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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

or

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

For the transition period from to

Commission file number: 001-36536

CAREDX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**94-3316839**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

8000 Marina Boulevard, 4th Floor
Brisbane, California 94005
(Address of principal executive offices and zip code)

(415) 287-2300
(Registrant's telephone number, including area code)

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

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CDNA	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

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

There were 52,542,786 shares of the registrant's Common Stock issued and outstanding as of October 26, 2026.

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" and "our" as used in this 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 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, including as a result of changes in Medicare coverage policies and reimbursement rates for our tests;
- our plans and ability to continue updating our testing services and patient and digital solutions to maintain our leading position in transplantation and to grow our specialty oncology business;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and patient and digital solutions, 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 and any repurchases of our common stock under our stock repurchase programs;
- 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 other 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 realize the expected benefits of the sale of our lab products business and to satisfy our post-closing obligations to Eurobio Scientific S.A.;
- our ability to successfully integrate Naveris, Inc. and realize the expected strategic and financial benefits of the acquisition, and the amount and timing of any contingent consideration payable to Naveris' former securityholders;
- 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; and
- our ability to successfully assert, defend against or settle any litigation brought by or against us or other legal matters or disputes.

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. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially and adversely from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission (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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 250,480	$ 65,429
Marketable securities	—	111,779
Accounts receivable	47,730	42,628
Inventory	9,144	26,705
Prepaid and other current assets	13,943	10,591
Total current assets	321,297	257,132
Property and equipment, net	27,011	32,971
Operating lease right-of-use assets	23,541	22,760
Marketable securities, non-current	—	24,165
Intangible assets, net	139,781	31,960
Goodwill	121,709	40,336
Restricted cash	1,410	551
Other assets	6,708	3,353
Total assets	$ 641,457	$ 413,228
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,808	$ 9,988
Accrued compensation	40,564	38,107
Accrued and other liabilities (Note 8)	87,603	41,754
Total current liabilities	138,975	89,849
Deferred tax liability	536	181
Contingent consideration, non-current	14,035	161
Operating lease liabilities, less current portion	20,316	19,679
Other liabilities	139	257
Total liabilities	174,001	110,127
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at September 30, 2026 and December 31, 2025; 52,460,815 and 50,916,644 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	52	50
Additional paid-in capital (Note 2)	953,558	927,457
Accumulated other comprehensive loss	—	(5,515)
Accumulated deficit (Note 2)	(486,154)	(618,891)
Total stockholders' equity	467,456	303,101
Total liabilities and stockholders' equity	$ 641,457	$ 413,228

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,	
	2026	2025	2026	2025
Revenue:				
Testing services revenue	$ 119,191	$ 72,168	$ 310,516	$ 196,122
Product revenue	—	12,478	23,137	35,121
Patient and digital solutions revenue	20,171	15,409	55,357	40,176
Total revenue	139,362	100,055	389,010	271,419
Operating expenses:				
Cost of testing services	24,683	14,705	57,698	45,224
Cost of product	—	5,629	9,176	16,196
Cost of patient and digital solutions	15,604	10,320	42,008	26,307
Research and development	21,324	16,769	65,116	52,123
Sales and marketing	31,650	24,449	95,464	71,719
General and administrative	37,989	28,429	109,381	78,881
Gain on sale of lab products business	—	—	(112,966)	—
Litigation settlement expense	—	—	600	5,710
Total operating expenses	131,250	100,301	266,477	296,160
Income (loss) from operations	8,112	(246)	122,533	(24,741)
Other income:				
Interest income, net	2,208	2,013	5,852	7,161
Other income (expense), net	372	(107)	(398)	260
Total other income	2,580	1,906	5,454	7,421
Income (loss) before income taxes	10,692	1,660	127,987	(17,320)
Income tax benefit	8,600	15	4,750	74
Net income (loss)	$ 19,292	$ 1,675	$ 132,737	$ (17,246)
Net income (loss) per share (Note 3):				
Basic	$ 0.37	$ 0.03	$ 2.57	$ (0.32)
Diluted	$ 0.35	$ 0.03	$ 2.45	$ (0.32)
Weighted-average shares used to compute net income (loss) per share:				
Basic	52,116,051	52,507,582	51,582,605	54,016,446
Diluted	54,984,989	53,736,790	54,277,326	54,016,446

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,	
	2026	2025	2026	2025
Net income (loss)	$ 19,292	$ 1,675	$ 132,737	$ (17,246)
Other comprehensive (loss) income:				
Foreign currency translation adjustment, net of tax	—	158	5,515	2,614
Comprehensive income (loss)	$ 19,292	$ 1,833	$ 138,252	$ (14,632)

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 amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2025, as previously reported	50,916,644	$ 50	$ 1,043,925	$ (5,515)	$ (735,359)	$ 303,101
Cumulative effect of retrospective adoption of ASU 2025-12 (Note 2)	—	—	(116,468)	—	116,468	—
Balance at December 31, 2025, as adjusted	50,916,644	50	927,457	(5,515)	(618,891)	303,101
Issuance of common stock under employee stock purchase plan	61,866	—	991	—	—	991
RSU settlements, net of shares withheld	265,940	1	(2,511)	—	—	(2,510)
Issuance of common stock for services	1,492	—	25	—	—	25
Issuance of common stock for cash upon exercise of stock options	28,709	—	109	—	—	109
Employee stock-based compensation expense	—	—	9,767	—	—	9,767
Foreign currency translation adjustment, net of tax	—	—	—	(757)	—	(757)
Net income	—	—	—	—	2,809	2,809
Balance at March 31, 2026	51,274,651	$ 51	$ 935,838	$ (6,272)	$ (616,082)	$ 313,535
Issuance of common stock under employee stock purchase plan	92,553	—	1,506	—	—	1,506
Repurchase and retirement of common stock (Note 2)	(569,569)	(1)	(12,231)	—	—	(12,232)
RSU settlements, net of shares withheld	574,425	1	(6,017)	—	—	(6,016)
Issuance of common stock for services	1,981	—	37	—	—	37
Issuance of common stock for cash upon exercise of stock options	108,495	—	1,245	—	—	1,245
Employee stock-based compensation expense	—	—	10,615	—	—	10,615
Foreign currency translation adjustment, net of tax	—	—	—	6,272	—	6,272
Net income	—	—	—	—	110,636	110,636
Balance at June 30, 2026	51,482,536	$ 51	$ 930,993	$ —	$ (505,446)	$ 425,598
RSU settlements, net of shares withheld	165,435	—	(4,569)	—	—	(4,569)
Issuance of common stock for services	1,746	—	38	—	—	38
Issuance of common stock for cash upon exercise of stock options	811,098	1	17,467	—	—	17,468
Employee stock-based compensation expense	—	—	9,629	—	—	9,629
Net income	—	—		—	19,292	19,292
Balance at September 30, 2026	52,460,815	$ 52	$ 953,558	$ —	$ (486,154)	$ 467,456

