in revenue for tests performed in prior periods, as all performance obligations were satisfied at the time the contract was established.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended September 30, 2025 and 2024, approximately 32% and 37%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2025 and 2024, approximately 34% and 38%, respectively, of total revenue was derived from Medicare.

As of September 30, 2025 and December 31, 2024, approximately 31% and 27%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either September 30, 2025 or December 31, 2024.

Recent Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (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. This guidance will be effective for the Company’s annual disclosures for the fiscal year ending December 31, 2025, and the Company will update its disclosures accordingly.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*. This standard requires entities to disaggregate certain costs and expenses into specific categories and by relevant expense caption in the statement of operations. This guidance will be effective for the Company’s annual disclosures for the fiscal year ending December 31, 2027 and for interim period disclosures beginning in the fiscal year ending December 31, 2028. The Company is currently evaluating the potential impact of the new standard on its financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*. This standard modernizes the accounting guidance for internal-use software costs to better reflect current development practices, including agile and iterative methodologies. This guidance is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years. The Company intends to adopt the guidance on a prospective basis upon its effective date and is currently evaluating the impact of the adoption on its financial statements and related disclosures.

3. NET INCOME (LOSS) PER SHARE

Basic and diluted net income (loss) per share have been computed by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period.

For the three months ended September 30, 2025, common share equivalents have been included in the calculation of diluted net income per share.

For the nine months ended September 30, 2025 and the three and nine months ended September 30, 2024, all common share equivalents have been excluded from the calculation of diluted net loss per share, as their effect would be antidilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net income (loss) used to compute basic and diluted net income (loss) per share	\$ 1,675	\$ (10,637)	\$ (17,246)	\$ (35,148)
Denominator:				
Weighted-average shares used to compute basic net income (loss) per share	52,507,582	52,903,338	54,016,446	52,266,106
Effects of dilutive shares:				
Stock options	240,043	—	—	—
Restricted stock units and performance restricted stock units	989,165	—	—	—
Weighted-average shares used to compute diluted net income (loss) per share	53,736,790	52,903,338	54,016,446	52,266,106
Net income (loss) per share:				
Basic	\$ 0.03	\$ (0.20)	\$ (0.32)	\$ (0.67)
Diluted	\$ 0.03	\$ (0.20)	\$ (0.32)	\$ (0.67)

The following potentially dilutive securities have been excluded from diluted net loss per share as of September 30, 2025 and 2024 because their effect would be antidilutive:

	As of September 30,	
	2025	2024
Stock options outstanding	2,655,325	3,741,694
Restricted stock units and performance restricted stock units outstanding	3,999,915	6,418,992
Employee stock purchase plan	52,471	40,899
Total	6,707,711	10,201,585

4. FAIR VALUE MEASUREMENTS

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 Company uses the U.S. GAAP fair value 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.

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The following table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of September 30, 2025 and December 31, 2024 (in thousands):

	September 30, 2025						
	Fair Value Measured Using						
	(Level 1)	(Level 2)	(Level 3)	Total Balance			
Assets							
Cash equivalents:							
Money market funds	\$ 25,499	\$ —	\$ —	\$ 25,499	\$ 25,499		
Total	<u><u>\$ 25,499</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 25,499</u></u>	<u><u>\$ 25,499</u></u>		
Liabilities							
Short-term liabilities:							
Contingent consideration	\$ —	\$ —	\$ 1,461	\$ 1,461	\$ 1,461		
Long-term liabilities:							
Contingent consideration	\$ —	\$ —	\$ 160	\$ 160	\$ 160		
Total	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 1,621</u></u>	<u><u>\$ 1,621</u></u>	<u><u>\$ 1,621</u></u>		

	December 31, 2024						
	Fair Value Measured Using						
	(Level 1)	(Level 2)	(Level 3)	Total Balance			
Assets							
Cash equivalents:							
Money market funds	\$ 52,230	\$ —	\$ —	\$ 52,230	\$ 52,230		
Total	<u><u>\$ 52,230</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 52,230</u></u>	<u><u>\$ 52,230</u></u>		
Liabilities							
Short-term liabilities:							
Contingent consideration	\$ —	\$ —	\$ 2,414	\$ 2,414	\$ 2,414		
Long-term liabilities:							
Contingent consideration	\$ —	\$ —	\$ 174	\$ 174	\$ 174		
Total	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 2,588</u></u>	<u><u>\$ 2,588</u></u>	<u><u>\$ 2,588</u></u>		

The following table presents the changes in estimated fair value and payments of the Company's Level 3 financial instruments that are measured at fair value on a recurring basis (in thousands):

	(Level 3)	
	Contingent Consideration	\$ 2,588
Balance as of December 31, 2024		\$ 2,588
Change in estimated fair value of contingent consideration from business combinations		547
Change in estimated fair value of contingent consideration from asset acquisitions		(14)
Payments related to contingent consideration		<u>(1,500)</u>
Balance as of September 30, 2025		<u><u>\$ 1,621</u></u>

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 using the fund's net asset value reported by the fund sponsor, utilizing actively traded exchange information. As of September 30, 2025 and December 31, 2024, money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual

conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met based on management's estimate of the probability of success and projected revenues for revenue-based considerations at discounted rates of 7% at September 30, 2025 and ranging from 7% to 12% at December 31, 2024. 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 in a directionally similar impact on the fair value measurement of the contingent consideration liability. The carrying amount of the contingent consideration liability represents its fair value.

5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

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

	September 30, 2025	September 30, 2024
Cash and cash equivalents	\$ 91,435	\$ 95,400
Restricted cash	551	592
Total cash, cash equivalents and restricted cash at the end of the period	<u><u>\$ 91,986</u></u>	<u><u>\$ 95,992</u></u>

Marketable Securities

All short-term marketable securities were considered held-to-maturity at September 30, 2025. The Company determined that it had the positive intent and ability to hold until maturity all short-term marketable securities that have been in a continuous loss position. The Company assesses whether the decline in value of short-term marketable securities is temporary or other-than-temporary. In making its assessment, the Company evaluates the current market and interest rate environment as well as specific issuer information. There has been no recognition of any other-than-temporary impairment at September 30, 2025.

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

	September 30, 2025			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Fair Value
Short-term marketable securities:				
U.S. agency securities	\$ 82,805	\$ 822	\$ —	\$ 83,627
Corporate debt securities	19,977	145	—	20,122
Total short-term marketable securities	<u><u>\$ 102,782</u></u>	<u><u>\$ 967</u></u>	<u><u>\$ —</u></u>	<u><u>\$ 103,749</u></u>
December 31, 2024				
Short-term marketable securities:				
U.S. agency securities	\$ 90,918	\$ 1,652	\$ (4)	\$ 92,566
Corporate debt securities	55,046	718	—	55,764
Total short-term marketable securities	<u><u>\$ 145,964</u></u>	<u><u>\$ 2,370</u></u>	<u><u>\$ (4)</u></u>	<u><u>\$ 148,330</u></u>

No marketable securities had maturities of more than one year as of September 30, 2025 and December 31, 2024.

6. GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill is tested annually for impairment at the reporting unit level during the fourth quarter or upon the identification of triggering events that would more likely than not reduce the fair value of goodwill below its carrying amount. There were no indicators of impairment as of September 30, 2025. The balance of the Company's goodwill was \$40.3 million as of September 30, 2025 and December 31, 2024.

Intangible Assets

The following table presents details of the Company's intangible assets as of September 30, 2025 (dollars in thousands):

	September 30, 2025					
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)	
Intangible assets with finite lives:						
Acquired and developed technology	\$ 36,517	\$ (23,396)	\$ (2,198)	\$ 10,923	5.9	
Customer relationships	25,581	(11,967)	(1,728)	11,886	7.3	
Commercialization rights	11,579	(6,707)	—	4,872	3.8	
Trademarks and tradenames	4,860	(2,341)	(247)	2,272	6.8	
Total intangible assets with finite lives	78,537	(44,411)	(4,173)	29,953		
Intangible assets with indefinite lives:						
Acquired in-process technology	1,250	—	—	1,250		
Favorable license agreement	2,243	—	—	2,243		
Total intangible assets with indefinite lives	3,493	—	—	3,493		
Total intangible assets	\$ 82,030	\$ (44,411)	\$ (4,173)	\$ 33,446		

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

	December 31, 2024					
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)	
Intangible assets with finite lives:						
Acquired and developed technology	\$ 37,367	\$ (21,357)	\$ (2,531)	\$ 13,479	6.6	
Customer relationships	25,718	(10,777)	(2,332)	12,609	8.4	
Commercialization rights	11,579	(5,760)	—	5,819	4.6	
Trademarks and tradenames	5,220	(2,094)	(356)	2,770	8.5	
Total intangible assets with finite lives	79,884	(39,988)	(5,219)	34,677		
Intangible assets with indefinite lives:						
Acquired in-process technology	1,250	—	—	1,250		
Favorable license agreement	2,257	—	—	2,257		
Total intangible assets with indefinite lives	3,507	—	—	3,507		
Total intangible assets	\$ 83,391	\$ (39,988)	\$ (5,219)	\$ 38,184		

As of September 30, 2025, other than the \$1.7 million intangible asset that was impaired and written off during the three months ended September 30, 2025, the Company did not identify any impairment indicators suggesting that the carrying value of the intangible assets was not recoverable.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2025	2024	2025	2024	
Cost of testing services	\$ 348	\$ 329	\$ 1,041	\$ 987	
Cost of product	447	419	1,301	1,250	
Cost of patient and digital solutions	152	170	457	679	
Sales and marketing	655	634	1,931	1,895	
Total	\$ 1,602	\$ 1,552	\$ 4,730	\$ 4,811	

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2025 (in thousands):

Years Ending December 31,	Total
Remainder of 2025	\$ 1,585
2026	5,305
2027	5,292
2028	5,292
2029	4,577
Thereafter	7,902
Total future amortization expense	\$ 29,953

7. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Finished goods	\$ 9,538	\$ 4,819
Work in progress	5,132	3,793
Raw materials	13,658	10,891
Total inventory	\$ 28,328	\$ 19,503

Accrued and Other Liabilities

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

	September 30, 2025	December 31, 2024
Clinical studies	\$ 14,746	\$ 16,166
Short-term lease liability	6,432	6,103
Professional fees	6,252	5,971
Deferred revenue	5,763	4,848
Laboratory processing fees and materials	4,748	3,184
Other accrued expenses	6,019	7,080
Total accrued and other liabilities	\$ 43,960	\$ 43,352

8. 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; 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, 2025, the carrying value of the right-of-use asset was \$24.0 million. The related current and non-current lease liabilities as of September 30, 2025 were \$6.4 million and \$21.2 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, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating lease cost	\$ 1,835	\$ 1,957	\$ 5,499	\$ 5,893

	September 30, 2025	December 31, 2024
Other information:		
Weighted-average remaining lease term - Operating leases (in years)	4.24	4.61
Weighted-average discount rate - Operating leases (%)	7.0 %	7.1 %

Maturities of operating lease liabilities as of September 30, 2025 are as follows (in thousands):

Years Ending December 31,	Operating Leases
Remainder of 2025	\$ 1,999
2026	7,888
2027	8,226
2028	7,551
2029	2,558
Thereafter	3,461
Total lease payments	31,683
Less imputed interest	4,039
Present value of future minimum lease payments	27,644
Less operating lease liability, current portion	6,432
Operating lease liability, long-term portion	\$ 21,212

As of September 30, 2025, the Company's leases had remaining terms of 0.67 years to 7.34 years, some of which include options to extend the lease term.

The following table summarizes the supplemental cash flow information related to leases for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Cash paid for amounts included in the measurement of lease liabilities				
Operating cash flows used for operating leases	\$ 1,518	\$ 1,567	\$ 4,496	\$ 4,396

Royalty Commitments

Illumina

On May 4, 2018, the Company entered into a license agreement with Illumina, Inc. (the “Illumina Agreement”). The Illumina Agreement requires the Company to pay royalties in the mid-single to low-double digits on sales of products covered by the Illumina Agreement.

Other Royalty Commitment

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

Other Commitments

Effective as of July 2023, the Company entered into a license and collaboration agreement with a private entity (the “Collaboration Agreement”) 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. Pursuant to the Collaboration Agreement, the Company will share an agreed-upon percentage of revenue with the private entity, if and when revenues are generated from iBox.

Litigation and Indemnification Obligations

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the condensed consolidated financial statements indicates that it is probable that a liability had been incurred at the date of the condensed consolidated financial statements, and (ii) the range of loss can be reasonably estimated.

Natera

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 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. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising. Both parties appealed. On October 8, 2024, the U.S. Court of Appeals for the Third Circuit remanded the case to make additional findings. On December 23, 2024, the Court issued an order concluding that there was sufficient evidence to support the jury’s findings of falsity on eight advertisements by Natera. Following the decision, the parties submitted additional briefing to the Court. On August 28, 2025, the U.S. Court of Appeals for the Third Circuit issued a decision affirming the District Court’s findings on both liability and damages. On September 25, 2025, the Company filed a petition for panel rehearing or rehearing *en banc* of the Court’s damages decision. On October 10, 2025, the Third Circuit denied the petition. The Company did not record a receivable or a gain from the judgment as the amount has not yet been realized.

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In addition, Natera filed suit against the Company on January 13, 2020, in the Court alleging, among other things, that AlloSure infringes Natera's U.S. Patent 10,526,658. This case was consolidated with the Company's patent infringement suit on February 4, 2020. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera's U.S. Patent 10,597,724. The suit seeks a judgment that the Company has infringed Natera's patents, an order preliminarily and permanently enjoining the Company from any further infringement of such patents and unspecified damages. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera's U.S. Patents 10,655,180 and 11,111,544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera's U.S. Patent 10,526,658. On July 6, 2022, the Company moved to dismiss the rest of Natera's claims. On September 6, 2022, the Company withdrew its motion to dismiss. On December 11, 2023, the Court dismissed the case alleging infringement of Natera's U.S. Patent 10,597,724. Natera appealed that decision. On March 13, 2024, the Federal Circuit dismissed Natera's appeal after Natera failed to file its brief and other required papers. On May 30, 2024, Natera filed a second notice of appeal of the dismissal of U.S. Patent 10,597,724. On June 19, 2024, the Company moved to dismiss Natera's appeal. On September 11, 2024, the Federal Circuit denied that motion.

On January 26, 2024, following a five-day trial, a jury concluded that the Company did not infringe Natera's U.S. Patent 10,655,180 but did infringe Natera's U.S. Patent 11,111,544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera's U.S. Patent 11,111,544 expires in September 2026. Following trial, Natera moved for an injunction on the Company's prior AlloSure process and the parties engaged in motion practice regarding the jury's verdict and discovery as to whether the Company's current AlloSure process infringes Natera's U.S. Patent 11,111,544. On September 11, 2024, Natera informed the Court that it was abandoning claims of ongoing infringement. On January 3, 2025, the Court issued an order denying Natera's motion to set aside the jury's finding that the Company did not infringe Natera's U.S. Patent 10,655,180. On February 24, 2025, the Court issued an order concluding that Natera's U.S. Patents 11,111,544 and 10,655,180 were invalid for lack of written description, thereby overturning the jury verdict. On February 25, 2025, the Court issued an order denying Natera's motion for an injunction as moot. Natera has appealed the Court's invalidation of the three patents it asserted against CareDx. The Company intends to defend these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail.

In addition, Natera's U.S., Patent 10,597,724 is currently subject to an ex parte reexamination before the United States Patent and Trademark Office ("PTO"). Natera's U.S. Patent 11,111,544 was previously subject to an ex parte reexamination before the PTO. On February 14, 2025, a PTO examiner issued a non-final Office action rejecting Claims 21, 26, and 27 of the patent, the claims CareDx was found to have infringed in the litigation. On July 9, 2025, the PTO issued a reexamination certificate finding that Natera had overcome the prior rejections.

After the jury finding, the Company recognized the damages of \$96.3 million as other liabilities on the consolidated balance sheets as of December 31, 2023 as the loss was probable and reasonably estimable at that time. After the Court order overturned the jury finding, the Company derecognized the \$96.3 million as of December 31, 2024 as the Company concluded that the loss was no longer probable. It is reasonably possible that the Company may not prevail if Natera continues to pursue the case through appeal, in which case the range of loss could be up to the jury awarded amount of \$96.3 million plus potential interest.

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

As previously disclosed, in 2021, the Company received a civil investigative demand ("CID") from the United States Department of Justice ("DOJ") requesting that the Company produce certain documents in connection with a False Claims Act investigation by the DOJ regarding certain business practices related to the Company's kidney testing and phlebotomy services, and a subpoena from the SEC in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of the Company's accounting and public reporting practices. By letter dated September 19, 2023, the Company was notified by the staff of the SEC that the SEC has concluded its investigation as to the Company and does not intend to recommend an enforcement action by the SEC against the Company. The notice was provided under the guidelines set out in the final paragraph of Securities Act Release No. 5310.