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 amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024, as previously reported	54,771,203	$ 51	$ 1,013,193	$ (8,569)	$ (626,242)	$ 378,433
Cumulative effect of retrospective adoption of ASU 2025-12 (Note 2)	—	—	(28,705)	—	28,705	—
Balance at December 31, 2024, as adjusted	54,771,203	51	984,488	(8,569)	(597,537)	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	$ 994,277	$ (7,089)	$ (607,890)	$ 379,349
Issuance of common stock under employee stock purchase plan	84,234	1	1,398	—	—	1,399
Repurchase and retirement of common stock (Note 2)	(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	$ 949,888	$ (6,113)	$ (616,458)	$ 327,370
Repurchase and retirement of common stock (Note 2)	(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	$ 931,827	$ (5,955)	$ (614,783)	$ 311,140

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,	
	2026	**2025**
Operating activities:		
Net income (loss)	$ 132,737	$ (17,246)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	30,112	26,773
Depreciation and amortization	13,914	11,136
Impairment of intangible asset and associated construction in progress	—	2,258
Amortization of right-of-use assets	4,517	4,020
Loss on disposal of asset	210	—
Gain on sale of lab products business	(112,966)	—
Revaluation of contingent consideration to estimated fair value	—	547
Non-cash income tax benefit in connection with business acquisition (Note 6)	(9,839)	—
Amortization of premium and accretion of discount on marketable securities, net	1,414	1,493
Other	492	48
Changes in operating assets and liabilities:		
Accounts receivable	(9,016)	17,215
Inventory	1,085	(6,993)
Prepaid and other assets	(6,870)	(8,359)
Operating leases liabilities, net	(4,967)	(4,455)
Accounts payable	2,185	3,186
Accrued compensation	2,726	(15,438)
Accrued and other liabilities	(420)	5,542
Deferred revenue	2,341	942
Net cash provided by operating activities	47,655	20,669
Investing activities:		
Acquisition of Naveris, Inc., net of cash acquired	(145,769)	—
Acquisition of intangible asset	—	(675)
Purchases of marketable securities	(39,850)	(84,351)
Maturities of marketable securities	59,744	126,039
Sales of marketable securities	114,636	—
Purchase of long term investment	(2,500)	—
Proceeds from sale of lab products business, net	164,792	—
Additions of property and equipment	(7,292)	(3,942)
Net cash provided by investing activities	143,761	37,071
Financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	2,497	2,272
Taxes paid related to net share settlement of restricted stock units	(13,097)	(10,451)
Proceeds from exercise of stock options	18,822	4,310
Payment of contingent consideration	(1,500)	(1,500)
Repurchase and retirement of common stock	(12,232)	(75,563)
Net cash used in financing activities	(5,510)	(80,932)
Effect of exchange rate changes on cash and cash equivalents	4	(96)
Net increase (decrease) in cash, cash equivalents and restricted cash	185,910	(23,288)
Cash, cash equivalents and restricted cash at beginning of period	65,980	115,274
Cash, cash equivalents and restricted cash at end of period	$ 251,890	$ 91,986

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

CareDx, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. ("CareDx" or the "Company"), together with its subsidiaries, is a precision medicine company dedicated to advancing care in transplant, specialty oncology, and cell therapy. The Company delivers solutions designed to empower clinicians and improve patient outcomes. The Company's portfolio spans non-invasive molecular testing, clinical practice management software, AI-powered data and analytics tools, and patient support solutions designed to connect diagnostic insight, clinical workflow, and patient engagement to help improve patient outcomes. The Company's headquarters are in Brisbane, California. It operates laboratories in California, North Carolina and Massachusetts. It maintains pharmacies in Mississippi, Louisiana, and Georgia.

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's commercially available specialty oncology service is NavDx®, a blood-based test that detects and monitors human papillomavirus ("HPV")-mediated cancers — including head, neck, and anal cancers — from diagnosis through post-treatment molecular residual disease ("MRD") surveillance. 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 provides digital and patient solutions, including clinical practice management software, data and analytics tools, and patient support offerings.

Sale of Lab Products Business

On April 15, 2026, the Company entered into a Purchase Agreement (the "Purchase Agreement") with Eurobio Scientific S.A. ("Eurobio") to sell Eurobio the shares of CareDx AB, the Company's wholly-owned Swedish subsidiary, and certain assets related to the Company's kitted laboratory products business and related software (collectively, the "products business").

The transaction closed on June 30, 2026 and the Company received cash proceeds of approximately $171.7 million, reflecting the base purchase price of $170.0 million, as adjusted for estimated working capital, cash, and other adjustments, subject to finalization of other customary post-closing purchase price adjustments, excluding transaction costs. During the nine months ended September 30, 2026, the Company recognized a gain on sale of lab products business of approximately $113.0 million, measured as the consideration received less the carrying amount of the net assets transferred to Eurobio or otherwise derecognized (including $4.4 million of goodwill allocated to the lab products business, which reduced the gain on sale), net of transaction costs of approximately $4.8 million. The foreign currency translation adjustment related to the reclassification adjustment for accumulated foreign currency translation impacts from the sale of the foreign entities and was included in the gain on sale of lab products business. The gain on sale of lab products business was presented within operating expenses in the unaudited condensed consolidated statements of operations.

The products business was a component of the Company's operations. The Company evaluated the sale under ASC 205-20, Presentation of Financial Statements — Discontinued Operations, and concluded that the transaction did not represent a strategic shift that has or will have a major effect on the Company's operations and financial results. Accordingly, the historical operating results of the products business continue to be reported within continuing operations.