In a court document unsealed on October 7, 2024, the DOJ notified the United States District Court for the Eastern District of New York that it was declining to intervene in a qui tam action filed against the Company by a former employee that served as the basis for the CID. Accordingly, CareDx understands that the DOJ has closed its investigation of the Company with no finding of wrongdoing. On April 8, 2025, the private plaintiff who originally filed the qui tam action in 2021 (the "Relator") filed an amended complaint on the public docket. On July 16, 2025, the District Court held a conference, at which it set a briefing schedule for a motion to dismiss. On October 17, 2025, Relator filed an opposition to the Company's motion to dismiss, and on October 31, 2025, the Company filed its reply in further support of its motion to dismiss. The Company denies the allegations in the qui tam action and intends to vigorously defend itself.

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. Although the Company remains committed to compliance with all

applicable laws and regulations, it cannot predict the outcome of, or any other requests or investigations that may arise in the future.

Securities Class Action

On May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action (the "Securities Class Action") in the U.S. District Court for the Northern District of California against the Company and certain individuals.

On April 1, 2025, a mediation was held between the parties to the Securities Class Action with the assistance of Phillips ADR Enterprises.

On April 22, 2025, the parties in the Securities Class Action reached an agreement-in-principle to resolve the Securities Class Action under which the Company would pay or cause to be paid a settlement payment of approximately \$20.25 million. On May 16, 2025, the parties reached a definitive stipulation of settlement. On May 23, 2025, plaintiffs filed a motion for preliminary approval. On July 23, 2025, the District Court issued an order preliminarily approving the settlement triggering the Company's obligation to fund its portion of the settlement. Pursuant to the settlement agreement, the Company and its insurers each deposited their respective obligations into an escrow account. The Company recorded its escrow deposits in prepaid and other current assets in the condensed consolidated balance sheets as of September 30, 2025.

In accordance with the Court's July 23, 2025 order, plaintiffs filed a motion for final approval and a motion for an award of attorneys' fees and expenses on September 30, 2025. These motions remain under consideration and a fairness and approval hearing is scheduled for December 2, 2025.

The Company has recorded the settlement payment obligation of approximately \$20.25 million as accrued litigation settlement expense and also recorded approximately \$14.9 million in expected insurance proceeds as prepaid and other current assets on the condensed consolidated balance sheet as of September 30, 2025. The Company recorded a net litigation settlement expense of approximately \$5.4 million for the nine months ended September 30, 2025 based on the agreement-in-principle to settle the Securities Class Action but there is no guarantee that the agreement will be approved by the Court.

Derivative Actions

On February 26, 2025, the plaintiffs in a previously-dismissed consolidated derivative action initiated a new action, captioned Edelman v. Bickerstaff, 3:25-c-02036 (N.D. Cal. filed Feb. 26, 2025), purporting to reinstate their claims and updating and amending their prior complaint (the "Edelman Derivative Action"). The Edelman Derivative Action asserts claims 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 alleging, among other things, breaches of fiduciary duty and various state and federal claims based on the factual allegations of the Securities Class Action.

On March 19, 2025, the parties to the Edelman Derivative Action and the Securities Action filed an administrative motion to consider whether the Edelman Derivative Action should be related to the Securities Class Action. On April 1, 2025, the Court granted the motion.

On April 1, 2025, a mediation was held between the parties to the Edelman Derivative Action with the assistance of Phillips ADR Enterprises. No settlement was reached during the mediation.

On April 10, 2025, the Court held an Initial Case Management Conference in the Edelman Derivative Action and thereafter issued a Case Management and Scheduling Order setting a trial date of July 19, 2027, among other deadlines.

On April 21, 2025, plaintiffs in the Edelman Derivative Action submitted a letter motion to the Court seeking to have the Court lift the discovery stay provided by the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4 (the "PSLRA"). On April 23, 2025, CareDx submitted a brief in opposition and a hearing was held on June 10, 2025. On June 12, 2025, the Court issued an order denying plaintiffs' letter motion to lift the PSLRA's discovery stay.

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

On March 10, 2025, the parties to the Burns Derivative Action filed an amended stipulation and proposed order to continue the stay in that action, which was so-ordered by the Court on the same day. On April 1, 2025, a mediation was held between the parties to the Burns Derivative Action with the assistance of Phillips ADR Enterprises. No settlement was reached. On June 9, 2025, in accordance with the Court's March 10, 2025 order, the parties submitted a joint status report, informing the Court that subject to Court approval, the Securities Class Action has been settled and that settlement discussions in the Burns and Edelman Derivative Actions were ongoing.

On July 22, 2025, the parties reached an agreement in principle to resolve the case, subject to the negotiation of an agreed-upon attorney fee, and informed the Court. On July 31, 2025, the parties submitted a joint status report, notifying the Court that the parties selected a JAMS mediator to oversee attorney's fee negotiation.

On September 9, 2025, the parties participated in a mediation session to mediate attorneys' fees which was unsuccessful. On September 11, 2025, the parties in the Edelman Derivative Action submitted a joint status report notifying the Court that because a request for attorneys' fees is not evaluated at the preliminary approval stage, plaintiffs intended to file a motion for preliminary approval of the derivative settlement.

On September 26, 2025, the parties entered into a stipulation and agreement of compromise, settlement and release resolving and settling, subject to court approval, both the Edelman and Burns Derivative Actions. The same day, plaintiffs in the Edelman Derivative Action filed their unopposed motion for preliminary approval. The deadline to oppose the motion was October 10, 2025 and no opposition was filed. On October 13, 2025, plaintiffs filed a notice of non-opposition, requesting that the Court enter an order granting the motion for preliminary approval without oral argument, which is currently scheduled for December 2, 2025 in the Edelman Derivative Action. The motion for preliminary approval remains under consideration.

On October 1, 2025 the parties to the Burns Derivative Action filed a third amended stipulation and proposed order to continue the stay in that action through the pendency of a determination on the proposed settlement in the Edelman Derivative Action. The court entered this stipulated order on October 6, 2025.

There is no guarantee that the parties will reach a definitive settlement or, if they do, that the settlement will be approved by the Court. In the event there is no settlement, the Company intends to defend itself vigorously. The Company believes that it has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for these suits.

Insurance Matter

In December 2022, the Company filed a lawsuit against its directors and officers liability insurance carriers in San Mateo County Superior Court. The Company seeks a declaration that costs and fees incurred by the Company in responding to governmental investigatory requests are covered under its policies. The Company also asserts breach of contract against its primary insurer Great American Insurance Company for denying the claim. On June 4, 2024, the Superior Court of the State of California for the County of San Mateo entered an order granting a motion for summary judgment by the insurers. The Company is currently pursuing an appeal of the matter. The policies provide up to \$15 million in coverage limits. Following the U.S. District Court for the Northern District of California's preliminary approval of the Securities Class Action settlement, the parties requested, and the Court granted, dismissal of the appeal.

9. STOCK INCENTIVE PLANS

As of September 30, 2025, the Company had a total of 1,519,924 shares available for grant under its 2016 Inducement Equity Incentive Plan, 2019 Inducement Equity Incentive Plan, and 2024 Equity Incentive Plan.

Stock Options

The following table summarizes stock option activity during the nine months ended September 30, 2025:

	Number of Shares	Weighted-Average Exercise Price
Stock options outstanding at December 31, 2024	3,409,912	\$ 22.63
Exercised	(270,747)	15.92
Forfeited	(89,180)	24.46
Expired	(394,660)	39.39
Stock options outstanding at September 30, 2025	<u>2,655,325</u>	20.67
Stock options exercisable at September 30, 2025	<u>1,911,733</u>	\$ 22.77

Restricted Stock Units (“RSUs”) and Performance Restricted Stock Units (“PSUs”)

The following table summarizes RSUs and PSUs activity during the nine months ended September 30, 2025:

	Number of Shares	Weighted-Average Grant Date Fair Value
RSUs and PSUs outstanding at December 31, 2024	4,842,670	\$ 15.38
RSUs granted	1,542,206	18.90
RSUs vested	(1,520,059)	15.92
RSUs forfeited	(828,277)	14.28
PSUs granted	270,405	18.99
PSUs vested	(250,863)	15.14
PSUs forfeited	(56,167)	25.41
RSUs and PSUs outstanding at September 30, 2025	<u>3,999,915</u>	\$ 15.54

The PSUs granted to employees include financial and operational vesting metrics to be met over a performance period of two years. The number of shares underlying outstanding and unvested PSUs was 221,413 and 335,583 as of September 30, 2025 and December 31, 2024, respectively.

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 that 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 2025 that ended on June 30, 2025, 84,234 shares were purchased pursuant to the ESPP for aggregate proceeds of \$1.4 million from the issuance of such shares, which occurred on June 30, 2025.

During the offering period in 2024 that ended on December 31, 2024, 66,747 shares were purchased pursuant to the ESPP for aggregate proceeds of \$0.9 million from the issuance of such shares, which occurred on January 2, 2025.

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, 2025 and 2024, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Cost of testing services	\$ 299	\$ 418	\$ 991	\$ 1,232
Cost of product	51	234	390	776
Cost of patient and digital solutions	118	326	527	1,048
Research and development	1,146	1,775	3,912	5,163
Sales and marketing	1,782	2,786	6,512	8,757
General and administrative	5,022	11,384	14,441	32,919
Total	\$ 8,418	\$ 16,923	\$ 26,773	\$ 49,895

As of September 30, 2025, unrecognized stock-based compensation expense related to stock options, RSUs, and PSUs was approximately \$6.5 million, \$35.4 million, and \$2.1 million, respectively. The remaining unrecognized compensation cost related to the unvested stock options, RSUs, and PSUs is expected to be recognized over a weighted-average period of 2.32 years, 2.16 years, and 2.28 years, respectively.

10. STOCKHOLDERS' EQUITY

Stock Repurchase Programs

On February 20, 2025, the Company's Board of Directors approved a Stock Repurchase Program (the "February 2025 Repurchase Program"), whereby the Company was authorized to purchase up to \$50.0 million in shares of its common stock over a period of up to two years, commencing on February 20, 2025, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three months ended June 30, 2025, the Company purchased an aggregate of 3.0 million shares of its common stock under the February 2025 Repurchase Program for an aggregate purchase price of \$50.0 million.

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, the Company's Board of Directors authorized a new share repurchase program of up to \$50.0 million in shares of its common stock over a period of up to two years, commencing on May 30, 2025 (the "May 2025 Repurchase Program"). The May 2025 Repurchase Program may be carried out, subject to approval by a committee of the Company's Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three and nine months ended September 30, 2025, the Company purchased an aggregate of 2.0 million shares of its common stock under the May 2025 Repurchase Program for an aggregate purchase price of \$25.6 million. As of September 30, 2025, \$24.4 million was available for future share repurchases under the May 2025 Repurchase Program.

During the nine months ended September 30, 2025, the Company purchased an aggregate of 5.0 million shares of its common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of \$75.6 million.

Common Stock

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

The Company has reserved common stock, on an if-converted basis, for issuance as follows:

	September 30, 2025	December 31, 2024
Common stock options outstanding	2,655,325	3,409,912
RSUs and PSUs outstanding	3,999,915	4,842,670
Remaining shares reserved for issuance under the 2016 Inducement Equity Incentive Plan, 2019 Inducement Equity Incentive Plan, and 2024 Equity Incentive Plan	1,519,924	4,559,101
Shares reserved under the Employee Stock Purchase Plan	407,806	558,787
Total	8,582,970	13,370,470

Preferred Stock

As of September 30, 2025 and December 31, 2024, the Company had 10,000,000 shares of preferred stock authorized with a par value of \$0.001 per share. No shares of preferred stock were outstanding as of September 30, 2025 and December 31, 2024.

11. INCOME TAXES

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

For the three and nine months ended September 30, 2025, the Company recorded an income tax benefit of \$15,000 and \$74,000, respectively. For the three and nine months ended September 30, 2024, the Company recorded an income tax expense of \$0.2 million and \$0.1 million, respectively. The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income, and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates 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.

12. 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 President and 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 has determined that it has one operating segment and, therefore, one reportable segment.

Revenue by geographic regions are based upon the customers' ship-to address for product revenue, the region of testing for testing services revenue and the region where the performance obligation is satisfied for patient and digital solutions revenue. The following table summarizes reportable revenue by geographic regions (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Testing services revenue				
United States	\$ 72,073	\$ 60,408	\$ 195,181	\$ 184,757
Rest of World	95	399	941	805
	<u>\$ 72,168</u>	<u>\$ 60,807</u>	<u>\$ 196,122</u>	<u>\$ 185,562</u>
Product revenue				
United States	\$ 7,593	\$ 6,850	\$ 21,293	\$ 18,701
Rest of World	4,885	3,362	13,828	10,715
	<u>\$ 12,478</u>	<u>\$ 10,212</u>	<u>\$ 35,121</u>	<u>\$ 29,416</u>
Patient and digital solutions revenue				
United States	\$ 15,392	\$ 11,824	\$ 40,090	\$ 32,102
Rest of World	17	40	86	126
	<u>\$ 15,409</u>	<u>\$ 11,864</u>	<u>\$ 40,176</u>	<u>\$ 32,228</u>
Total revenue				
Total United States	\$ 95,058	\$ 79,082	\$ 256,564	\$ 235,560
Total Rest of World	4,997	3,801	14,855	11,646
	<u>\$ 100,055</u>	<u>\$ 82,883</u>	<u>\$ 271,419</u>	<u>\$ 247,206</u>

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

	September 30, 2025	December 31, 2024
Long-lived assets:		
United States	\$ 30,612	\$ 33,286
Rest of World	233	266
Total	\$ 30,845	\$ 33,552

The CODM assesses the Company's performance by using net income (loss). The CODM uses net income (loss) predominately in the annual budget and forecasting process. The Company's objective in making resource allocation decisions is to optimize the consolidated financial results. The CODM considers budget-to-actual variances on a quarterly basis for the profit measure when making decisions. The CODM organizes the business and leaders functionally. The CODM assesses performance and resources are allocated to functions which utilize those allocations across the business's services, products and digital solutions offerings.

The following table summarizes the reconciliation to net income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Testing services revenue	\$ 72,168	\$ 60,807	\$ 196,122	\$ 185,562
Product revenue	12,478	10,212	35,121	29,416
Patient and digital solutions revenue	15,409	11,864	40,176	32,228
Total revenue	100,055	82,883	271,419	247,206
Less:				
Cost of testing services ¹	14,058	12,700	43,192	39,168
Cost of product ¹	5,131	5,559	14,505	15,828
Cost of patient and digital solutions ¹	10,050	7,417	25,323	20,537
Personnel cost	33,915	29,186	93,988	86,557
Professional and legal fees	10,307	10,224	32,847	32,430
Research materials and clinical trials expense	1,791	3,526	9,022	11,730
Depreciation and amortization expense	3,020	3,040	8,921	9,526
Stock-based compensation expense	8,418	16,923	26,773	49,895
Litigation settlement expense	—	—	5,710	—
Transformational initiative costs ²	524	—	2,395	—
Other segment items ³	13,179	7,946	33,149	25,396
Interest income, net	(2,013)	(3,001)	(7,160)	(8,713)
Segment and condensed consolidated net income (loss)	\$ 1,675	\$ (10,637)	\$ (17,246)	\$ (35,148)

¹ Cost of testing services, cost of product and cost of patient and digital solutions include depreciation expense.

² Transformational initiative costs consist of consulting expenses which relate to the Company's ongoing transformation strategy that the Company has undertaken as a series of initiatives focused on operational excellence, enterprise-wide efficiency, and long-term strategic growth, including rebranding costs.

³ Other segment items include the following: acquisition costs, software expenses, corporate expenses, rent and maintenance expense, travel and event related expense, one-time impairment charge on intangible asset and associated construction in progress, and other expenses (income).

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, 2024, filed with the Securities and Exchange Commission, or the SEC, on February 28, 2025.

Overview

We are a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. We offer testing services, products, and patient and digital solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients.

Our commercially available post-transplant testing services consist of AlloSure® Kidney, a donor-derived cell-free DNA, or dd-cfDNA, solution for kidney transplant patients, AlloMap® Heart, a gene expression profiling solution for heart transplant patients, AlloSure® Heart, a dd-cfDNA solution for heart transplant patients, HeartCare, the combined use of AlloMap Heart and AlloSure Heart, and AlloSure® Lung, a dd-cfDNA solution for lung transplant patients. We have initiated several clinical studies to generate data on our existing and planned future testing services. We have signed multiple biopharma research partnerships for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. We also offer high-quality products in the pre-transplant space that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. We also provide digital transplant solutions and various offerings that help transplant centers with patient management, outcomes quality and operational support.

Highlights for the Three Months Ended September 30, 2025

- Revenue of \$100.1 million, an increase of 21% year-over-year
- Testing services revenue of \$72.2 million, an increase of 19% year-over-year
- Testing services volume of 50,300, an increase of 13% year-over-year
- Net income of \$1.7 million, compared to a net loss of \$10.6 million in the third quarter of 2024
- Cash, cash equivalents and marketable securities of \$194.2 million as of September 30, 2025, net of a \$25.6 million share repurchase carried out during the quarter; no debt as of September 30, 2025

Financial Operations Overview

Revenue

We derive our revenue from testing services, products sales, patient and digital solutions revenues. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

Our testing services revenue is derived from AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung tests, which represented 72% of our total revenue for each of the three and nine months ended September 30, 2025, and 73% and 75% of our total revenue for the three and nine months ended September 30, 2024, respectively. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; and (v) how quickly we can successfully commercialize new product offerings.

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 12% and 13% of our total revenue for the three and nine months ended September 30, 2025, respectively, and 12% of our total revenue for each of the three and nine months ended September 30, 2024. 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), TransChart and Tx Access licenses, services and SaaS agreements across the digital portfolio, as well as our pharmacy sales at The Transplant Pharmacy, or TTP. Patient and digital solutions revenue represented 15% of our total revenue for each of the three and nine months ended September 30, 2025, and 14% and 13% of our total revenue for the three and nine months ended September 30, 2024, respectively.

Factors Affecting Our Performance

The Number of AlloSure, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung Tests We Receive and Report

The growth of our testing services is tied to the number of AlloSure Kidney, AlloMap Heart and AlloSure Heart, HeartCare and AlloSure Lung 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.

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 United States. The Ottr software implementation and XynQAPI implementation and support teams are based in Omaha, Nebraska. In addition, patient solutions offered by TTP in Flowood, Mississippi include hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. Additionally, with HLA Data Systems, we are able to support HLA laboratories in managing their day-to-day workflow.

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 ongoing 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

(In thousands)

	Three Months Ended September 30,		Change	Change (%)
	2025	2024		
Revenue:				
Testing services revenue	\$ 72,168	\$ 60,807	\$ 11,361	19 %
Product revenue	12,478	10,212	2,266	22 %
Patient and digital solutions revenue	15,409	11,864	3,545	30 %
Total revenue	<u>100,055</u>	<u>82,883</u>	<u>17,172</u>	<u>21 %</u>
Operating expenses:				
Cost of testing services	14,705	13,447	1,258	9 %
Cost of product	5,629	6,212	(583)	(9)%
Cost of patient and digital solutions	10,320	7,913	2,407	30 %
Research and development	16,769	17,486	(717)	(4)%
Sales and marketing	24,449	19,802	4,647	23 %
General and administrative	28,429	31,744	(3,315)	(10)%
Total operating expenses	<u>100,301</u>	<u>96,604</u>	<u>3,697</u>	<u>4 %</u>
Loss from operations	(246)	(13,721)	13,475	(98)%
Other income:				
Interest income, net	2,013	3,001	(988)	(33)%
Other (expense) income, net	(107)	283	(390)	*
Total other income	<u>1,906</u>	<u>3,284</u>	<u>(1,378)</u>	<u>(42)%</u>
Income (loss) before income taxes	1,660	(10,437)	12,097	(116)%
Income tax benefit (expense)	15	(200)	215	*
Net income (loss)	<u>\$ 1,675</u>	<u>\$ (10,637)</u>	<u>\$ 12,312</u>	<u>(116)%</u>

*Percentage not meaningful

Testing services revenue

Testing services revenue increased by \$11.4 million, or 19%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was primarily driven by testing services volume growth of 13% as compared to the same period in 2024. The difference between revenue and volume growth is primarily driven by increased collections related to tests performed and revenue recognized in prior periods as per ASC 606.

Product revenue

Product revenue increased by \$2.3 million, or 22%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was primarily due to higher sales of our commercial NGS-based kitted solutions resulting from growth in our existing business including conversions of targeted customers.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by \$3.5 million, or 30%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was primarily driven by growth in our digital solutions, particularly an expanded customer base from Ottr software and higher pharmacy sales.

Cost of testing services

Cost of testing services increased by \$1.3 million, or 9%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was attributed to higher testing services volume, partially offset by the continuous efficiency measures to lower laboratory expenses.

Cost of product

Cost of product decreased by \$0.6 million, or (9)%, for the three months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily due to improved manufacturing efficiencies and lower costs resulting from favorable pricing terms negotiated with key manufacturers.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by \$2.4 million, or 30%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was primarily due to an increase in the cost of goods from our pharmacy business resulting from higher sales.

Research and development

Research and development expenses decreased by \$0.7 million, or (4)%, for the three months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily due to decreases of \$1.6 million in clinical trial and laboratory supply expenses, and \$0.6 million in stock-based compensation expense, partially offset by an increase of \$1.6 million in personnel-related costs.

Sales and marketing

Sales and marketing expenses increased by \$4.6 million, or 23%, for the three months ended September 30, 2025, compared to the same period in 2024. The increase was primarily due to increases of \$4.1 million in personnel-related costs, \$1.1 million in marketing expenses, and \$0.7 million in consulting expenses, partially offset by decreases of \$1.0 million in stock-based compensation expense, and \$0.2 million in travel expenses.

General and administrative

General and administrative expenses decreased by \$3.3 million, or (10)%, for the three months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily due to decreases of \$6.4 million in stock-based compensation expense and \$0.8 million in consulting expenses partially offset by increases of \$2.3 million in one-time impairment charge related to an intangible asset and associated construction in progress, \$0.8 million in software-related costs, and \$0.7 million in personnel-related expenses.

Interest income, net

Interest income, net decreased by \$1.0 million for the three months ended September 30, 2025, compared to the same period in 2024, primarily due to a decrease in cash and cash equivalents and marketable securities.

Other (expense) income, net

Other (expense) income, net decreased by \$0.4 million for the three months ended September 30, 2025, compared to the same period in 2024, primarily due to a decrease in unrealized investment loss during the period.

Income tax benefit (expense)

Income tax benefit (expense) increased by \$0.2 million for the three months ended September 30, 2025, compared to the same period in 2024. The increase is primarily attributable to a change in mixed profit (loss) across jurisdictions.

Comparison of the Nine Months Ended September 30, 2025 and 2024

(In thousands)

	Nine Months Ended September 30,		Change	Change (%)
	2025	2024		
Revenue:				
Testing services revenue	\$ 196,122	\$ 185,562	\$ 10,560	6 %
Product revenue	35,121	29,416	5,705	19 %
Patient and digital solutions revenue	40,176	32,228	7,948	25 %
Total revenue	271,419	247,206	24,213	10 %
Operating expenses:				
Cost of testing services	45,224	41,387	3,837	9 %
Cost of product	16,196	17,854	(1,658)	(9)%
Cost of patient and digital solutions	26,307	22,264	4,043	18 %
Research and development	52,123	55,890	(3,767)	(7)%
Sales and marketing	71,719	60,634	11,085	18 %
General and administrative	78,881	92,791	(13,910)	(15)%
Litigation settlement expense	5,710	—	5,710	*
Total operating expenses	296,160	290,820	5,340	2 %
Loss from operations	(24,741)	(43,614)	18,873	(43)%
Other income:				
Interest income, net	7,161	8,712	(1,551)	(18)%
Other income (expense), net	260	(107)	367	*
Total other income	7,421	8,605	(1,184)	(14)%
Loss before income taxes	(17,320)	(35,009)	17,689	(51)%
Income tax benefit (expense)	74	(139)	213	*
Net loss	\$ (17,246)	\$ (35,148)	\$ 17,902	(51)%

*Percentage not meaningful

Testing services revenue

Testing services revenue increased by \$10.6 million, or 6%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was primarily driven by testing services volume growth of 13% as compared to the same period in 2024. This increase was partially offset by increased collections resulting in positive revenue adjustments recognized during the nine months ended September 30, 2024 under ASC 606 related to specific tests performed in prior periods.

Product revenue

Product revenue increased by \$5.7 million, or 19%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was primarily due to higher sales of our commercial NGS-based kitted solutions resulting from growth in our existing business including conversions of targeted customers.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by \$7.9 million, or 25%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was primarily driven by growth in our digital solutions, particularly an expanded customer base from Ottr software and higher pharmacy sales.

Cost of testing services

Cost of testing services increased by \$3.8 million, or 9%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was attributed to higher testing services volume, partially offset by the continuous efficiency measures to lower laboratory expenses.

Cost of product

Cost of product decreased by \$1.7 million, or (9)%, for the nine months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily due to improved manufacturing efficiencies and lower costs resulting from favorable pricing terms negotiated with key manufacturers.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by \$4.0 million, or 18%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was primarily due to an increase in the cost of goods from our pharmacy business resulting from higher sales.

Research and development

Research and development expenses decreased by \$3.8 million, or (7)%, for the nine months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily attributable to decreases of \$3.2 million in clinical trial and laboratory supply expenses, \$1.5 million in consulting expenses, and \$1.2 million in stock-based compensation expense, partially offset by increases of \$1.4 million in software-related expenses and \$1.3 million in personnel-related costs.

Sales and marketing

Sales and marketing expenses increased by \$11.1 million, or 18%, for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was primarily attributable to increases of \$8.0 million in personnel-related costs, \$2.9 million in consulting expenses, \$2.1 million in marketing expenses, and \$0.3 million in travel expenses, partially offset by a decrease of \$2.2 million in stock-based compensation expense.

General and administrative

General and administrative expenses decreased by \$13.9 million, or (15)%, for the nine months ended September 30, 2025, compared to the same period in 2024. The decrease was primarily attributable to decreases of \$18.4 million in stock-based compensation expense and \$1.9 million in legal expenses, partially offset by increases of \$2.3 million in one-time impairment charge related to an intangible asset and associated construction in progress, \$1.6 million in software-related costs, \$1.0 million in consulting expenses, \$0.9 million in personnel-related costs, and \$0.5 million in travel expenses.

Litigation settlement expense

Litigation settlement expense increased by \$5.7 million for the nine months ended September 30, 2025, compared to the same period in 2024. The increase was mainly due to settlement of the Securities Class Action lawsuit. See Note 8, *Commitments and Contingencies*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption “Litigation and Indemnification Obligations”, which is incorporated herein by reference.

Interest income, net

Interest income, net decreased by \$1.6 million for the nine months ended September 30, 2025, compared to the same period in 2024, primarily due to a decrease in cash, cash equivalents, and marketable securities.

Other income (expense), net

Other income (expense), net increased by \$0.4 million for the nine months ended September 30, 2025, compared to the same period in 2024, primarily due to an increase in foreign exchange gains.

Income tax benefit (expense)

Income tax benefit (expense) increased by \$0.2 million for the nine months ended September 30, 2025, compared to the same period in 2024. The increase is primarily attributable to a change in mixed profit (loss) across jurisdictions.

Cash Flows for the Nine Months Ended September 30, 2025 and 2024

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

	Nine Months Ended September 30,	
	2025	2024
Net cash provided by (used in) :		(in thousands)
Operating activities	\$ 20,669	\$ 16,159
Investing activities	37,071	1,628
Financing activities	(80,932)	(4,703)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(96)	125
Net (decrease) increase in cash, cash equivalents and restricted cash	<u><u>\$ (23,288)</u></u>	<u><u>\$ 13,209</u></u>

Operating Activities

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

Cash provided by operating activities for the nine months ended September 30, 2025 was \$20.7 million. Net operating assets decreased by \$8.4 million. Our noncash items primarily included \$26.8 million in stock-based compensation expense, \$11.1 million of depreciation and amortization expense, \$4.0 million of amortization of right-of-use assets, \$2.3 million of one-time impairment charge related to an intangible asset and associated construction in progress, \$1.5 million of amortization of premium on short-term marketable securities, net, and \$0.5 million of revaluation of contingent consideration to estimated fair value.

Cash provided by operating activities for the nine months ended September 30, 2024 was \$16.2 million. Net operating assets decreased by \$15.6 million. Our noncash items included \$40.2 million in stock-based compensation expense, \$10.8 million of depreciation and amortization expense, \$4.2 million of amortization of right-of-use assets, \$0.8 million of revaluation of contingent consideration to estimated fair value, and \$1.2 million of amortization of premium on short-term marketable securities, net.

Investing Activities

For the nine months ended September 30, 2025, net cash provided by investing activities of \$37.1 million was primarily related to proceeds from maturities of marketable securities of \$126.0 million, partially offset by purchases of marketable securities of \$84.4 million, \$3.9 million related to additions of capital expenditures, and \$0.7 million related to acquisition of an intangible asset.

For the nine months ended September 30, 2024, net cash provided by investing activities of \$1.6 million was primarily related to proceeds from maturities of marketable securities of \$149.8 million, offset by purchases of marketable securities of \$143.2 million, and \$5.0 million related to additions of capital expenditures, net.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2025 of \$80.9 million was primarily due to repurchase and retirement of common stock of \$75.6 million, taxes paid related to net share settlements of restricted stock units of \$10.5 million, and payment for contingent consideration of \$1.5 million, partially offset by proceeds from issuances of common stock under our employee stock purchase plan of \$2.3 million, and proceeds from exercise of stock options of \$4.3 million.

Net cash used in financing activities for the nine months ended September 30, 2024 of \$4.7 million was primarily due to taxes paid related to net share settlements of restricted stock units of \$6.5 million, repurchase and retirement of common stock of \$0.5 million and payments of contingent consideration of \$2.4 million. These payments were offset by proceeds from issuances of common stock under our employee stock purchase plan of \$1.4 million and proceeds from exercise of stock options of \$3.3 million.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations and had an accumulated deficit of \$719.0 million at September 30, 2025. As of September 30, 2025, we had cash, cash equivalents and marketable securities of \$194.2 million and no debt outstanding.

We believe our existing cash balance and expected cash from existing operations, including cash from current license agreements and future license and collaboration agreements, or a combination of these, will be sufficient to meet our anticipated cash requirements for the next 12 months.

Shelf Registration Statement

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

Stock Repurchase Programs

On February 20, 2025, our Board of Directors approved a Stock Repurchase Program (the “February 2025 Repurchase Program”), whereby we were authorized to purchase up to \$50.0 million in shares of our common stock over a period of up to two years, commencing on February 20, 2025, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three months ended June 30, 2025, we repurchased an aggregate of 3.0 million shares of our common stock under the February 2025 Repurchase Program for an aggregate purchase price of \$50.0 million.

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, our Board of Directors authorized a new share repurchase program of up to \$50.0 million in shares of our common stock over a period of up to two years, commencing on May 30, 2025 (the “May 2025 Repurchase Program”). The May 2025 Repurchase Program may be carried out, subject to approval by a committee of our Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three and nine months ended September 30, 2025, we purchased an aggregate of 2.0 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of \$25.6 million. As of September 30, 2025, \$24.4 million was available for future share repurchases under the May 2025 Repurchase Program.

During the nine months ended September 30, 2025, we purchased an aggregate of 5.0 million shares of our common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of \$75.6 million.

Contractual Obligations

For a discussion regarding our significant contractual obligations as of September 30, 2025 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, refer to Note 8, *Commitments and Contingencies*, to 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.

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, *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. Some of these accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. We believe that the following critical accounting policies reflect the more significant estimates and assumptions used in the preparation of our financial statements. We believe the following critical accounting policies are affected by significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements:

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

There were no material changes in the matters for which we make critical accounting estimates in the preparation of our unaudited condensed consolidated financial statements during the three and nine months ended September 30, 2025 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, 2024, filed with the SEC on February 28, 2025.

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.

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 and cash equivalents of \$91.4 million at September 30, 2025, which consisted of bank deposits and money market funds. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of \$0.9 million on our unaudited condensed consolidated balance sheets.

Foreign Currency Exchange Risk

We have operations in Sweden and sell to other countries throughout the world. As a result, we are subject to 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 United States and are denominated in Swedish Krona, and the Euro, 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, 2025, would have negatively impacted our unaudited condensed consolidated balance sheets for the nine months ended September 30, 2025 by \$0.2 million and would have negatively impacted our product revenue by \$1.4 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 but may do so in the future if our exposure to foreign currencies should become more significant. 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, 2025. 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, 2025, in light of the material weakness identified in our internal control over financial reporting, our disclosure controls and procedures were not effective at the reasonable assurance level and are not effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the principal executive officer and principal financial officer, as appropriate to allow timely discussion regarding required disclosure.