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, 2025, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the United States Securities and Exchange Commission (the "SEC") on February 25, 2026.

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, 2025 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, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026.

Business Combination - Acquisition of Naveris, Inc.

The Company accounts for acquired businesses using the acquisition method of accounting under ASC 805, Business Combinations. With respect to business combinations, the Company determines the purchase price, including contingent consideration, and allocates the purchase price of acquired businesses to the tangible and intangible assets acquired and liabilities assumed, based on estimated fair values. The excess of the purchase price over the identifiable assets acquired and liabilities assumed is recorded as goodwill. The allocation of the purchase price for the acquisition of Naveris is preliminary and subject to change during the measurement period, which may extend up to one year from the acquisition date (see Note 6).

The Company engaged a third-party professional service provider to assist in determining the fair values of the purchase consideration, assets acquired, and liabilities assumed. Such valuations require management to make significant estimates and assumptions, especially with respect to contingent consideration and intangible assets, such as developed technology, trade names, and customer relationships. Critical estimates that the Company has used in valuing these elements include, but are not limited to, future expected cash flows using valuation techniques (e.g., Monte Carlo simulation models) and discount rates. Management’s estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable.

The fair values of the developed technology and customer relationships were determined using income-based valuation methods, and the trade names were valued using a relief-from-royalty method. Significant inputs used in the intangible asset valuations included forecasted revenue (including unit volumes and average selling price growth) and margins, an obsolescence factor reflecting the expected decline of the existing technology, expected research and development cost savings, contributory asset charges, customer attrition rates, royalty rates, long-term growth rates, and risk-adjusted discount rates.

The purchase price of Naveris included contingent consideration payable upon the achievement of specified revenue-based milestones in respect of fiscal years ending December 31, 2026 and December 31, 2027, with any payments expected to be made in 2027 and 2028, respectively. A portion of the contingent consideration is attributable to post-combination services and is recognized as compensation expense over the requisite service period. The fair value of the contingent consideration was estimated using a Monte Carlo simulation based on significant unobservable inputs, such as projected NavDx revenue. The valuation used a risk-neutral framework and a mid-period discounting convention. The contingent consideration is classified within Level 3 of the fair value hierarchy and is remeasured at fair value at each reporting date until settlement, with changes in fair value recognized in operating expenses in the condensed consolidated statements of operations.

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 in the Company’s 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; 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); contingent consideration; gain on sale of lab products business, including estimated post-closing purchase price adjustments; and legal contingencies. Actual results could differ from those estimates.

For the three and nine months ended September 30, 2026, the Company recognized net revenue for tests performed in prior periods of $14.7 million and $44.5 million, respectively. These amounts consisted of $17.3 million and $52.9 million, respectively, of revenue recognized for tests performed in prior periods, as all performance obligations were satisfied at the time the contract was established, partially offset by an increase in the refund reserve to third-party payers of $2.6 million and $8.4 million, respectively.

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.

Concentrations of Credit Risk and Other Risks and Uncertainties

For the three months ended September 30, 2026 and 2025, approximately 31% and 32%, respectively, of total revenue was derived from Medicare. For the nine months ended September 30, 2026 and 2025, approximately 30% and 34%, respectively, of total revenue was derived from Medicare.

As of September 30, 2026 and December 31, 2025, approximately 25% and 21%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either September 30, 2026 or December 31, 2025.

Recent Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board ("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 consolidated 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 is currently evaluating the provisions of this ASU.

In December 2025, the FASB issued ASU 2025-11, *Narrow-Scope Improvements (Topic 270): Interim Reporting*. This update makes targeted, narrow-scope improvements to the interim reporting guidance in Topic 270 to clarify application and improve consistency in practice. The amendments do not change the underlying principles of interim reporting. The amendments in this ASU are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company expects to adopt the guidance in its Form 10-Q for the interim period ending March 31, 2028. The Company is currently evaluating the provisions of this ASU.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements. ASU 2025-12 addresses suggestions received from stakeholders regarding the Accounting Standards Codification and makes other incremental improvements to U.S. GAAP. The update represents changes to the Codification that clarify, correct errors in or make other improvements to a variety of topics that are intended to make it easier to understand and apply. ASU 2025-12 is effective for fiscal years beginning after December 15, 2026 and interim periods within those fiscal years. Entities are required to apply the amendments to ASC 260 retrospectively. Amendments to all other ASC topics may be applied prospectively or retrospectively. Early adoption is permitted. Other than Issue 10 of ASU 2025-12, which the Company early adopted as discussed under Recently Adopted Accounting Guidance, the Company is currently evaluating the remaining provisions of this ASU.

Recently Adopted Accounting Guidance

In December 2025, the FASB issued Accounting Standards Update No. 2025-12, "Codification Improvements," which addresses stakeholders' feedback on the Accounting Standards Codification and makes other incremental improvements to generally accepted accounting principles. Specifically, Issue 10 of ASU 2025-12 added a clarification within ASC 505-30 to provide a policy election to permit the excess of repurchase price over par value in a stock repurchase transaction to be accounted for entirely as a reduction in additional paid-in capital when the repurchased shares are retired, provided that such reduction does not cause additional paid-in capital to become negative.

The Company early adopted Issue 10 of ASU 2025-12 during the quarter ended June 30, 2026, applying the amendments retrospectively to the beginning of the earliest period presented. Management believes that presenting the excess of repurchase price over par value entirely as a reduction to additional paid-in capital, as explicitly permitted by ASU 2025-12, is preferable because it enhances comparability with other entities in this industry applying the same guidance and provides a clearer presentation of the components of stockholders' equity. As a result, the Company retrospectively adjusted additional paid-in capital and accumulated deficit for all periods presented.

This adjustment resulted in a reclassification of $116.5 million between additional paid-in capital and accumulated deficit as of the beginning of fiscal year 2026, with no effect on total stockholders' equity for that period. The cumulative effect of the change on accumulated deficit as of the beginning of fiscal year 2025 was an increase of $28.7 million, with a corresponding offsetting decrease to additional paid-in capital, and no effect on total stockholders' equity.

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 and nine months ended September 30, 2026 and 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, 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,	
	2026	2025	2026	2025
Numerator:				
Net income (loss) used to compute basic and diluted net income (loss) per share	$ 19,292	$ 1,675	$ 132,737	$ (17,246)
Denominator:				
Weighted-average shares used to compute basic net income (loss) per share	52,116,051	52,507,582	51,582,605	54,016,446
Effects of dilutive shares	2,868,938	1,229,208	2,694,721	—
Weighted-average shares used to compute diluted net income (loss) per share	54,984,989	53,736,790	54,277,326	54,016,446
Net income (loss) per share:				
Basic	$ 0.37	$ 0.03	$ 2.57	$ (0.32)
Diluted	$ 0.35	$ 0.03	$ 2.45	$ (0.32)

The following potentially dilutive securities have been excluded from diluted net income (loss) per share as of September 30, 2026 and 2025 because their effect would be antidilutive:

	As of September 30,	
	2026	2025
Shares of common stock subject to outstanding options	55,435	2,655,325
Restricted stock units and performance restricted stock units	1,891	3,999,915
Employee stock purchase plan	34,122	52,471
Total common stock equivalents	91,448	6,707,711

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.

The following table sets forth the Company's financial assets and liabilities, measured at fair value on a recurring basis, as of September 30, 2026 and December 31, 2025 (in thousands):

	September 30, 2026			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
Liabilities				
Short-term liabilities:				
Contingent consideration	$ —	$ —	$ 30,151	$ 30,151
Long-term liabilities:				
Contingent consideration	—	—	14,035	14,035
Total	$ —	$ —	$ 44,186	$ 44,186

	December 31, 2025			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	$ 21,435	$ —	$ —	$ 21,435
Total	$ 21,435	$ —	$ —	$ 21,435
Liabilities				
Short-term liabilities:				
Contingent consideration	$ —	$ —	$ 1,617	$ 1,617
Long-term liabilities:				
Contingent consideration	—	—	161	161
Total	$ —	$ —	$ 1,778	$ 1,778

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	
Balance as of December 31, 2025	$ 1,778
Adjustment to contingent consideration	(117)
Addition of contingent consideration from business combination (see Note 6)	44,025
Payments related to contingent consideration	(1,500)
Balance as of September 30, 2026	$ 44,186

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 December 31, 2025, 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 mainly relates to the Naveris Transaction. See Note 6 to these financial statements. There has been no

material change in the fair value of the contingent consideration from business combination during the three and nine months ended September 30, 2026.

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, 2026	September 30, 2025
Cash and cash equivalents	$ 250,480	$ 91,435
Restricted cash	1,410	551
Total cash, cash equivalents and restricted cash at the end of the period	$ 251,890	$ 91,986

Marketable Securities

The Company held no marketable securities as of September 30, 2026. As of December 31, 2025, the Company had $135.9 million of marketable securities, which were classified as held-to-maturity and carried at amortized cost.

6. BUSINESS COMBINATION

Acquisition of Naveris

On July 1, 2026, the Company and Nautilus Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of the Company ("Merger Sub"), completed the acquisition of Naveris, Inc., a Delaware corporation ("Naveris"), pursuant to the Agreement and Plan of Merger dated April 28, 2026 (the "Merger Agreement") by and among the Company, Naveris, Merger Sub, and Shareholder Representative Services LLC, solely in its capacity as the representative of the securityholders of Naveris ("Shareholder Representative"). Pursuant to, and subject to the terms and conditions set forth in the Merger Agreement, Merger Sub merged with and into Naveris, with Naveris continuing as the surviving corporation and a wholly owned subsidiary of the Company (the "Naveris Transaction"). As a result, the Company acquired 100% of the outstanding equity interests of Naveris.

Naveris is a commercial-stage precision oncology diagnostics company with a blood-based monitoring solution for viral-mediated cancers. Its lead product, NavDx, is based on Tumor Tissue Modified Viral (TTMV) DNA technology.

The Naveris Transaction was accounted for as a business combination using the acquisition method of accounting. The purchase price was allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date. The results of operations of Naveris have been included in the Company's condensed consolidated financial statements beginning July 1, 2026.

Purchase consideration

The estimated acquisition date fair value of consideration transferred was approximately $203.3 million and consisted of the following (in thousands):

	Amount
Consideration transferred:	
Net cash payment to sellers, including escrow and securityholder representative reserve fund	$ 151,715
Cash settlement of vested option awards and other pre-combination amounts	7,560
Fair value of contingent consideration (revenue milestones)	44,025
Total consideration transferred	$ 203,300

At the closing of the Naveris Transaction, $5.0 million of the consideration was deposited into an escrow account to secure post-closing purchase price adjustments, and $0.5 million was withheld as a reserve fund for the Shareholder Representative. Of these amounts, $0.1 million was related to unvested stock options and recorded as a prepaid asset.

Under the terms and subject to the conditions set forth in the Merger Agreement, Naveris' equity holders will be eligible to receive up to $100.0 million in additional cash consideration contingent upon the achievement of specified revenue-based milestones in respect of fiscal years ending December 31, 2026 and December 31, 2027, with any payments expected to be made in 2027 and 2028, respectively. The total acquisition-date fair value of the contingent consideration was $45.2 million, of which $44.0 million was included in the purchase price. The remaining $1.2 million is attributable to unvested stock options that are subject to post-combination services.

The fair value of the contingent consideration was estimated using a Monte Carlo simulation based on significant unobservable inputs, including projected NavDx revenue, revenue volatility, a revenue risk premium, an operational leverage ratio, a credit spread, and term-matched risk-free rates based on the U.S. Treasury yield curve. The valuation used a risk-neutral framework and a mid-period discounting convention. The contingent consideration is classified within Level 3 of the fair value hierarchy. The contingent consideration liability will be remeasured at fair value at each reporting date until settlement, with changes in fair value recognized in operating expenses in the condensed consolidated statements of operations. Refer to Note 4, Fair Value Measurements, for the rollforward of the contingent consideration liability. Contingent consideration liability amounting to $44.0 million represents a non-cash investing activity for the three months ended September 30, 2026.