Previously Reported Material Weaknesses

As disclosed in Item 9A, “Controls and Procedures,” within our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, which was filed with the SEC on February 28, 2025, the following material weakness was identified as of December 31, 2024:

COSO Framework. We did not fully maintain components of the COSO framework, including elements of the control environment, risk assessment, 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) monitoring and risk assessment are performed to monitor and identify risks related to complex and/or non-routine transactions; and (iii) performing control activities in accordance with established policies in a timely manner.

Specifically, we determined that insufficient risk assessment was performed to identify risks related to complex and/or non-routine transactions and financial reporting personnel failed to perform control activities and to provide necessary oversight and monitoring of the accounting and reporting of complex and/or non-routine transactions. This control deficiency creates a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis and constitutes a material weakness in our internal control over financial reporting. This material weakness

resulted in immaterial corrected errors in the reporting of stock-based compensation expense as disclosed in Part II Item 9B of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

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 Weakness

Our management is committed to maintaining a strong internal control environment. In response to the material weakness that exists as of September 30, 2025 described above, our management has taken actions to remediate the material weakness in internal control over financial reporting, which included but are not limited to the following:

- Implemented training to ensure a clear understanding of risk assessment, control execution, and monitoring activities related to financial reporting and continue driving accountability of Sarbanes-Oxley Act of 2002 control activities.
- Updated our internal accounting policies and engaged resources at the Company with experience in performing control activities over complex and/or non-routine transactions, through hiring and/or use of third-party consultants and specialists.
- Enhanced the design of controls related to stock-based equity compensation, specifically around the recognition of stock-based equity compensation expense as outlined in ASC 718.

We remain committed to continuing to maintain a strong system of controls. Our remediation efforts, particularly those aimed in strengthening our control environment, have led to significant improvements in the design and implementation of our control framework. We have transitioned into the testing and evaluation phase to assess whether the controls are operating as intended. We continue to monitor the effectiveness of our controls and remain focused on addressing all elements necessary for the full remediation of the previously identified material weakness.

Changes in Internal Control over Financial Reporting

Other than the changes intended to remediate the material weakness noted above, there have been no changes in our internal control over financial (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) reporting during the three months ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information set forth in Note 8, *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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our unaudited condensed consolidated financial statements and related notes, before investing in our common stock. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

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 three months ended September 30, 2025, our net income was \$1.7 million. As of September 30, 2025, we had an accumulated deficit of \$719.0 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of our testing services and product portfolio, 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
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

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

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

For the three months ended September 30, 2025, revenue from Medicare for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung represented 48% 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. For example, on December 30, 2024, we received a CPT code for our AlloSure Kidney, AlloSure Heart and AlloSure Lung tests (PLA Code 0540U), which subjects such tests to a repricing process. In June 2025, we recommended that CMS price our AlloSure tests consistent with the pricing for PLA Code 0493U, which is currently reimbursed at \$2,753 on the Clinical Laboratory Fee Schedule. If CMS adopts this recommendation, the new reimbursement rate would represent an \$88 decrease to the current pricing for our AlloSure Kidney test, and no change to our current pricing for AlloSure Heart and AlloSure Lung tests. The final reimbursement rate for PLA Code 0540U is expected to be listed on the Clinical Laboratory Fee Schedule starting January 1, 2026. However, we cannot predict final pricing under the new CPT code, including whether CMS will agree with our recommendation.

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.

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.

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 16, 2024, CMS issued a press release entitled “MolDX Local Coverage Determination Statement,” announcing that after careful consideration of the feedback received from interested parties, as well as the public comments and further review of evidence, the Medicare Administrative Contractors, or MACs, decided not to finalize the proposed LCD issued on August 10, 2023. CMS further stated that due to the importance of identifying solid organ allograft rejection early and to ensure the public has additional opportunities to comment on the policy, the MACs intend to issue a new LCD in the coming months. CMS stated that neither it nor the MACs have changed coverage for the blood tests that monitor for organ transplantation rejection when ordered by their physicians in medically appropriate circumstances, and explained that transplant patients would continue to have access to these blood tests, including: when there are signs or symptoms of rejection; after a physician-assessed pretest, including for surveillance testing; after an indeterminate biopsy; as a replacement for a biopsy when deemed clinically appropriate by the patient’s qualified physician; and for evaluation of the adequacy of immunosuppression. On July 17, 2025, MolDX and Noridian released a new draft proposed revision to the existing foundational LCD (DL40058, DL40060) with a revised accompanying billing article (DA60146, DA60152), or the Proposed LCD. The Proposed LCD, which is subject to comment, may introduce new coverage criteria, utilization limitations, and a new bundled payment concept for certain CareDx testing, which could lead to lower rates of reimbursement. We cannot predict the ultimate outcome of the LCD process, including as it relates to the Proposed LCD, and whether it will produce changes in coverage, reimbursement practices, utilization limitations, or payment amounts, any of which could adversely affect our business, operating results and prospects.

If future reimbursement price levels are less than the current prices, 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.

On a five-year rotational basis, Medicare requests bids for its regional 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 United States 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 AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, or AlloSure Lung at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare or AlloSure Lung could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

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

Our financial results currently are largely dependent on sales of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare 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 issued by Palmetto MolDX in 2023 (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 tests, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects.

Successful commercialization of AlloSure Kidney, AlloMap Heart and AlloSure Heart, HeartCare and AlloSure Lung 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 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.

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. For example, we are currently involved in a dispute with a significant Medicare Advantage payer concerning payment of claims. We are seeking recovery of claims amounts that we believe were improperly denied, underpaid or recouped. The payer could also seek to recoup additional previously paid claims within an 18-month look-back period. We are also subject to claims reviews and/or audits by third-party 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.

Seeking payer coverage and other approvals is a time-consuming and costly process. 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, HeartCare, AlloSure Lung and future solutions could be limited.

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. We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail. See Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption “Litigation and Indemnification Obligations,” which is incorporated herein by reference.

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.

The development and commercialization of additional diagnostic solutions are key to our growth strategy. New test or product development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize additional diagnostic solutions.

Key elements of our strategy are to discover, develop, validate and commercialize a portfolio of new diagnostic solutions. We cannot be sure that we will be able to successfully complete development of or commercialize any of our planned future solutions, or that they will prove to be capable of reliably being used for organ surveillance in the heart or in other types of organs. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;

- obtain the necessary testing samples and related data;
- conduct clinical validation studies;
- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from ordering clinicians at a larger number of transplant centers;
- gain acceptance from ordering laboratories associated with transplant centers; and
- seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations.

We have included a discussion of a number of anticipated targets in the reports we filed with the SEC. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization efforts may be delayed or fail for many reasons, including:

- failure of the test at the research or development stage;
- difficulty in accessing suitable testing samples, especially testing samples with known clinical results;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner; or
- failure to obtain or maintain necessary clearances or approvals to market the test.

In addition, the publication of clinical data in peer-reviewed publications is necessary to promote clinician adoption and favorable reimbursement decisions. Clinicians typically take a significant amount of time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung and our future solutions, and demonstrate the clinical benefits of these solutions. If our solutions fail to gain commercial acceptance by patients, clinicians or third-party payers, our business and results of operations would be negatively affected.

The administration of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our current and future products and patient and digital solutions would suffer and our business would be harmed.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new diagnostic solutions, or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those new diagnostic solutions. In addition, as we develop diagnostic solutions, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a test is abandoned or delayed. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical trial, which could harm our business.

The field of diagnostic testing in transplantation is evolving and is subject to rapid technological change. If we are unable to develop solutions to keep pace with rapid medical and scientific change, our operating results could be harmed.

The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations that could make AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and our other products and patient and digital solutions, including those in development, outdated. We must continually innovate, expand and update our test offerings to address unmet needs in monitoring transplant-related conditions.

AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and our other products and patient and digital solutions, including those in development, could become obsolete unless we continually innovate, enhance and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, or our other products and patient and digital solutions and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our tests, products and patient and digital solutions could decline, which would harm our business and financial results.

If clinicians, hospital administrators, medical centers and laboratories do not adopt our diagnostic solutions, we will not achieve future sales growth.

Clinicians and healthcare administrators are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we continue to educate clinicians, administrators and laboratory directors about our testing services, products and patient and digital solutions, and demonstrate the clinical and diagnostic benefits of these services, products and patient and digital solutions. We believe that clinicians, transplant centers and laboratories may not use our services, products and patient and digital solutions unless they determine, based on published peer-reviewed journal articles, the experience of other clinicians or laboratory verification, that our services, products and patient and digital solutions provide accurate, reliable and cost-effective information that is useful in pre-transplant matching and monitoring their post-transplant recipients.

Our product kits are sold to hundreds of laboratories, mainly in Europe and the U.S. Laboratories order our products based on the accuracy, speed and cost of the test together with the cost and availability of equipment on which to run the test. Switching to or adopting our products may require the purchase of new and costly testing equipment. To attract new laboratory customers, the performance of our products must provide performance or cost advantages over similar products sold by our competitors.

If clinicians, hospital administrators and laboratories do not adopt or continue to use our tests and products or our future solutions and tests, our business and financial results will suffer.

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, including our net income (loss), have been, and we expect that our operating results will continue to be, subject to quarterly fluctuations as a result of a variety of factors, many of which are outside of our control, including those listed elsewhere in this “Risk Factors” section. In addition, to the extent that we continue to spend considerable amounts on research and development expenditures, commercialization efforts for new diagnostic solutions and new acquisitions and their related integration into our business, we expect to incur costs before achieving any anticipated future benefits.

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

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

Our AlloSure Kidney solution for kidney transplant recipients competes against existing diagnostic tests utilized by pathologists, which involves evaluating biopsy samples to determine the presence or absence of rejection. However, because of

the risks and discomforts of the invasive kidney biopsy procedure, as well as the expense and relatively low rate of finding moderate to severe grade rejection, biopsy is not a standard practice for surveillance of transplanted kidneys. Additional competition for kidney surveillance diagnostics currently comes from general, non-specific clinical chemistry tests such as serum creatinine, urine protein, immunosuppression drug levels, donor specific antibodies 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, Oncocyte, and Verici have commercially available molecular diagnostics tests. Other entrants with kitted products have indicated they are entering the market for post-transplant surveillance, including Thermo Fisher, Devyser, Bio-Rad, EuroBio, and Oncocyte.

Competition for our AlloSure Heart, AlloMap Heart, and HeartCare solutions for heart transplant recipients comes largely from biopsies in the first few years, which generally involves evaluating biopsy samples to determine the presence or absence of rejection. Beyond the first year or two, competition for heart transplant surveillance diagnostics includes echocardiography. Throughout, biopsy and echocardiography are supplemented by general, non-specific clinical chemistry tests such as, immunosuppression drug levels, donor specific antibodies and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs. This practice has been the standard of care in the United States for many years, and we will need to continue to educate clinicians, transplant recipients and payers about the various benefits of our test in order to change clinical practice. 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 and Eurofins has commercially available molecular diagnostics tests.

Competition for our AlloSure Lung solution for lung transplant recipients comes largely from spirometry to assess lung function and biopsy to diagnose rejection in the first few years. These tests are supplemented by general, non-specific clinical chemistry tests such as, immunosuppression drug levels, donor specific antibodies and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs. This practice has been the standard of care in the United States for many years, and we will need to continue to educate clinicians, transplant recipients and payers about the various benefits of our test in order to change clinical practice. 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, has commercially available molecular diagnostics tests.

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

Competition for our patient and digital solutions includes 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, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung tests, which could force us to lower the current list price of our test and impact our operating margins and our ability to achieve profitability. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung tests, 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.

If we are unable to successfully and continually update our products on a timely basis, our ability to attract and retain customers could be impaired and our competitive position could be harmed.

We operate in an environment characterized by rapid development and continuing innovation. We will need to continue to maintain the value of our product offering. To compete successfully, we must continually update our product range and produce continually updated test kits and software. The failure to maintain the quality of our products or inability to keep pace with this innovation could render our existing or future solutions obsolete or less attractive to lab directors and clinicians. Any failure to anticipate or develop new or enhanced solutions in a timely manner could result in decreased revenue and harm to our business and prospects. If we fail to introduce new or enhanced solutions that meet the needs of our customers, we will lose market share and our business, operating results and prospects will be adversely affected.

Our research and development efforts will be hindered if we are not able to acquire or contract with third parties for access to tissue and blood samples.

Our clinical development relies on our ability to secure access to tissue and blood samples, as well as recipient information, including biopsy results and clinical outcomes from the same patient. Furthermore, the studies through which our future solutions are developed may rely on access to multiple samples from the same recipient over a period of time as opposed to samples at a single point in time or archived samples. We will require additional samples and recipient data for future research, development and validation. Access to recipients and samples on a real-time, or non-archived, basis is limited and often on an exclusive basis, and there is no guarantee that future initiatives will be successful in obtaining and validating additional samples. Additionally, the process of negotiating access to new and archived donor and recipient data and samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues, such as usage rights, institutional review board approval, recipient consent, privacy rights and informed consent of recipients, publication rights, intellectual property ownership and research parameters. If we are not able to acquire or negotiate access to new and archived donor and recipient data and tissue and blood samples with source institutions, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future solutions will be limited or delayed.

If we cannot maintain existing clinical collaborations and enter into new ones, our efforts to commercialize and develop products could be delayed.

In the past, we have entered into clinical collaborations with highly regarded academic institutions and leading treatment centers in the transplant field. Our success in the future may depend in part on our ability to enter into agreements with other leading institutions in the transplant field. Securing these agreements can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration.

In addition to completing clinical collaborations, publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining coverage and reimbursement for solutions such as ours. Our inability to control when, if ever, results of such studies are published may delay or limit our ability to derive sufficient revenues from any test that may result from a collaboration.

We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our potential solutions may be delayed if collaborators fail to fulfill their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Any issues arising from these arrangements will affect our ability to serve the entire region, and our reputation may suffer even if we subsequently locate new partners, which may permanently affect our business. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

From time to time, we expect to engage in discussions with potential clinical collaborators, which may or may not lead to collaborations. We cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies that may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations becomes known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the other entity's announcement of a collaboration with an entity other than us may result in adverse speculation about us, our current and future solutions or our technology, resulting in harm to our reputation and our business.

If we are unable to successfully manage our growth and support demand for our tests, our business may suffer.

As the volume of the tests that we perform grows, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements and expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process our tests. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products are developed, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. We plan to expand our sales force to support additional products. There is significant competition for qualified, productive sales personnel with advanced sales skills and technical knowledge in our field. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training and retaining sufficient qualified sales personnel.

The value of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung depends, in large part, on our ability to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung tests on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new equipment or processes or hire new personnel could result in higher costs of processing or an inability to meet market demand in a timely manner.

There can be no assurance that we will be able to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung or our future solutions, if any, on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand for our current and future solutions, our reputation could be harmed and our future prospects and our business could suffer.

In addition, our growth may place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

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

From 2023 to 2024, our revenue increased from \$280.3 million to \$333.8 million, which represents an increase of 19%. From the three months ended September 30, 2024 to the three months ended September 30, 2025, our revenue increased from \$82.9 million to \$100.1 million, which represents an increase of \$17.2 million or 21%. 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, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung and secure reimbursement for our future solutions;
- our decision to continue our Medicare reimbursement submissions for AlloSure Kidney;
- our decision to issue future financial guidance and the terms of such guidance;
- our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies;
- our ability to attract, retain and motivate qualified personnel;
- the initiation, renewal or expiration of significant contracts with our commercial partners;
- pricing changes by us, our suppliers or our competitors; and
- general economic conditions and other factors.

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

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

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

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

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

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

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, these investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our Board of Directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

Ongoing focus on corporate responsibility matters by investors, stockholders, lawmakers, listing exchanges or other constituencies may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition or results of operations, including the sustainability of our business over time. In addition, in March 2024, the SEC adopted rules that, among other matters, establish a framework for reporting of climate-related risks. However, the SEC voluntarily stayed implementation of the final rules pending completion of judicial review. To the extent the proposed rules survive ongoing and possibly additional forthcoming legal challenges, they may impose additional reporting obligations, and we could incur increased costs.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of recipient samples to our laboratory and enhanced tracking of these recipient samples. Should a carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions, including those affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis.

Our ability to commercialize our testing solutions that we develop is dependent on our relationships with laboratory services providers and their willingness to support our current and future solutions.