Preliminary purchase price allocation

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed as of July 1, 2026 (in thousands):

	Amount
Assets acquired and liabilities assumed	
Cash and cash equivalents	$ 13,506
Accounts receivable	4,374
Inventories	1,321
Prepaid expenses and other current assets	845
Property and equipment	2,326
Operating lease right-of-use assets	9,033
Intangible assets	125,119
Other non-current assets	920
Total assets acquired	157,444
Accounts payable	(484)
Accrued expenses and other current liabilities	(17,655)
Operating lease liabilities, current	(2,343)
Operating lease liabilities, non-current	(9,250)
Deferred tax liabilities	(10,153)
Total liabilities assumed	(39,885)
Net assets acquired	117,559
Total consideration transferred	203,300
Goodwill	$ 85,741

The allocation of the purchase price is preliminary and is based on information available as of the reporting date. The Company is continuing to obtain and evaluate information necessary to finalize the estimated fair values of the assets acquired and liabilities assumed, primarily related to identifiable intangible assets, income taxes and other assumed liabilities, the estimated acquisition date fair value of contingent consideration as well as the final post-closing adjustments to the purchase consideration for Naveris' cash, indebtedness, transaction expenses and net working capital. Measurement-period adjustments, if any, will be recognized in the reporting period in which the adjustment amounts are determined, with a corresponding adjustment to goodwill. The measurement period will not exceed one year from the acquisition date.

Identifiable intangible assets

The preliminary fair values and estimated useful lives of the identifiable intangible assets acquired were as follows (in thousands, except useful lives):

	Fair value	Useful life
Intangible asset		
Trade names	$ 5,574	9 years
Developed technology - NavDx platform	108,907	10 years

Customer relationships	10,638	12 years
Total identifiable intangible assets	$ 125,119	

The fair values of the developed technology and customer relationships were determined using income-based valuation methods, and the trade names were valued using a relief-from-royalty method. Significant inputs used in the intangible asset valuations included forecasted revenue and margins, an obsolescence factor reflecting the expected decline of the existing technology, expected research and development cost savings, contributory asset charges, customer attrition rates, royalty rates, long-term growth rates, and risk-adjusted discount rates. These fair value measurements are classified within Level 3 of the fair value hierarchy. The finite-lived intangible assets are amortized on a straight-line basis over their estimated useful lives, with a weighted-average useful life of approximately 10.1 years. Amortization expense is recognized in cost of testing services and sales and marketing expense in the condensed consolidated statements of operations. The Company expects to recognize amortization expense related to these intangible assets of approximately $12.4 million annually.

Goodwill

Goodwill of approximately $85.7 million represents the excess of the purchase price over the fair value of the identifiable net assets acquired. Goodwill is primarily attributable to expected synergies from combining the Company's precision medicine capabilities with Naveris' oncology diagnostics platform, the value of the assembled workforce and other benefits that do not qualify for separate recognition, as well as the effect of the deferred tax liabilities recognized on the acquired intangible assets. The goodwill is not expected to be deductible for income tax purposes. Following the Naveris Transaction, the Company continues to operate as a single operating and reportable segment.

Income taxes

In connection with the Naveris Transaction, the Company recognized net deferred tax liabilities of approximately $10.2 million, primarily related to the book-tax basis differences of the acquired intangible assets and tax loss carryforwards. There was no tax-deductible goodwill acquired in the Naveris Transaction. These net deferred tax liabilities provide a source of future taxable income that supports the realization of a portion of the Company's existing deferred tax assets. As a result, the Company released approximately $9.8 million of its valuation allowance, which was recognized as a discrete income tax benefit in the three months ended September 30, 2026. Because the release relates to the Company's pre-existing deferred tax assets, the benefit was recorded outside of the acquisition accounting and did not affect goodwill.

Acquisition-related costs and post-combination compensation

The Company incurred approximately $12.0 million of acquisition-related costs through September 30, 2026, primarily consisting of legal and advisory fees, of which approximately $3.7 million were incurred during the three months ended September 30, 2026. These costs were expensed as incurred and included in general and administrative expense in the condensed consolidated statements of operations.

Amounts attributable to post-combination service are accounted for separately from the Naveris Transaction. These include portions of the unvested stock option payments and related escrow and contingent amounts, transaction bonuses, settlement of promised equity grants and the accelerated portion of an executive's bonus and stock option awards. Total post-combination compensation related to these arrangements is approximately $4.4 million. The post-combination compensation cost will be recognized over the applicable service periods through April 2030.

Revenue and net loss of Naveris

The results of operations of Naveris from the acquisition date through September 30, 2026 are included in the Company's condensed consolidated statements of operations. For the three months ended September 30, 2026, Naveris contributed revenue of approximately $12.5 million and net loss of approximately $6.4 million.

Unaudited pro forma financial information

The following unaudited pro forma financial information presents the combined results of operations of the Company and Naveris for the three and nine months ended September 30, 2026 and 2025 as if the Naveris Transaction had occurred on January 1, 2025 (in thousands). The unaudited pro forma financial information is based on the historical financial information of the Company and Naveris and includes certain pro forma adjustments described below. The unaudited pro forma information for the nine months ended September 30, 2026 reflects Naveris revenue and net loss from January 1, 2026 through the acquisition date. The unaudited pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved had the Naveris Transaction occurred on the date indicated, nor is it indicative of future operating results.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue	$ 139,362	$ 109,151	$ 411,688	$ 295,088
Net income (loss)	$ 19,292	$ (3,433)	$ 111,498	$ (35,691)

The unaudited pro forma financial information includes, where applicable, adjustments primarily for:

(i) amortization expense associated with identifiable intangible assets acquired in the Naveris Transaction, including developed technology, customer relationships and trade names;

(ii) interest income on money market funds as if such investment was liquidated as of January 1, 2025;

(ii) nonrecurring acquisition-related transaction costs incurred by the Company and Naveris, which are reflected as if such costs were incurred on January 1, 2025; and

(iii) adjustments related to acquisition-related compensation arrangements, including bonuses, stock option awards, equity awards and other compensation arrangements associated with the Naveris Transaction.

7. 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.

On June 30, 2026, the Company completed the sale of its lab products business (see Note 1 to these financial statements). In accordance with ASC 350-20, the Company allocated $4.4 million of goodwill to the divested business based on the relative fair values of the business disposed of and the portion of the reporting unit retained. This amount was derecognized upon closing and included in the net assets sold in determining the gain on sale of lab products business.

On July 1, 2026, the Company recognized approximately $85.7 million of goodwill in connection with the Naveris Transaction. See Note 6 to these financial statements.

The Company evaluated the goodwill balance in the retained reporting unit for impairment indicators and no impairment was identified.

The following table presents changes in the carrying amount of goodwill for the nine months ended September 30, 2026 (in thousands):

	Goodwill
Balance as of December 31, 2025	$ 40,336
Goodwill acquired (Note 6)	85,741
Goodwill derecognized upon sale of lab products business (Note 1)	(4,368)
Balance as of September 30, 2026	$ 121,709

Intangible Assets

The following table presents details of the Company's intangible assets as of September 30, 2026 (in thousands):

	September 30, 2026				
	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	$ 116,292	$ (7,744)	$ —	$ 108,548	9.6
Customer relationships	23,189	(5,813)	—	17,376	10.0
Commercialization rights	11,579	(7,970)	—	3,609	2.8
Trademarks and tradenames	8,174	(1,419)	—	6,755	8.4
Total intangible assets with finite lives	159,234	(22,946)	—	136,288	
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	$ 162,727	$ (22,946)	$ —	$ 139,781	

The following table presents details of the Company's intangible assets as of December 31, 2025 (in thousands):

	December 31, 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	$ (24,127)	$ (2,203)	$ 10,187	5.8
Customer relationships	25,581	(12,413)	(1,639)	11,529	7.1
Commercialization rights	11,579	(7,022)	—	4,557	3.6
Trademarks and tradenames	4,860	(2,434)	(232)	2,194	6.6
Total intangible assets with finite lives	78,537	(45,996)	(4,074)	28,467	
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	$ (45,996)	$ (4,074)	$ 31,960	

In connection with the sale of the lab products business completed on June 30, 2026 (see Note 1 to these financial statements), the Company derecognized intangible assets, consisting primarily of acquired and developed technology, customer relationships and trademarks. These assets were included in the net assets sold in determining the gain on sale of lab products business. Estimated future amortization expense presented below reflects only intangible assets retained by the Company.

In connection with the Naveris Transaction, the Company acquired finite-lived intangible assets with a fair value of approximately $125.1 million, consisting of developed technology, customer relationships, and trade names. See Note 6 to these financial statements.

As of September 30, 2026, 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,	
	2026	2025	2026	2025
Cost of testing services	$ 2,925	$ 348	$ 3,438	$ 1,041
Cost of product	—	447	512	1,301
Cost of patient and digital solutions	152	152	457	457
Sales and marketing	817	655	1,634	1,931
Total	$ 3,894	$ 1,602	$ 6,041	$ 4,730

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of September 30, 2026 (in thousands):

Years Ending December 31,	Total
Remainder of 2026	$ 3,886
2027	15,539
2028	15,539
2029	14,825
2030	13,840
Thereafter	72,659
Total future amortization expense	$ 136,288

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Finished goods	$ 2,544	$ 9,804
Work in progress	—	3,740
Raw materials	6,600	13,161
Total inventory	$ 9,144	$ 26,705

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

	September 30, 2026	December 31, 2025
Contingent consideration	$ 30,151	$ 1,617
Refund reserve	16,367	3,500
Clinical studies	10,577	12,356
Short-term lease liability	8,685	6,515
Professional fees	7,013	4,988
Deferred revenue	6,946	4,653
Other accrued expenses	7,864	8,125
Total accrued and other liabilities	$ 87,603	$ 41,754

9. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements at various locations which include Brisbane, California; Flowood, Mississippi; Omaha, Nebraska; Atlanta, Georgia. In connection with the Naveris Transaction (see Note 6 to these financial statements), the Company assumed operating leases for facilities in Waltham, Massachusetts and Durham, North Carolina. Effective June 30, 2026, the Australia and Sweden leases were transferred as part of the sale of the lab products business (see Note 1 to these financial statements). Accordingly, the Company derecognized operating lease right-of-use assets and related operating lease liabilities, which were included in the net assets sold in determining the gain on sale of lab products business.

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, 2026, the carrying value of the right-of-use asset was $23.5 million. The related current and non-current lease liabilities as of September 30, 2026 were $8.7 million and $20.3 million, respectively. The current and non-current lease liabilities are included in accrued and other liabilities and operating lease liabilities, 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, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 2,356	$ 1,835	$ 6,029	$ 5,499

	September 30, 2026	December 31, 2025
Other information:		
Weighted-average remaining lease term - Operating leases (in years)	3.62	4.02
Weighted-average discount rate - Operating leases (%)	6.7 %	7.0 %

Maturities of operating lease liabilities as of September 30, 2026 are as follows (in thousands):

Years Ending December 31,	Operating Leases
Remainder of 2026	$ 2,514
2027	10,429
2028	9,340
2029	4,160
2030	3,441
Thereafter	2,606
Total lease payments	32,490
Less imputed interest	(3,489)
Present value of future minimum lease payments	29,001
Less operating lease liability, current portion	(8,685)
Operating lease liability, long-term portion	$ 20,316

As of September 30, 2026, the Company's leases had remaining terms of 1.13 years to 6.34 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, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cash paid for amounts included in the measurement of lease liabilities				
Operating cash flows used for operating leases	$ 2,003	$ 1,518	$ 5,124	$ 4,496

Royalty Commitments

From time to time, the Company enters into license agreements related to certain technologies used in its products. These agreements generally require the Company to pay sales-based royalties on net sales of products covered by the applicable licenses. Royalty rates under these agreements range from the low single digits to the low double digits on sales of products covered by such agreements.

Other Commitments

Effective as of July 2023, the Company entered into a license and collaboration agreement with a private entity, or 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., or 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, or the Court, alleging the Company made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of Court to amend its counterclaims to include additional allegations regarding purportedly false claims the Company made with respect to AlloSure, and the Court granted Natera's request. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury finding that Natera violated the Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding the Company $44.9 million in damages, comprised of $21.2 million in compensatory damages and $23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury. 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. On February 9, 2026, the Company filed a petition for Supreme Court review. On June 1, 2026, the U.S. Supreme Court denied the Company's petition for a writ of certiorari, leaving the Third Circuit's decision in place. The Company did not record a receivable or a gain from the judgment as the amount was not yet realized.