We rely on third-party laboratory services providers to draw and partially process the patient blood samples that are analyzed in our Brisbane, California laboratory. Our business will suffer if these service providers do not support AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung or the future solutions that we may develop. For example, these laboratories may determine that processing the samples for our solutions requires too much additional effort. Additionally, if transplant facilities have relationships with large reference laboratories that will not process and send out our specimens, the clinicians at these facilities may deem ordering our tests outside of these relationships too inconvenient for their patients. A lack of acceptance of our current and future solutions by these service providers could result in lower test volume.

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, 2025, we had cash, cash equivalents and marketable securities of \$194.2 million and an accumulated deficit of \$719.0 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 study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of our testing services, our products and patient and digital solutions or enhancements to those tests, products and patient and digital solutions;
- acquire or license products or technologies including through acquisitions; and
- finance our capital expenditures and general and administrative expenses.

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.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and laboratory and field personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we

were to lose one or more of these key employees, including due to disease, disability or death, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. We do not currently maintain “key person” insurance on any of our employees.

Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, biostatisticians, engineers, licensed laboratory technicians and chemists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities, public and private research institutions and other organizations in recruiting and retaining highly qualified scientific personnel. Moreover, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-competes, may lead to increased uncertainty in hiring and competition for talent.

In addition, our success depends on our ability to attract and retain laboratory and field personnel with extensive experience in transplant recipient care and surveillance and close relationships with clinicians, pathologists and other hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung or our future solutions, if any.

New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development, verification and commercialization programs.

Undetected errors or defects in our products could result in voluntary corrective actions or agency enforcement actions, including recall of our products, as well as harm our reputation, decrease market acceptance of our products and expose us to product liability or professional liability claims, which could exceed our resources.

Our products may contain undetected errors or defects that are not identified until after the products are first introduced. Disruptions or other performance problems with our products, or the perception of disruption or performance problems with our products, may require us to initiate a product recall, and may damage our customers’ businesses and harm our reputation. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim, product recall or similar occurrence may cause us to incur significant expense, decrease market acceptance of our products and adversely impact our business and operating results.

In addition, the marketing, sale and use of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung and our other products and solutions, or activities related to our research and clinical studies could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. For example, a defect in one of our diagnostic solutions could lead to a false positive or false negative result, affecting the eventual diagnosis. Any incomplete or inaccurate analysis on the part of our technicians could also affect the reliability of the test results. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot provide assurance that our product liability insurance would adequately protect our assets from the financial impact of defending product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. In addition, any product liability claim brought against us, with or without merit, could increase our product liability insurance rates and prevent us from securing insurance coverage in the future at reasonable coverage levels, or at all. Additionally, any product liability lawsuit could cause injury to our reputation, result in the suspension of our testing pending an investigation into the cause of the alleged failure, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could negatively impact our results of operations.

We rely extensively on third-party service providers. Failure of these parties to perform as expected, or interruptions in our relationship with these providers or their provision of services or supplies to us, could interfere with our ability to provide test results for our testing services business and kits for our products business.

Our relationship with any of our third-party service providers may impair our ability to perform our services. The failure of any of our third-party service providers to adequately perform their service obligations may reduce our revenues and increase our expenses or prevent us from providing our products and services in a timely manner if at all. In addition, our reputation, business and financial performance could be materially harmed if we are unable to, or are perceived as unable to provide test kits and perform reliable services.

We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use in the production of our products and/or in the performance of our tests. The failure of these suppliers to perform as expected, or an interruption in our relationship with them, could interfere with our ability to provide our products and tests. These sole source suppliers include Thermo Fisher, which supplies us with instruments, laboratory reagents and consumables; Roche Molecular Systems, which supplies us with laboratory reagents and consumables; Illumina, Inc., or Illumina, which supplies us with instruments, laboratory reagents and consumables; Becton, Dickinson and Company, and Streck, which supplies us with cell preparation tubes; Beckman Coulter, which provides laboratory reagents and consumables; and Qiagen N.V., which supplies us with a proprietary buffer reagent and reagent kits. We do not have guaranteed supply agreements with Thermo Fisher, Becton, Dickinson and Company or Avantor, which exposes us to the risk that these suppliers may choose to discontinue doing business with us at any time. We periodically forecast our needs to these sole source suppliers and enter into standard purchase orders based on these forecasts.

In 2023, we received FDA approval for an updated AlloMap that uses a real-time PCR platform from Roche and we are able to switch to that analytical platform and reduce reliance on the ABI 7900. We believe that there are relatively few suppliers other than Thermo Fisher, Roche, Illumina, Becton, Dickinson and Company and Qiagen N.V. that are currently capable of supplying the instruments, reagents and other supplies necessary for our current products and services. Even if we were to identify secondary suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Thermo Fisher, Becton, Dickinson and Company or Avantor, or Avantor encounters delays or difficulties in securing from Qiagen N.V., including as a result of impacts on their respective businesses due to the ongoing conflict between Ukraine and Russia, the global impact of restrictions and sanctions imposed on Russia, and the Israel-Hamas war, the quality and quantity of reagents, supplies or instruments that we require for our current products and services or other solutions we develop, we may need to reconfigure our test processes, which would result in delays in commercialization or an interruption in sales. Clinicians and customers who order our current products and services rely on the continued and timely availability of our products and services. If we are unable to provide results within a timely manner, clinicians may elect not to use our products or services in the future and our business and operating results could be harmed.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As part of our longer-term growth strategy, we intend to target select international markets to grow our presence outside of the United States. We also currently distribute products in Europe, Canada, Asia, the Middle East, and Central and South America. To promote the growth of our business internationally, we will need to attract additional partners to expand into new markets.

Relying on partners for our sales and marketing subjects us to various risks, including:

- our partners may fail to commit the necessary resources to develop a market for our products, may spend the majority of their time selling products unrelated to ours, or may be unsuccessful in marketing our products for other reasons;
- under certain agreements, our partners' obligations, including their required level of promotional activities, may be conditioned upon our ability to achieve or maintain a specified level of reimbursement coverage;
- agreements with our partners may terminate prematurely due to disagreements or may result in disputes or litigation with our partners;
- we may not be able to renew existing partner agreements, or enter into new agreements, on acceptable terms;
- our existing relationships with partners may preclude us from entering into additional future arrangements;
- our partners may violate local laws or regulations, potentially causing reputational or monetary damage to our business;
- our partners may engage in sales practices that are locally acceptable but do not comply with standards required under U.S. laws that apply to us; and
- our partners may be negatively affected by the financial instability of, and austerity measures implemented by, the countries in which they operate.

If our present or future partners do not perform adequately, or we are unable to enter into agreements in new markets, we may be unable to achieve revenue growth or market acceptance in jurisdictions in which we depend on partners. In addition, conducting international operations subjects us to risks that, generally, we have not faced in the United States, including:

- uncertain or changing regulatory registration and approval processes;
- failure by us to obtain regulatory approvals or adequate reimbursement for the use of our current and future solutions in various countries;
- competition from companies located in the countries in which we offer our products that may put us at a competitive disadvantage;
- financial risks, such as longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- risks related to our operations in Russia and Iran, including restrictions on our access to banking services, changes in the United States, EU or other sanctions laws that limit financial transactions or increase or compliance burden and potential legal exposure and counterparty risk;
- logistics and regulations associated with shipping recipient samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process solutions locally;
- difficulties in managing and staffing international operations and assuring compliance with foreign corrupt practices laws;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities;
- multiple, conflicting and changing laws and regulations such as healthcare regulatory requirements and other governmental approvals, permits and licenses;
- the imposition of trade barriers such as tariffs, quotas, trade wars, preferential bidding or import or export licensing requirements;
- political and economic instability, including interruptions in international relations, wars, terrorism and political unrest, general security concerns, outbreak of disease, boycotts, curtailment of trade and other business restrictions, including the ongoing conflict between Ukraine and Russia, the global impact of restrictions and sanctions imposed on Russia, tariffs imposed on global trade and the ongoing conflicts in the Middle East;
- fluctuations in currency exchange rates;
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, its books and records provisions or its anti-bribery provisions, as well as risks associated with other anti-bribery and anti-corruption laws; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of the above could harm our business and, consequently, our revenues and results of operations. Our expanding international operations could be affected by changes in laws, trade regulations and tariffs, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our current and future products and solutions, as well as by inter-governmental disputes. As of the date of this Quarterly Report on Form 10-Q, discussions remain ongoing in respect of certain trade restrictions and tariffs on imports from Canada, China, and Mexico, as well as retaliatory tariffs enacted in response to such actions. In light of these events, there continues to exist significant uncertainty about the future relationship between the United States and other countries with respect to such trade policies, treaties, and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the United States. Any of these factors could depress economic activity and restrict our access to potential partners, suppliers or other third parties we seek to do business with and, in turn, have a material adverse effect on the business and financial condition of such third parties, which in turn would negatively impact us.

In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals,

fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities, which could result in the disruption of our distribution and sales activities.

Our success expanding internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

We are incorporating, and may in the future further incorporate, AI technologies into some of our internal processes. These technologies may present business, compliance and reputational risks.

We currently use artificial intelligence, or AI, in certain of our internal processes to increase employee efficiency and productivity and to optimize software and algorithm development process, and we may decide to expand our use of AI in the future. As with many new and emerging technologies, AI presents numerous risks and challenges that could adversely affect our business. If we fail to keep pace with rapidly evolving AI technological developments, especially in the healthcare sector, our competitive position and business results may suffer.

At the same time, use of AI has recently become the subject of significant media attention and political debate. While we do not currently use AI in any of our products, the introduction and use of AI technologies, particularly generative AI, into new or existing offerings may result in new or expanded risks and liabilities, including due to enhanced governmental or regulatory scrutiny, litigation, compliance issues, ethical concerns, confidentiality or security risks, as well as other factors that could adversely affect our reputation, as well as our business, operating results and financial condition. For example, AI technologies can lead to unintended consequences, including generating content that appears correct but is factually inaccurate, misleading, or otherwise flawed, or that results in unintended biases and discriminatory outcomes, which could negatively impact our customers and affect our product offerings, harm our reputation and business, and expose us to liability. Laws, regulations or industry standards that develop in response to the use of AI may be burdensome or may restrict our ability to use, develop or deploy AI, particularly generative AI technologies, in our products or processes to the extent we may choose to do so in the future, or our efforts to expand our business. For example, the European Union's, or E.U., Artificial Intelligence Act, which became effective on August 1, 2024, governs the development, marketing, and use of AI in the E.U. and could impose significant additional costs on us to comply or significant fines for failing to comply.

We use AI technologies from third parties, which may include licensed and open source software. If we are unable to maintain rights to use these AI technologies on commercially reasonable terms, we may be forced to acquire or develop alternate AI technologies, which may limit or delay our ability to provide competitive offerings and may increase our costs. These AI technologies also may incorporate data from third-party sources, which may expose us to risks associated with data rights and protection. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including with respect to intellectual property ownership and license rights, cybersecurity, and data protection laws, among others, and has not yet been fully addressed by courts or regulators. The evolving legal, regulatory, and compliance framework for AI technologies may also impact our ability to protect our own data and intellectual property against infringing use.

Disputes with labor unions may adversely affect our ability to operate in our Sweden facility and may impact our financial results.

Our production group in Sweden is represented by an IF Metall collective bargaining agreement. Our failure to successfully renegotiate this labor agreement as it expires could lead to work stoppages or other disputes with labor unions. Our manufacturing facility in Sweden is used to support the production, packaging and labeling of our proprietary test kits: Olerup SSP, QTYPE, AlloSeq cfDNA and HCT. Disruptions to our manufacturing facility through various forms of labor disputes could adversely affect us. Any strike, work stoppage, or other dispute with a labor union distracts management from operating the business, may displace employees from ordinary job positions to fill in vacant positions, may affect our reputation, and could materially adversely affect our business, results of operations, and financial condition.

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

Many of the countries in which we operate, including the United States and several of the members of the E.U. have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. 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; prolonged periods of increased inflation globally and in the United States in particular; the imposition of trade barriers such as tariffs, quotas, trade wars, preferential bidding or import or export licensing requirements; liquidity concerns at 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 ongoing U.S. federal government shutdown and future disagreements could cause the U.S. federal government to shut down for periods of time in the future.

Prolonged or repeated federal government shutdowns, 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. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be further diminished, our expenses could increase faster than anticipated or payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts, and we may utilize our capital resources sooner than expected. 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 effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. In addition, we have recorded gross unrecognized tax benefits in our financial statements that, if recognized, would impact our effective tax rate. We are subject to tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. There can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our net income or financial condition. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences, and the implementation of tax-planning strategies.

Additionally, the U.S. Congress recently enacted the One Big Beautiful Bill Act, or the OBBBA, which includes significant provisions, including tax cut extensions and modifications to the international tax framework, as well as provisions that may impact Medicare and the U.S. healthcare system more broadly. While we continue to evaluate the impact of these legislative changes as additional guidance becomes available, uncertainty remains regarding the timing and interpretation by tax authorities in affected jurisdictions. These legislative changes could have an adverse impact on our future effective tax rate, tax liabilities, and cash tax.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting changes or require us to change our compensation policies.

Accounting methods and policies for diagnostic companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock-based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our consolidated financial statements, including those described in the reports we file with the SEC. In addition, the preparation of our 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 consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Any changes or modifications to the methodology used for determining our estimates, assumptions and forecasts could have a material adverse effect on our business, financial condition and results of operations.

Our current or future restructuring plans may not optimize costs and simplify our organizational and corporate structure and may materially impair our business operations.

We have previously announced restructuring plans intended to optimize costs and simplify our organizational and corporate structure, and we most recently implemented such plans in January, May and December 2023, and November and December 2024. 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 Acquisitions, Partnerships and Investments

Intangibles, including goodwill, acquired in connection with acquisitions may subsequently be impaired and, if so, could increase our net accumulated deficit.

Under United States Generally Accepted Accounting Principles, or U.S. GAAP, we are required to evaluate our goodwill and indefinite-lived intangibles for impairment when events or changes in circumstances indicate the carrying value may not be recoverable; specifically, we are required to evaluate whether the intangible assets and goodwill as a result of an acquisition continue to have a fair value that meets or exceeds the amounts recorded on our balance sheet. We test goodwill and indefinite-lived intangibles for impairment at least annually and more frequently if impairment indicators are present. If the fair values of such assets decline below their carrying value on the balance sheet, we may be required to recognize an impairment charge related to such decline.

Under U.S. GAAP, we are also required to evaluate finite-lived intangible assets, which are long-lived assets, for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of the intangible asset may not be recoverable. Finite-lived intangible assets are intangible assets that we are amortizing over their estimated useful lives. If recoverability is in question, we would then compare the carrying amounts of the intangible assets with the future net undiscounted cash flows expected to be generated by such asset. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the intangible asset over the asset's fair value determined using discounted estimates of future cash flows.

Lower than expected revenue growth, a trend of weaker than anticipated financial performance, a decline in our market capitalization for a sustained period of time, unfavorable changes in market or economic and industry conditions all could significantly impact our impairment analysis. If we determine an impairment exists, we may be required to recognize further impairment charges that, if incurred, could have a material adverse effect on our financial condition and results of operations.

Recent and future acquisitions and investments could disrupt our business, harm our financial condition and operating results, dilute your ownership of us and increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements to expand our existing know-how, expertise and intellectual property in other fields, including for the development of other commercial tests. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our test offerings or distribution. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not successfully complete acquisitions that we target in the future. Risks we may face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- reduction of available cash reserves, assumption of debt or dilutive issuances of equity securities due to payment of consideration;
- coordination of research and development and sales and marketing functions;
- integration of product and service offerings;
- expectations for acquired technology or research and development may prove unsuccessful;
- inability to retain key personnel from the acquired company;
- financial reporting, revenue recognition or other financial control deficiencies of or arising from the acquired company that we do not adequately address and that cause our reported results to be incorrect or delayed;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties;
- integrating a global workforce of the acquired company into our business;

- obtaining the approval of minority shareholders to complete an acquisition; and
- commercialization of new products being developed by the acquired company.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill and other intangible assets, any of which could harm our business and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

We may not be able to achieve the anticipated strategic benefits from our acquisition of Ottr, XynManagement, TransChart, MedActionPlan, TTP, HLA Data Systems, or any other businesses or assets that we may acquire.

The integration of any businesses or assets we may acquire will be a time-consuming process. The integration process will require substantial management time and attention, which may divert attention and resources from other important areas, including our existing business. In addition, we may not be able to fully realize the anticipated strategic benefits of any such combination or integration and any other businesses or assets we have or may acquire, which includes, with respect to Ottr, the complementary Ottr software, with respect to XynManagement, XynQAPI, TransChart and MedActionPlan, as well as TTP, and HLA Data Systems' services and technologies, and in each case the benefits of any significant cross-selling opportunities. If we are not able to achieve the anticipated strategic benefits of any such combination, it could adversely affect our business, financial condition and results of operations, and could adversely affect the market price of our common stock if the anticipated financial and strategic benefits of the acquisition are not realized as rapidly as, or to the extent anticipated by investors and analysts. Failure to achieve these anticipated benefits could result in increased costs and decreases in future revenue and/or net income following the acquisition.

Our License and Commercialization Agreement with Illumina may not result in material benefits to our business.

Under the License and Commercialization Agreement, or the License Agreement, with Illumina, we are obligated to complete timely development and commercialization of future products, including meeting certain commercialization milestones. The failure to meet any such milestones could result in the loss of exclusivity for the affected licensed products. Additionally, we are required to pay royalties in the mid-single to low-double digits on sales of future commercialized products.

We cannot make any assurances that our efforts under the License Agreement will be successful. As a result, we may not be able to fully realize the anticipated strategic benefits of the License Agreement. If we fail to successfully execute on the License Agreement, we may not realize the benefits expected from the transaction and our business may be harmed.

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.

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 from 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 2022 in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us in the first quarter of 2023 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. Ultimately, 100% of claims which were appealed were resolved in our favor. We have also 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 have appealed the denied claims consistent with our statutory rights. In the first quarter of 2025, we received an additional UPIC records request. 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, HeartCare and AlloSure Lung 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.

Healthcare reform measures could hinder or prevent the commercial success of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung.

The pricing and reimbursement environment may change in the future and become more challenging as a result of any of several possible regulatory developments, including policies advanced by the U.S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to profitably sell any diagnostic products we may develop and commercialize. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our diagnostic products from governmental agencies or other third-party payers, which would adversely affect our business strategy, operations and financial results. For example, as a result of the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or collectively, the Affordable Care Act, substantial changes have been made and may continue to be made to the current system for paying for healthcare in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. The Affordable Care Act also provided that payments under the Medicare CLFS were to receive a negative 1.75% annual adjustment through 2015. Although we have not been subject to such adjustment in the past, we cannot be certain that the claims administrators will not attempt to apply this adjustment in the future.

Among other things, the Affordable Care Act includes payment reductions to Medicare Advantage plans. These cuts have been mitigated in part by a CMS demonstration program that expired in 2015. We cannot be assured that future cuts would be mitigated by CMS. Any reductions in payment to Medicare Advantage plans could materially impact coverage and reimbursement for AlloMap Heart.

In addition to the Affordable Care Act, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, the U.S. Congress passed the "Middle Class Tax Relief and Job Creation Act of 2012", which in part reduced the potential future cost-based increases to the Medicare CLFS by 2%. PAMA introduced a multi-year phase in of a new payment system for services paid under the CLFS. Under this new system, beginning in 2017 laboratories began reporting to CMS the payment rates paid to the laboratories by commercial third-party payers including Medicare and Medicaid managed care plans, for each test and the volume of each test performed. CMS began using the reported data to set new payment rates under the CLFS in 2018. For most tests, rates will only be adjusted every three years.

For newly developed tests that are considered to be “advanced diagnostic lab tests,” the Medicare payment rate will be the actual list price offered to third-party payers for the first three quarters that the tests are offered, subject to later adjustment. CMS will establish subsequent payment rates using the commercial third-party payer data reported for those tests.

PAMA includes a substantial new payment system for clinical laboratory tests under the 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), private payer payment rates and volumes for their tests. The PAMA rules use 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.

There have been public announcements by President Trump and members of the U.S. Congress regarding plans to repeal and replace the Affordable Care Act. We cannot predict the ultimate form or timing of any repeal, replacement or expansion of the Affordable Care Act or the effect such repeal, replacement or expansion would have on our business. Regardless of the impact of any repeal, replacement or expansion of the Affordable Care Act on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could decrease the amount of reimbursement available from governmental and other third-party payers. On April 1, 2013, cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including AlloSure Kidney and AlloMap Heart, and is expected to remain in effect through at least 2025. The OBBBA, which was recently signed into law, reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly for Medicaid programs. Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung and our future diagnostic solutions, increase costs, divert management’s attention and adversely affect our ability to generate revenue and achieve profitability.

In addition to the Affordable Care Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payers.

While in general it is difficult to predict specifically what effects the Affordable Care Act or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

In December 2020, the U.S. Congress passed the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019, or the Immuno Bill. The Immuno Bill extends Medicare’s Part B coverage of immunosuppressive drugs for kidney transplant recipients beyond the current three-year limit, allowing patients to more easily maintain access to their treatment and prevent graft failure, costly dialysis treatments and retransplantation. While the Immuno Bill will help improve the long-term outcomes of transplant patients, future policies advanced by the U.S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities could result in changes to the Immuno Bill and Medicare’s coverage of immunosuppressive drugs for kidney transplant recipients in the future.

Further, the current federal administration has announced that it is looking for opportunities to improve efficiency and identify fraud and ineffective use of resources at government agencies. This includes government agencies we may interact with like the CMS, the HHS, and the FDA. There is a possibility that changes will be made at the CMS, the HHS, the FDA and other governmental agencies that we may interact with and that these changes could have a material adverse impact on our business.

Risks Related to the Healthcare Regulatory Environment

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 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 2024 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2026.

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 AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, or AlloSure Lung 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. 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. A similar situation may occur if Congress decides to enable newly proposed regulations, such as the updated Verifying Accurate Leading-edge IVCT Development Act of 2021. 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 rule that may eventually be adopted.

For AlloSure Kidney and other similar testing solutions, if required by the FDA or if new laws are enacted we may be required to conduct additional analytical studies and clinical trials to demonstrate clinical validity and safety and effectiveness of our tests, and submit to the FDA a premarket approval application, or PMA, or 510(k) premarket notification application. We would need to obtain FDA approval or clearance for any existing tests currently offered as LDTs, and subsequent to commercialization of any new tests. There can be no assurance that any of our tests or additional uses of our tests for which we seek clearance or approval in the future will be cleared or approved on a timely basis, or at all, and there can be no assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our current and future tests. Moreover, any new FDA or regulatory requirements could complicate our compliance efforts.

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.

If we are required to conduct additional analytical studies and clinical trials prior to marketing our solutions under development, those trials could lead to delays or a failure to obtain necessary regulatory approvals and harm our ability to be profitable.

If the FDA or the U.S. Congress decides to regulate LDTs and other future solutions under development as medical devices, we could be required to conduct additional premarket analytical studies and clinical testing subsequent to continued commercialization in the case of AlloSure LDTs and/or conduct premarket clinical and analytical testing prior to submitting a regulatory application for commercial sales for future products not yet developed. If we are required to conduct premarket analytical studies and clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of analytical or clinical testing could significantly increase our development costs and delay test

commercialization and also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient blood or tissue samples or insufficient data regarding the associated clinical outcomes. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials and reduce our control over such activities. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, applicable regulatory requirements, or for other reasons, our clinical trials may have to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our solutions under development and our ability to be profitable.

Any test for which we obtain regulatory clearance will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our contractors or commercial partners fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and our other products and solutions, along with the manufacturing processes, packaging, labeling, distribution, import, export, and advertising and promotional activities for such products and solutions, are or will be subject to continual requirements of, and review by, CMS, state licensing agencies, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements relating to product labeling, advertising, promotion, recordkeeping and adverse event reporting. Regulatory clearance of a test or device may be subject to limitations by the regulatory body as to the indicated uses for which the product may be marketed or to other conditions of approval. For example, we are exploring utilization of AlloMap Heart in areas that could be considered outside the scope of our current labeling. Broader uses would require FDA clearance as well as changes to the labeling.

In addition, clearance may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the test or device. Discovery of previously-unknown problems with our current or future solutions, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on operations of our laboratory;
- restrictions on manufacturing processes;
- restrictions on marketing of a test;
- warning or untitled letters;
- withdrawal of the test from the market;
- refusal to approve applications or supplements to approved applications that we may submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension, limitation or withdrawal of regulatory clearances;
- exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; and
- imposition of civil or criminal penalties.

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

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

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

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented to the government, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or making a false statement material to a false or fraudulent claim;
- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare 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 healthcare 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 later requested that we submit an application for state licensure for certain specimen processing activities. We are in the process of applying for that license. We previously received a request for information from a separate state regulatory agency and 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 raises 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 or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines,

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

Foreign governments may impose reimbursement standards, which may adversely affect our future profitability.

When we market our products and our solutions under development in foreign jurisdictions, we are subject to rules and regulations in those jurisdictions. In some foreign countries, including countries in the EU, the reimbursement of our current and future solutions is subject to governmental control. In these countries, reimbursement negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a test candidate. If reimbursement of our future solutions in any jurisdiction is unavailable or limited in scope or amount, or if reimbursement rates are set at unsatisfactory levels, we may be unable to, or decide not to, market our test in that jurisdiction.

Risks Related to Our Intellectual Property

Our competitive position depends on maintaining intellectual property protection.

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

As of September 30, 2025, we had 8 U.S. patents related to diagnosing transplant rejection and autoimmune disease, which will expire between October 2025 and May 2035. In addition, we had 4 U.S. patents related to organ function recovery and allograft preservation, which will expire between July 2038 and June 2041.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. For example, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid. The Court's finding does not have any impact on our ability to continue providing AlloSure. This ruling may limit our ability to prevent Natera and other competitors and third parties from developing and marketing products similar to ours and we may not be able to prevent Natera and others from developing or selling products that are covered by our products or technologies without payment to us. In addition, our exclusive license agreement with Stanford that previously covered certain patents related to diagnostic and predictive technologies terminated in October 2023. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

Changes in either the patent laws or interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. Patent applications in the United States and many foreign jurisdictions are not published until at least 18 months after filing, and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent is issued on the application. In addition, publications in the scientific literature often lag behind actual discoveries.

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

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

We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages.

We may in the future receive offers to license patents or notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is unpredictable, expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third-party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business.

In addition, revising our current or future solutions to exclude any infringing technologies would require us to re-validate the test, which would be costly and time-consuming. Also, we may be unaware of pending patent applications that relate to our current or future solutions. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our current or future solutions or using technology that contains the allegedly infringing intellectual property, which could harm our business. See Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations," which is incorporated herein by reference, for a discussion of our recently completed and ongoing litigation with Natera.

We may be required to take further action to maintain and protect our intellectual property rights against third parties.

In the event we determine that a party is infringing our intellectual property rights, we may try to negotiate a license arrangement with such party or we may determine to initiate a lawsuit against such party. The process of negotiating a license with a third-party can be lengthy, and may take months or even years in some circumstances. In addition, it is possible that third parties who we believe are infringing our intellectual property rights are unwilling to license our intellectual property from us on terms we can accept, or at all. See Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations," which is incorporated herein by reference, for a discussion of our recently completed and ongoing litigation with Natera.

The decision to commence litigation over infringement of a patent is complex and may lead to several risks to us, including the following, among others:

- the time, significant expense and distraction to management of managing such litigation;
- the uncertainty of litigation and its potential outcomes;
- the possibility that in the course of such litigation, the defendant may challenge the validity of our patents, which could result in a re-examination or post grant review of our patents and the possibility that the claims in our patents may be limited in scope or invalidated altogether;
- the potential that the defendant may successfully persuade a court that its technology or products do not infringe our intellectual property rights;
- the impact of such litigation on other licensing relationships we have or seek to establish, including the timing of renewing or entering into such relationships, as applicable, as well as the terms of such relationships;
- the potential that a defendant may assert counterclaims against us; and
- adverse publicity to us or harm to relationships we have with customers or others.

If we are unable to protect or enforce our intellectual property rights effectively in all major markets, our business would be harmed.

Filing, prosecuting, defending and enforcing patents on all of our technologies and solutions throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the United States and in select foreign jurisdictions and cannot guarantee that we will obtain the patent protection necessary to protect our competitive position in all major markets. Competitors may use our technologies or solutions in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our current and future products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Further, the legal systems of certain countries make it difficult or impossible to obtain patent protection for diagnostic solutions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business.

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

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

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected.

AlloMap, AlloSure, Olerup SSP, QTYPE, Ottr and CareDx are registered trademarks of our company in the United States. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This process can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims by third parties that we or our employees have wrongfully used or disclosed alleged trade secrets or misappropriated intellectual property, or claiming ownership of what we view as our own intellectual property.

As is commonplace in our industry, we employ individuals who were previously employed at other diagnostics, medical device, life sciences or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information of others in the course of their work for us and no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade

secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. We may also be forced to bring claims against third parties or defend against third-party claims in order to determine the ownership of our intellectual property. An adverse result in the prosecution or defense of any such claims could require us to pay substantial monetary damages and could result in the loss of valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our business is dependent on licenses from third parties.

We license technology from third parties necessary to develop and commercialize our products. On May 4, 2018, we entered into the License 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. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients.

In April 2020, we entered into a license agreement with Cornell University pursuant to which we were granted exclusive rights to three patents and two patent applications covering methods and technology for measurement of gene expression in urine to diagnose kidney transplant rejection.

In June 2021, we entered into a strategic agreement, which was amended in April 2022, with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation by incorporating a variety of clinical inputs to create a universal composite scoring system.

In March 2023, we entered into a license and collaboration agreement with a private entity pursuant to which we were granted an irrevocable, non-transferable right to commercialize their 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.

Our rights to use these and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses.

Termination of the license could prevent us from producing or selling some or all of our products. Failure of a licensor to abide by the terms of a license or to prevent infringement by third parties could also harm our business and negatively impact our market position.

Risks Related to Cybersecurity and Data Privacy

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

We store sensitive intellectual property and other proprietary business information, including that of our customers, payers and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. We work with a third-party billing software to collect and store sensitive data, including legally-obtained-protected health information, credit card information and personally identifiable information about our customers, payers, recipients and collaboration partners. A data breach or loss of data could have a material adverse effect on our operations, including the potential for material fines and business interruption.

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such

information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, we may face increased cybersecurity risks due to our reliance on internet technology, which may create additional opportunities for cybercriminals to exploit vulnerabilities. While we maintain monitoring practices and protections for our information technology to reduce these risks and test our systems on an ongoing basis for any potential threats, there can be no assurance that these efforts will prevent a cyber-attack or other security breach.

Third parties have attempted, and may in the future attempt, to fraudulently induce employees, contractors or consumers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and/or physical facilities in order to gain access to our data or our critical information, which could result in significant legal and financial exposure. While we still continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third-party training regarding phishing, malware, and other cyber risks, monitoring of networks and systems and maintenance of back up of protective systems), which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shut downs due to attack by hackers or breaches, phishing scams, ransomware, systems failures, computer viruses, employee errors or other malfeasance. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party service providers, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill our payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future products and solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. We have insurance coverage in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents. Furthermore, in the future such insurance may not be available on commercially reasonable terms, or at all.

In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, the CCPA took effect on January 1, 2020 and requires, among other things, covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. The CPRA, which took effect in January 2023, amended the CCPA, and also created a new state agency that has authority to implement and enforce the CCPA and the CPRA. The CCPA and the CPRA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the amendments to the CCPA on our business. Additionally, state legislation continues to be a driving force behind the changing privacy law landscape in the United States. For example, Virginia passed the Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, Utah passed the Consumer Privacy Act, and Connecticut passed the Connecticut Data Privacy Act, all of which became effective in 2023. Further, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee and Texas also adopted privacy laws, which take effect from July 1, 2024 through 2026. Internationally, the General Data Protection Regulation, or the GDPR, took effect in May 2018 within the EEA, and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico and Australia, have also implemented laws relating to data privacy and protection.

Risks Related to Our Common Stock

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

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. From January 2, 2025 to September 30, 2025, our closing stock price ranged from \$25.07 to \$11.57 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 their presentation at medical conferences;
- the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others;
- new or less expensive tests and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new solutions, and our success in commercializing these developments;
- our ability to efficiently integrate the business of our acquisitions;
- the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel;
- public health emergencies;
- share repurchases completed by us; and
- general market conditions.

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

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, 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 a significant amount of our common stock. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

Sales of substantial amounts of our common stock in the public markets, or sales of our common stock by our executive officers and directors under Rule 10b5-1 plans, could adversely affect the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

In addition, our executive officers and directors have and may adopt written plans, known as "Rule 10b5-1 Plans," under which they will contract with a broker to sell shares of our common stock on a periodic basis to diversify their assets and investments. Sales made by our executive officers and directors pursuant to Rule 10b5-1, regardless of the amount of such sales, could adversely affect the market price of our common stock.