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 expired 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. Oral argument on the appeal is scheduled for November 9, 2026. 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 was subject to an ex parte reexamination before the United States Patent and Trademark Office, or PTO. On December 17, 2025, a PTO examiner issued a non-final office action rejecting Claims 1 and 4-6 of the patent. On July 17, 2026, the PTO issued a reexamination certificate finding that Natera had overcome the prior rejections of the 10,597,724 patent, concluding the reexamination proceeding.

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 of the 11,111,544 patent, concluding the reexamination proceeding.

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, or CID, from the United States Department of Justice, or 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, or 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 denied the allegations in the qui tam action. On April 23, 2026, the Relator filed a notice of voluntary dismissal of the case, the DOJ informed the District Court that it consented to dismissal of the action, and the District Court dismissed the matter.

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 April 22, 2025, the Company reached an agreement-in-principle to resolve a securities class action (the "Securities Class Action"), under which the Company would pay or cause to be paid a settlement payment of approximately $20.25 million. On December 4, 2025, the United States District Court for the Northern District of California provided final approval of the settlement and the Company paid the settlement amount.

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 Class 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.

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.

On December 9, 2025, the Court issued an order preliminarily approving the parties' settlement. On March 31, 2026, with the assistance of a JAMS mediator, the parties agreed to a monetary settlement of $0.6 million, inclusive of attorney's fees. On July 3, 2026, the Court entered a final order approving the settlement. On July 10, 2026, the Chancery Court in the Burns Derivative Action dismissed the action.

10. STOCK INCENTIVE PLANS

As of September 30, 2026, the Company had a total of 3,901,252 shares available for grant under its 2016 Inducement Equity Incentive Plan, 2019 Inducement Equity Incentive Plan, 2024 Equity Incentive Plan and 2025 Inducement Equity Incentive Plan.

Stock Options

There were no stock options granted to employees during the nine months ended September 30, 2026.

The following table summarizes stock option activity during the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Exercise Price
Stock options outstanding at December 31, 2025	2,478,871	$ 20.47
Exercised	(948,302)	19.85
Forfeited	(16,824)	17.50
Expired	(38,607)	28.36
Stock options outstanding at September 30, 2026	1,475,138	20.70
Stock options exercisable at September 30, 2026	1,089,368	$ 23.10

Restricted Stock Units and Performance Restricted Stock Units

The following table summarizes restricted stock units, or RSUs, and performance restricted stock units, or PSUs, activity during the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Grant Date Fair Value
RSUs and PSUs outstanding at December 31, 2025	3,930,939	$ 15.54
RSUs granted	1,226,759	22.46
RSUs vested	(1,439,710)	15.38
RSUs forfeited	(686,808)	15.64
PSUs granted	570,634	20.46
PSUs vested	(118,304)	18.99
PSUs forfeited	(111,570)	19.25
RSUs and PSUs outstanding at September 30, 2026	3,371,940	$ 18.67

The Company granted PSUs under the stock incentive plans. The PSUs granted to employees include financial and operational vesting metrics to be met over a performance period of three years. The number of shares expected to vest, based on initial grant date expected performance achievement, underlying outstanding PSUs was 611,163 and 226,183 as of September 30, 2026 and December 31, 2025, respectively.

During the nine months ended September 30, 2026, the Company granted 570,634 PSUs (“2026 PSUs”) to employees with an aggregate grant date fair value of $11.7 million at target achievement. The 2026 PSUs provide for a performance period from February 1, 2026 through January 31, 2029 to achieve a defined performance metric. The percentage of 2026 PSUs eligible to vest will be determined based on the metric achieved during the performance period and may range from 0% to 200%. As of September 30, 2026, the achievement of the metric was probable, resulting in expense recognition of $2.4 million and $6.5 million for the three and nine months ended September 30, 2026, respectively. Compensation expense is being recognized from the grant date through the final vest date of January 31, 2029. The PSU expense for the three and nine months ended September 30, 2025 was $0.5 million and $1.1 million, respectively, related to PSUs granted in prior periods.

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 2026 that ended on June 30, 2026, 92,553 shares were purchased pursuant to the ESPP for aggregate proceeds of $1.5 million from the issuance of such shares, which occurred on June 30, 2026.

During the offering period in 2025 that ended on December 31, 2025, 61,866 shares were purchased pursuant to the ESPP for aggregate proceeds of $1.0 million from the issuance of such shares, which occurred on January 2, 2026.

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, 2026 and 2025, included in the condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of testing services	$ 213	$ 299	$ 678	$ 991
Cost of product	—	51	104	390
Cost of patient and digital solutions	96	118	336	527
Research and development	1,197	1,146	3,641	3,912
Sales and marketing	831	1,782	4,232	6,512
General and administrative	7,318	5,022	21,121	14,441
Total	$ 9,655	$ 8,418	$ 30,112	$ 26,773

As of September 30, 2026, unrecognized stock-based compensation expense related to stock options, RSUs, and PSUs was approximately $3.3 million, $34.2 million, and $16.8 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 1.62 years, 2.05 years, and 2.18 years, respectively.

11. STOCKHOLDERS' EQUITY

Stock Repurchase Programs

On May 30, 2025, the Company's Board of Directors authorized a 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, or the May 2025 Repurchase Program. There were no repurchases made during the three months ended September 30, 2026 under the May 2025 Repurchase Program. During the nine months ended September 30, 2026, the Company purchased an aggregate of 0.6 million shares of its common stock under the May 2025 Repurchase Program for an aggregate purchase price of $12.2 million. As of September 30, 2026, no amounts were available for future share repurchases under the May 2025 Repurchase Program.

Additionally, on April 24, 2026, the Company's Board of Directors authorized the April 2026 Repurchase Program, which provides for the repurchase of up to $100.0 million in shares of the Company's common stock over a period of up to two years, commencing on April 30, 2026. The April 2026 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. There were no repurchases made during the three and nine months ended September 30, 2026 under the April 2026 Repurchase Program. As of September 30, 2026, $100.0 million remained available under the April 2026 Repurchase Program.