We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our Board of Directors. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock.

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.

On February 20, 2025, our Board of Directors approved a Stock Repurchase Program, or the February 2025 Repurchase Program, whereby we were authorized to purchase up to \$50.0 million in shares of our common stock over a period of up to two years, commencing on February 20, 2025, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three months ended June 30, 2025, we repurchased an aggregate of 3.0 million shares of our common stock, under the February 2025 Repurchase Program for an aggregate purchase price of \$50.0 million.

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, our Board of Directors authorized a new share repurchase program of up to \$50.0 million in shares of our common stock over a period of up to two years, commencing on May 30, 2025, or the May 2025 Repurchase Program. The May 2025 Repurchase Program may be carried out, subject to approval by a committee of our Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the three and nine months ended September 30, 2025, we purchased an aggregate of 2.0 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of \$25.6 million. As of September 30, 2025, \$24.4 million was available for future share repurchases under the May 2025 Repurchase Program.

During the nine months ended September 30, 2025, we purchased an aggregate of 5.0 million shares of our common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of \$75.6 million.

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.

If we are unable to substantially utilize our net operating loss carryforwards, our financial results could be harmed.

Section 382 of the U.S. Internal Revenue Code of 1986, as amended, generally limits the ability of a corporation that undergoes an “ownership change” to utilize its net operating loss carry-forwards, or NOLs, and certain other tax attributes against any taxable income in taxable periods after the ownership change. The amount of taxable income in each taxable year after the ownership change that may be offset by pre-change NOLs and certain other pre-change tax attributes is generally equal to the product of (a) the fair market value of the corporation’s outstanding shares (or, in the case of a foreign corporation, the fair market value of items treated as connected with the conduct of a trade or business in the United States) immediately prior to the ownership change and (b) the long-term tax exempt rate (i.e., a rate of interest established by the U.S. Internal Revenue Service, or IRS, that fluctuates from month to month). In general, an “ownership change” occurs whenever the percentage of the shares of a corporation owned, directly or indirectly, by “5-percent shareholders” (within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended) increases by more than 50 percentage points over the lowest percentage of the shares of such corporation owned, directly or indirectly, by such “5-percent shareholders” at any time over the preceding three years.

Based on a review of our equity transactions since inception, a portion of our NOLs have been limited due to the equity financings that we have completed. Future equity transactions may result in further substantial annual limitations on the utilization of our NOLs due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.

Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs.

We have identified a material weakness in our internal control over financial reporting as of December 31, 2022, which was not remediated as of September 30, 2025. If we are unable to remediate this material weakness 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. As disclosed in Item 9A, “Controls and Procedures” within our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting which was in connection with the preparation of our consolidated financial statements for the fiscal year ended December 31, 2022 and has not been remediated as of September 30, 2025. 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.

As of December 31, 2024, we identified a material weakness with respect to the 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, risk assessment, 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) monitoring and risk assessment are performed to monitor and identify risks related to complex and/or non-routine transactions; and (iii) performing control activities in accordance with established policies in a timely manner.

Specifically, we determined that insufficient risk assessment was performed to identify risks related to complex and/or non-routine transactions and financial reporting personnel failed to perform control activities and to provide necessary oversight and monitoring of the accounting and reporting of complex and/or non-routine transactions. This control deficiency creates a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis and constitutes a material weakness in our internal control over financial reporting. This material weakness resulted in immaterial corrected errors in the reporting of stock-based compensation expense as disclosed in Part II Item 9B of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

This material weakness has 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 weakness described above. However, the material weakness will not be fully remediated until management can demonstrate the full effectiveness of controls over a sufficient period of time, and we can give no assurance on the success of such measures or the outcome of our assessment of these measures at this time.

If the steps we take to remediate the material weakness are ineffective, the material weakness 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 weakness or avoid potential future material weaknesses.

Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock.

Our certificate of incorporation and bylaws and Section 203 of the General Corporation Law of the State of Delaware, or Section 203, contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include:

- our Board of Directors is authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti-takeover devices;
- advance notice is required for director nominations or for proposals that can be acted upon at stockholder meetings;
- our Board of Directors is currently classified such that not all members of our board are elected at one time, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- stockholder action by written consent is prohibited;

- special meetings of the stockholders may be called only by the chairman of our Board of Directors, a majority of our Board of Directors or by our chief executive officer or president (if at such time we have no chief executive officer); and
- stockholders are not permitted to cumulate their votes for the election of directors.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our certificate of incorporation and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock.

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

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. This provision does not apply to claims brought pursuant to the Securities Exchange Act, or the rules and regulations promulgated thereunder, or any other claim for which the U.S. federal courts have exclusive jurisdiction. Any person or entity holding, owning or otherwise acquiring any interest in any security of our company shall be deemed to have notice of and consented to this provision. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. This choice-of-forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to this exclusive forum provision. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or operating results.

General Risk Factors

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may adversely affect our operating results.

As a public company listed in the United States, we incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market LLC, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, if we fail to comply with these laws, regulations and standards, it might also be more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, on committees of our Board of Directors or as members of senior management.

If equity research analysts do not publish research or reports about our business, or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our common stock and a lack of research coverage may adversely affect the market price of our common stock. The price of our stock could decline if one or more equity research analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which could materially harm our stock price, exchange listing and our ability to finance our operations.

We are required to comply with the Sarbanes-Oxley Act and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act, or Section 404, and other requirements will increase our costs and require additional management resources. Pursuant to Section 404, we are required to, among other things, file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We are continuing to implement and update new finance and accounting systems as we grow our business and organization and to satisfy internal control and reporting requirements.

Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

The effectiveness of our controls and procedures may in the future be limited by a variety of factors, including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting or otherwise fail to maintain or implement effective controls and procedures for financial reporting, we could be unable to accurately and timely report our financial position, results of operations, and cash flows or key operating metrics, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our consolidated financial statements or other corrective disclosures, a decline in our stock price, suspension or delisting of our common stock from the Nasdaq Global Market, SEC investigations, civil or criminal sanctions, an inability to access the capital and commercial lending markets, defaults under our debt and other agreements or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

Techniques employed by short sellers may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. We believe that our securities have in the past been, and may continue to be, the subject of short selling. Reports and information have been published about us that we believe are mischaracterized or incorrect, and which have in the past been followed by a decline in our stock price.

It is not clear what additional effects the negative publicity will have on us, if any, other than potentially affecting the market price of our common stock. If we continue to be the subject of unfavorable allegations, we may have to expend a significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

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 settlement and vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such awards a number of shares of our common stock with an aggregate fair market value as required under applicable tax rates. The following table sets forth information with respect to shares of our common stock repurchased by us or withheld to satisfy certain tax withholding obligations during the three months ended September 30, 2025:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
July 1, 2025 - July 31, 2025				
Stock Repurchase Program ⁽¹⁾	—	—	—	\$ 50.0
Employee Transactions ⁽²⁾	3,703	\$ 17.98	N/A	N/A
August 1, 2025 - August 31, 2025				
Stock Repurchase Program ⁽¹⁾	1,761,563	\$ 12.76	1,761,563	\$ 27.5
Employee Transactions ⁽²⁾	61,741	\$ 12.72	N/A	N/A
September 1, 2025 - September 30, 2025				
Stock Repurchase Program ⁽¹⁾	225,000	\$ 13.77	225,000	\$ 24.4
Employee Transactions ⁽²⁾	19,843	\$ 13.48	N/A	N/A
Total				
Stock Repurchase Program ⁽¹⁾	1,986,563	\$ 12.87	1,986,563	\$ 24.4
Employee Transactions ⁽²⁾	85,287	\$ 13.12	N/A	N/A

⁽¹⁾ See Part I, Item 2 of this Quarterly Report on Form 10-Q under the heading “Stock Repurchase Programs” for further information relating to our stock repurchase programs.

⁽²⁾ Represents shares of our common stock withheld from employees for the payment of taxes.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the three months ended September 30, 2025, except as set forth below, 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(c) of Regulation S-K.

On September 4, 2025, Jeffrey A. Novack, our General Counsel, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Mr. Novack’s plan is for the sale of up to 45,123 shares of common stock in amounts and prices determined in accordance with a formula set forth in the plan and terminates on the earlier of the date that all the shares under the plan are sold and November 27, 2026, subject to early termination for certain specified events set forth in the plan.

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.
10.1#*	Release of Claims Agreement, dated August 6, 2025, between CareDx, Inc. and Abhishek Jain.
10.2#*	Consulting Agreement, dated August 6, 2025, between CareDx, Inc. and Abhishek Jain.
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.
#	Indicates management contract or compensatory plan or arrangement.
*	Filed herewith.
**	Furnished herewith.

SIGNATURES

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

Date: November 4, 2025

CAREDX, INC.
(Registrant)

By: /s/ JOHN W. HANNA
John W. Hanna
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ NATHAN SMITH
Nathan Smith
Chief Financial Officer
(Principal Accounting and Financial Officer)

CAREDX, INC.

RELEASE OF CLAIMS

This release of claims (this “**Agreement**”) is made by and between CareDx, Inc. (the “**Company**”) and Abhishek Jain (“**Executive**”). The Company and Executive are sometimes collectively referred to herein as the “**Parties**” and individually referred to as a “**Party**.”

RECITALS

WHEREAS, Executive signed an Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement with the Company on July 5, 2021 (as may be amended or restated, the “**Confidentiality Agreement**”);

WHEREAS, Executive is party to an Amended and Restated Change of Control and Severance Agreement with the Company effective as of March 27, 2025 (the “**Severance Agreement**”), which, among other things, provides for certain severance benefits to be paid to Executive by the Company upon the termination of Executive’s employment without Cause, unrelated to a Change of Control (as defined in the Severance Agreement) or following a Change of Control of the Company;

WHEREAS, Executive’s employment with the Company terminated effective as of the close of business on August 6, 2025 (the “**Termination Date**”);

WHEREAS, in accordance with Section 4 of the Severance Agreement between the Company and Executive, Executive has agreed to enter into and not revoke a standard release of claims in favor of the Company as a condition to receiving the severance benefits described in the Severance Agreement; and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions and demands that Executive may have against the Company and any of the Releasees (as defined below), including, but not limited to, any and all claims arising out of or in any way related to Executive’s employment relationship with the Company and the termination of that relationship.

NOW, THEREFORE, for good and valuable consideration, including the mutual promises and covenants made herein, the Company and Executive hereby agree as follows:

COVENANTS

1. Termination. Executive’s employment with the Company terminated on the Termination Date.
2. Payment of Salary and Receipt of All Benefits. Executive acknowledges and agrees that, in addition to the Consideration (as defined below), the Company has paid or provided all salary, wages, bonuses, accrued vacation/paid time off, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, draws, stock, stock options or other equity awards (including restricted stock unit awards), vesting, and any and all other benefits and compensation due to Executive and that no other reimbursements or compensation are owed to Executive.
3. Separation Benefits. In consideration of Executive’s release and waiver of claims set forth in Sections 4 and 5 hereof, and subject to Executive’s execution (no earlier than the Termination Date), delivery and non-revocation of this Agreement during the Revocation Period (as defined below),

and continued compliance with this Agreement, the Company will provide Executive with the following (collectively, the “*Consideration*”):

(a) *Cash Severance Payment*. Executive will be paid a lump-sum cash payment in an amount equal to twelve (12) months of the Executive’s base salary, as in effect immediately prior to the Termination Date, which amount shall be paid on the first regularly scheduled payroll date following the Effective Date (as defined below);

(b) *Fiscal 2025 Annual Cash Incentive*. If and to the extent that the Company achieves the applicable Company metrics under its fiscal 2025 cash bonus program, Executive will be paid a lump-sum cash payment equal to Executive’s target bonus for the 2025 fiscal year, as in effect immediately prior to the Termination Date, multiplied by the “Company Factor” resulting from the Company’s achievement of such metrics as determined by the Compensation and Human Capital Committee for the Company and for Executive’s department (the “*Actual 2025 Bonus*”). The Actual 2025 Bonus will be paid at the same time 2025 annual bonuses are generally paid to other senior executives of the Company, but in no event later than March 15, 2026; and

(c) *Continuation Coverage*. If Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“*COBRA*”) within the time period prescribed pursuant to COBRA for Executive and Executive’s eligible dependents, then the Company will reimburse Executive for the COBRA premiums for such coverage (at the coverage levels in effect immediately prior to the Termination Date) until the earlier of (A) a period of twelve (12) months from the Termination Date or (B) the date upon which Executive and/or Executive’s eligible dependents become covered under similar plans. The reimbursements will be made by the Company to Executive consistent with the Company’s normal expense reimbursement policy. Notwithstanding the foregoing, if the Company determines in its sole discretion that it cannot provide the foregoing benefit without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will, in lieu thereof, provide to Executive a taxable monthly payment, payable on the last day of a given month, in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s group health coverage in effect on the Termination Date (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive elects COBRA continuation coverage and will commence on the month following Executive’s termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the date the Company has paid an amount equal to twelve (12) payments. For the avoidance of doubt, the taxable payments in lieu of COBRA reimbursements may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings.

4. *Release of Claims*. Executive agrees that the Consideration to be paid in accordance with Section 3 hereof represents settlement in full of all outstanding obligations owed to Executive by the Company and its current and former officers, directors, employees, agents, investors, attorneys, stockholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions and subsidiaries, and predecessor and successor corporations and assigns (collectively, the “*Releasees*”). Executive, on Executive’s own behalf and on behalf of Executive’s respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from

any omissions, acts, facts, or damages that have occurred up until and including the Effective Date (as defined below) of this Agreement, including, without limitation, the following:

- (a) any and all claims relating to or arising from Executive's employment relationship with the Company and the termination of that relationship;
- (b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law and securities fraud under any state or federal law;
- (c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;
- (d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; the Sarbanes-Oxley Act of 2002; the California Family Rights Act; the California Labor Code; the California Workers' Compensation Act; and the California Fair Employment and Housing Act;
- (e) any and all claims for violation of the federal, or any state, constitution;
- (f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;
- (g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement; and
- (h) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this Section 4 (the "**Release**") will be and remain in effect in all respects as a complete general release as to the matters released. The Release does not extend to any severance obligations due Executive under the Severance Agreement. The Release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company; *provided, however*, in each case, Executive agrees to forgo any monetary benefit from the filing of a charge or complaint with a government agency except pursuant to a whistleblower program or where Executive's right to receive such a monetary benefit is otherwise not waivable by law. Executive represents that Executive has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action or other matter waived or released by this Section 4. Nothing in this Agreement waives Executive's rights to indemnification or any payments under any fiduciary insurance policy, if any, provided by any act or agreement of the Company, state or federal law or policy of insurance.

Executive represents that Executive has made no assignment or transfer of any right, claim, complaint, charge, duty, obligation, demand, cause of action or other matter waived or released by this Section 4. Nothing in this Agreement waives Executive's rights to indemnification or any payments under any fiduciary insurance policy, if any, provided by any act or agreement of the Company, state, or federal law or policy of insurance.

5. Acknowledgment of Waiver of Claims under ADEA. Executive acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("**ADEA**") and that this waiver and release is knowing and voluntary. Executive agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the Effective Date of this Agreement. Executive acknowledges that the Consideration given for this waiver and release Agreement is in addition to anything of value to which Executive was already entitled. Executive further acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney **prior** to executing this Agreement; (b) Executive has at least twenty-one (21) days within which to consider this Agreement; (c) Executive has seven (7) days following the execution of this Agreement by the parties to revoke this Agreement; (d) this Agreement will not be effective until the Revocation Period (as defined below) has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and delivers it to the Company in less than the twenty-one (21)-day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Executive acknowledges and understands that revocation must be accomplished by a written notification to the General Counsel of the Company that is received prior to the Effective Date.

6. California Civil Code Section 1542. Executive acknowledges that Executive has been advised to consult with legal counsel and is familiar with the provisions of California Civil Code Section 1542, a statute that otherwise prohibits the release of unknown claims, which provides as follows:

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.

Executive, being aware of California Civil Code Section 1542, agrees to expressly waive any rights Executive may have thereunder, as well as under any other statute or common law principles of similar effect.

7. No Pending or Future Lawsuits. Executive represents that Executive has no lawsuits, claims or actions pending in Executive's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Executive also represents that Executive does not intend to bring any claims on Executive's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees. Executive confirms that Executive has no knowledge of any wrongdoing involving improper or false claims against a federal or state government agency, or any other wrongdoing that involves Executive or any other present or former Company employees.

8. Sufficiency of Consideration. Executive hereby acknowledges and agrees that Executive has received good and sufficient consideration for every promise, duty, release, obligation, agreement and right contained in this Agreement.

9. Confidential Information. Executive reaffirms and agrees to observe and abide by the terms of the Confidentiality Agreement, specifically including the provisions therein regarding

nondisclosure of the Company's trade secrets and confidential and proprietary information, which agreement will continue in force; *provided, however*, that: (a) as to any provisions regarding competition contained in the Confidentiality Agreement that conflict with the provisions regarding competition contained in the Severance Agreement, the provisions of the Severance Agreement will control; (b) as to any provisions regarding solicitation of employees contained in the Confidentiality Agreement that conflict with the provisions regarding solicitation of employees contained in this Agreement, the provisions of this Agreement will control. Notwithstanding the foregoing, nothing contained in this Agreement, the Confidentiality Agreement, the Severance Agreement or in any other agreement with the Company shall be construed to prohibit Executive from reporting possible violations of federal or state law or regulation to any governmental agency or regulatory body or making other disclosures that are protected under any whistleblower provisions of federal or state law or regulation, or from filing a charge with or participating in any investigation or proceeding conducted by any governmental agency or regulatory body.

10. Full Discharge. Executive acknowledges and agrees that the payment(s) and other benefits provided pursuant to this Agreement are in full discharge of any and all liabilities and obligations of the Company to Executive, monetarily or with respect to employee benefits or otherwise, including but not limited to any and all obligations arising under the Severance Agreement, any other alleged written or oral employment agreement, policy, plan or procedure of the Company and/or any alleged understanding or arrangement between Executive and the Company (other than claims for accrued and vested benefits under an employee benefit, insurance, or pension plan of the (excluding any severance or similar plan or policy), subject to the terms and conditions of such plan(s)).

11. Return of Company Property; Passwords and Password-protected Documents. Executive confirms that Executive has returned to the Company in good working order all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software and printers, wireless handheld devices, cellular phones and pagers), access or credit cards, Company identification and any other Company-owned property in Executive's possession or control. Executive further confirms that Executive has cancelled all accounts for Executive's benefit, if any, in the Company's name, including, but not limited to, credit cards, telephone charge cards, cellular phone and/or pager accounts and computer accounts. Executive also confirms that Executive has delivered all passwords in use by Executive at the time of Executive's termination, a list of any documents that Executive created or of which Executive is otherwise aware that are password-protected, along with the password(s) necessary to access such password-protected documents.

12. No Cooperation. Executive agrees that Executive will not knowingly encourage, counsel or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or as related directly to the ADEA waiver in this Agreement. Executive agrees both to immediately notify the Company upon receipt of any such subpoena or court order, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges or complaints against any of the Releasees, Executive will state no more than that Executive cannot provide any such counsel or assistance. Notwithstanding any provision of this Agreement to the contrary, nothing herein or in any Company policy or agreement prevents Executive, without notifying the Company, from (i) speaking with law enforcement, Executive's attorney, the U.S. Equal Employment Opportunity Commission, any state or local division of human rights, or fair employment agency; (ii) filing a charge or complaint with, participating in an investigation or proceeding conducted by, or reporting possible violations of law or regulation to any government agency; (iii) participating in a whistleblower program administered by the U.S. Securities and Exchange Commission or any other government agency; (iv) truthfully testifying in a legal proceeding or responding to or complying with a subpoena, court order, or other legal process; or (v) filing or disclosing any facts necessary to receive unemployment insurance, Medicaid, or other public benefits to which Executive may be entitled; provided, however, in each case, Executive agrees to forgo any monetary benefit from the filing of a charge or complaint with a government agency except pursuant to a whistleblower program or where Executive's right to receive such a monetary benefit is otherwise not waivable by law.

13. Nondisparagement. Except as otherwise provide in Section 12 above, Executive agrees that Executive will not in any way, directly or indirectly, do or say anything at any time which disparages the Company, its business interests or reputation, or that of any of the other Releasees. This Section 13 shall not prevent the truthful testimony by any individual or entity in a legal proceeding or pursuant to a governmental, administrative or regulatory investigation.

14. No Admission of Liability. Executive understands and acknowledges that this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Executive. No action taken by the Company hereto, either previously or in connection with this Agreement, will be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Executive or to any third party.

15. Costs. The Parties will each bear their own costs, attorneys' fees and other fees incurred in connection with the preparation of this Agreement.

16. Arbitration. THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION AND ANY OF THE MATTERS HEREIN RELEASED, WILL BE SUBJECT TO ARBITRATION IN SAN MATEO COUNTY, CALIFORNIA, BEFORE JUDICIAL ARBITRATION & MEDIATION SERVICES ("JAMS"), PURSUANT TO ITS EMPLOYMENT ARBITRATION RULES & PROCEDURES ("JAMS RULES"). THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE ARBITRATOR WILL ADMINISTER AND CONDUCT ANY ARBITRATION IN ACCORDANCE WITH CALIFORNIA LAW, INCLUDING THE CALIFORNIA CODE OF CIVIL PROCEDURE, AND THE ARBITRATOR WILL APPLY SUBSTANTIVE AND PROCEDURAL CALIFORNIA LAW TO ANY DISPUTE OR CLAIM, WITHOUT REFERENCE TO ANY CONFLICT-OF-LAW PROVISIONS OF ANY JURISDICTION. TO THE EXTENT THAT THE JAMS RULES CONFLICT WITH CALIFORNIA LAW, CALIFORNIA LAW WILL TAKE PRECEDENCE. THE DECISION OF THE ARBITRATOR WILL BE FINAL, CONCLUSIVE, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION WILL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. THE PARTIES TO THE ARBITRATION WILL EACH PAY AN EQUAL SHARE OF THE COSTS AND EXPENSES OF SUCH ARBITRATION, AND EACH PARTY WILL SEPARATELY PAY FOR ITS RESPECTIVE COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR WILL AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS PARAGRAPH CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT WILL GOVERN.

17. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Executive represents and warrants that Executive has the capacity to act on Executive's own behalf and on behalf of all who might claim through Executive to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

18. No Representations. Executive represents that Executive has had the opportunity to consult with an attorney, and has carefully read and understands the scope and effect of the provisions of

this Agreement. Executive has relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement.

19. **Severability.** In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable or void, this Agreement will continue in full force and effect without said provision or portion of provision.

20. **Entire Agreement.** This Agreement represents the entire agreement and understanding between the Company and Executive concerning the subject matter of this Agreement and Executive's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements and understandings concerning the subject matter of this Agreement and Executive's relationship with the Company, with the exception of the Severance Agreement (until the consideration payable thereunder has been paid or provided, at which time the Severance Agreement shall also be superseded by this Agreement), the Confidentiality Agreement, and Executive's written equity compensation agreements with the Company.

21. **No Oral Modification.** This Agreement may only be amended in writing by the Parties.

22. **Governing Law.** This Agreement will be governed by the laws of the State of California without regard for choice-of-law provisions. Executive consents to personal and exclusive jurisdiction and venue in the State of California.

23. **Effective Date.** Executive understands that to accept this Agreement and the terms and conditions herein, Executive must execute this Agreement within twenty-one (21) days of the Termination Date (the "**Review Period**") (but in no event earlier than the Termination Date). Each Party has seven (7) days after that Party signs this Agreement to revoke it (the "**Revocation Period**"). This Agreement will become effective on the eighth (8th) day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "**Effective Date**"). For the avoidance of doubt, in the event that Executive fails to execute and deliver this Agreement prior to the expiration of the Review Period or revokes this Agreement during the Revocation Period, this Agreement will be null and void and of no effect.

24. **Counterparts.** This Agreement may be executed in counterparts and by facsimile, and each counterpart and facsimile will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

25. **Voluntary Execution of Agreement.** Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive expressly acknowledges that:

- (a) Executive has read this Agreement;
- (b) Executive has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel;
- (c) Executive understands the terms and consequences of this Agreement and of the releases it contains; and
- (d) Executive is fully aware of the legal and binding effect of this Agreement.

* * * * *

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

COMPANY

CAREDX, INC.

By: /s/ John W. Hanna

Name: John W. Hanna

Title: Chief Executive Officer

Dated: August 6, 2025

EXECUTIVE

Abhishek Jain, an individual

/s/ Abhishek Jain

(Signature)

Dated: August 6, 2025



CONSULTING AGREEMENT

This Consulting Agreement (“Agreement”) is entered into on August 6, 2025 and is effective on August 7, 2025 (“Effective Date”) and is between CareDx, Inc., with a business address at 8000 Marina Blvd, Brisbane, CA 94005 (“CareDx” or the “Company”) and Abhishek Jain (“Consultant”). CareDx and Consultant may be referred to individually as a (“Party”) and collectively as the (“Parties”).

1. Services

- a. Consultant will perform the consulting services 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. Upon written backup provided to CareDx, CareDx will reimburse Consultant for all 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 mandated 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 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 regulatory, administrative, judicial order or other legal mandate, provided that, to the extent legally permitted, Consultant has given CareDx prompt notice of the disclosure requirement, and that Consultant reasonably 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 written 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 non-CareDx consulting work or 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, trade secrets or Confidential Information. Consultant hereby represents to CareDx that he does not own, individually or jointly with any other person or persons, any original works of authorship, inventions, developments or trade secrets that belong to Consultant that are not assigned to CareDx ("Prior Inventions").
- c. To the extent any future act is required, Consultant will reasonably 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 reasonably 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, without the written agreement of CareDx. 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 until March 31, 2026 (the “Term”). This Agreement may be extended or renewed for additional agreed upon periods upon the written agreement of the Parties.

This Agreement will terminate automatically exclusively (i) upon Consultant’s death or disability (if such disability substantially impairs his ability to provide consulting to the Company), (ii) upon Consultant’s valid revocation of that certain Release of Claims Agreement by and between CareDx and Consultant, dated as of August 6, 2025 (the “Release Agreement”), or (iii) Consultant’s written request to terminate this Agreement (in each case, such a termination, an “Automatic Termination”).

Further, CareDx may terminate this Agreement for Good Cause (as hereinafter defined). For the purposes of this Agreement, “Good Cause” shall be defined as any act or omission by Consultant that, in CareDx’s sole and reasonable discretion, is materially detrimental to the Company’s business interests, reputation, or financial well-being, including but not limited to, acts of misconduct, material violation of CareDx policies, willful failure to fulfill the material terms of this Agreement, material breach of confidentiality, Consultant’s material breach of his Release Agreement, any criminal or fraudulent activities. CareDx’s determination of Good Cause must be reasonable and in good faith and shall be final and binding, and Consultant shall have no right to contest or dispute such determination.

In the event of an Automatic Termination or upon a termination for Good Cause, (i) Consultant will retain all stock options and stock units that have vested prior to the date of such Automatic Termination or termination for Good Cause, and (ii) Consultant’s unvested stock options and stock units will automatically expire. For the avoidance of doubt, Consultant shall not otherwise be entitled to any further compensation or benefits under this Agreement upon an Automatic Termination or a termination for Good Cause.

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, except for the continued vesting of Company equity specified herein, 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

- a. Despite Consultant’s confidentiality obligations set forth in this Agreement, Consultant understands that, pursuant to the U.S. Defend Trade Secrets Act of 2016, 18 U.S.C. § 1833(b) (the “*Act*”), nothing in this Agreement shall be construed to prohibit Consultant, without notifying the Company or receiving prior authorization from the Company, from (A) filing a charge or complaint with, participating in an investigation or proceeding conducted by, or

reporting possible violations of law or regulation to any federal, state or local government agency, (B) initiating communications directly with, responding to any inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including the U.S. Securities and Exchange Commission, or from making other disclosures that are protected under the whistleblower provisions of state or federal law or regulation, (C) truthfully testifying in a legal proceeding or responding to or complying with a subpoena, court order, or other legal process, (D) speaking with law enforcement, Consultant's attorney, the U.S. Equal Employment Opportunity Commission, any state or local division of human rights, or fair employment agency or (E) exercising any rights Consultant may have under applicable labor laws to engage in concerted activity with other employees.

- b. Under the Act, persons who disclose trade secrets in connection with lawsuits or other proceedings under seal (including lawsuits alleging retaliation), or in confidence to a federal, state or local government official, or attorney, solely for the purpose of reporting or investigating a suspected violation of law, enjoy immunity from civil and criminal liability under state and federal trade secrets laws for such disclosure. Consultant acknowledges that Consultant has hereby received adequate notice of this immunity, such that the Company is entitled to all remedies available for violations of the Act, including exemplary damages and attorney fees. Nothing in this Agreement is intended to conflict with the Act or create liability for disclosures of trade secrets that are expressly allowed by the Act.
- c. Notice. *"An individual shall not be held criminally or civilly liable under any Federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a Federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law. An individual shall not be held criminally or civilly liable under any Federal or state trade secret law for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal; and does not disclose the trade secret, except pursuant to court order."*

8. Restrictive Covenants

During the Term, Consultant will not directly or indirectly solicit employees or consultants of CareDx to terminate their relationship with CareDx, except within the scope of Consultant's work for the Company as directed by 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 directly or indirectly solicit or induce vendors or customers of CareDx to terminate their relationship with CareDx, except within the scope of Consultant's work for the Company as directed by 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 the Company such that Consultant shall not, absent permission in writing from Company's Chief Executive Officer, while providing services to the Company, (i) invest in, accept employment with, or render managerial, advisory or consulting services to any third party directly or indirectly competitive with the Company's current business or currently contemplated potential future businesses known to Consultant; 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

Consultant will indemnify, defend (with counsel reasonably acceptable to CareDx) and hold harmless CareDx and its directors, officers, employees, affiliates, shareholders, agents, representatives and successors in interest from and against any and all third party claims, demands, suits, actions, causes of actions, legal or administrative proceedings, losses, damages, liabilities, costs and expenses, including but not limited to, reasonable attorneys' fees, arising directly from: (a) Consultant's willful failure to comply with material applicable laws, or regulations concerning the performance of Services hereunder, including without limitation any actual violation of any third party's confidential information or other intellectual property rights in connection with the performance of the Services; (b) any intentional misconduct of Consultant concerning the performance of Services hereunder; or (c) the breach of any representation, warranty or covenant made by Consultant herein.

10. Limitation of Liability

Except for a willful breach of this Agreement by either Party 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.

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. Abhishek Jain

By: /s/ John W. Hanna By: /s/ Abhishek Jain

Name: John W. Hanna Date: August 6, 2025

Title: Chief Executive Officer

Date: August 6, 2025

EXHIBIT A

1. Contact

Consultant's contact information is as follows:

Name: Abhishek Jain

Address:

Phone:

Email:

2. Services

During the Term, Consultant will act as a non-employee consultant and agrees to (i) render Consultant's assistance and participation, giving at all times the full benefit of his knowledge, expertise, technical skill, and ingenuity, in all matters involved in or relating to any matter in which Consultant was involved during his employment with the Company and its affiliates or of which he has knowledge and (ii) assist to transition the duties and responsibilities of his role during his employment with the Company, and to answer questions and provide guidance as requested by the Company in connection with such transition. During the Term, Consultant will report to the Company's Chief Executive Officer, but shall also be available to consult with other members of the Company's leadership team as reasonably requested from time to time. 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

Consultant shall be available to provide services for a maximum of forty (40) hours in any given calendar month, and for an anticipated average of no more than twenty (20) hours per month beginning on the Effective Date.

4. Compensation and Expense Reimbursement

In consideration of Consultant's Services, during the Term, the outstanding equity awards held by Consultant set forth in **Schedule A** below will continue to vest pursuant to the terms of the applicable award agreements, which Consultant would have otherwise received had he remained employed during the Term. 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 this Agreement. For the avoidance of doubt, Consultant understands and agrees that the continued vesting of any stock options that previously qualified as "incentive stock options" (ISOs) will no longer qualify as ISOs as a result of the continued vesting provided for above and, as a result, such stock options will hereinafter be treated as nonqualified stock options.

In the event of an Automatic Termination or a termination for Good Cause, Consultant will retain all stock options and stock units that have vested prior to the date of such termination and Consultant's unvested stock options and stock units will automatically expire.

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

SCHEDULE A

A. Jain Equity Awards

As of August 6, 2025

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

I, John W. Hanna, certify that:

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

Date: November 4, 2025

By: /s/ JOHN W. HANNA

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

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

I, Nathan Smith, 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 4, 2025

By: /s/ NATHAN SMITH

Nathan Smith
Chief Financial Officer
(Principal Accounting and Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the "Company") for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

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

By: /s/ JOHN W. HANNA

John W. Hanna
President and Chief Executive Officer
(Principal Executive Officer)
Date: November 4, 2025

By: /s/ NATHAN SMITH

Nathan Smith
Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: November 4, 2025

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.