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, 2026	December 31, 2025
Common stock options outstanding	1,475,138	2,478,871
RSUs and PSUs outstanding	3,371,940	3,930,939
Remaining shares reserved for issuance under the 2016 Inducement Equity Incentive Plan, 2019 Inducement Equity Incentive Plan, 2024 Equity Incentive Plan and 2025 Inducement Equity Plan	3,901,252	3,188,940
Shares reserved under the Employee Stock Purchase Plan	521,187	541,706
Total	9,269,517	10,140,456

Preferred Stock

As of September 30, 2026 and December 31, 2025, 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, 2026 and December 31, 2025.

12. 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, 2026, the Company recorded an income tax benefit of $8.6 million and $4.8 million, respectively. For the three and nine months ended September 30, 2025, the Company recorded an income tax benefit of $15,000 and $74,000, respectively. The increase in the income tax benefit for the three and nine months ended September 30, 2026, compared to the same periods in 2025, was primarily attributable to the release of a portion of the Company’s valuation allowance in connection with the Naveris Transaction completed on July 1, 2026, as described below. For the nine months ended September 30, 2026, this benefit was partially offset by current tax expense of approximately $4.6 million related to the taxable gain recognized on the sale of the lab products business completed on June 30, 2026 (see Note 1 to these financial statements).

As part of the purchase accounting for the Naveris Transaction, the Company recorded approximately $10.2 million of deferred tax liabilities (“DTLs”), primarily related to differences between the book and tax bases of acquired identifiable intangible assets. Because these DTLs are expected to reverse and provide a source of taxable income against which the Company’s existing U.S. deferred tax assets may be utilized, the Company released $9.8 million of its valuation allowance. This release was recognized as an income tax benefit in the period of acquisition. A net deferred tax liability of approximately $0.4 million remains, as the 80% limitation on net operating loss utilization and the limitation on research and development credit usage prevent the Company’s existing deferred tax assets from fully offsetting the DTLs.

The Company evaluates the realizability of its net deferred tax assets by considering all available positive and negative evidence, including: (i) cumulative results of operations in recent years, (ii) the nature and sources of recent losses, (iii) projections of future taxable income, and (iv) the remaining carryforward periods for net operating losses and tax credits. Based on the Company’s history of U.S. losses and other relevant factors, management has concluded that it is more likely than not that the Company will not realize its U.S. net deferred tax assets and, accordingly, continues to maintain a valuation allowance against those assets. The Naveris DTL, however, represents an existing, objectively measurable tax liability whose reversal will generate taxable income irrespective of the Company’s future operating performance. Therefore, a partial release of the valuation allowance, limited to the amount expected to be realized upon the reversal of the Naveris DTL, is considered appropriate.

13. 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, or 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,	
	2026	2025	2026	2025
Testing services revenue				
United States	$ 118,675	$ 72,073	$ 309,252	$ 195,181
Rest of World	516	95	1,264	941
	$ 119,191	$ 72,168	$ 310,516	$ 196,122
Product revenue				
United States	$ —	$ 7,593	$ 14,579	$ 21,293
Rest of World	—	4,885	8,558	13,828
	$ —	$ 12,478	$ 23,137	$ 35,121
Patient and digital solutions revenue				
United States	$ 20,133	$ 15,392	$ 55,249	$ 40,090
Rest of World	38	17	108	86
	$ 20,171	$ 15,409	$ 55,357	$ 40,176
Total revenue				
Total United States	$ 138,808	$ 95,058	$ 379,080	$ 256,564
Total Rest of World	554	4,997	9,930	14,855
	$ 139,362	$ 100,055	$ 389,010	$ 271,419

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

	September 30, 2026	December 31, 2025
Long-lived assets:		
United States	$ 27,011	$ 32,635
Rest of World	—	336
Total	$ 27,011	$ 32,971

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 testing services and digital solutions offerings.

Following the Naveris Transaction, the Company continues to operate as a single operating and reportable segment. See Note 6 to these financial statements.

In connection with the sale of the lab products business completed on June 30, 2026 (see Note 1 to these financial statements), the Company derecognized property and equipment located in Stockholm, Sweden and Fremantle, Australia, which was included in the net assets sold in determining the gain on sale of lab products business.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Testing services revenue	$ 119,191	$ 72,168	$ 310,516	$ 196,122
Product revenue	—	12,478	23,137	35,121
Patient and digital solutions revenue	20,171	15,409	55,357	40,176
Total revenue	139,362	100,055	389,010	271,419
Less:				
Cost of testing services[1]	21,545	14,058	53,582	43,192
Cost of product[1]	—	5,131	8,560	14,505
Cost of patient and digital solutions[1]	15,356	10,050	41,215	25,323
Personnel cost	47,375	33,915	138,596	93,988
Professional and legal fees	5,948	10,307	19,721	32,847
Research materials and clinical trials expense	2,889	1,791	10,808	9,022
Depreciation and amortization expense	5,926	3,020	11,102	8,921
Stock-based compensation expense	9,629	8,418	30,011	26,773
Litigation settlement expense	—	—	600	5,710
Business development and portfolio optimization expense[2]	5,527	—	19,962	—
Transformational initiative costs	—	524	—	2,395
Gain on sale of lab products business	—	—	(112,966)	—
Other segment items[3]	8,083	13,179	40,934	33,149
Interest income, net	(2,208)	(2,013)	(5,852)	(7,160)
Segment and condensed consolidated net income (loss)	$ 19,292	$ 1,675	$ 132,737	$ (17,246)

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

[2] Business development and portfolio optimization expense primarily includes legal, consulting, financial advisory, due diligence, and other transaction-related costs incurred in connection with business development activities, including the sale of lab products business and the Naveris Transaction.

[3] Other segment items include the following: acquisition costs, software expenses, corporate expenses, rent and maintenance expense, travel and event related expense, income tax (expense) benefit 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, 2025, filed with the Securities and Exchange Commission, or the SEC, on February 25, 2026.

Overview

We are a precision medicine company dedicated to advancing care in transplant, specialty oncology, and cell therapy. We deliver solutions designed to empower clinicians and improve patient outcomes. Our portfolio spans non-invasive molecular testing, clinical practice management software, AI-powered data and analytics tools, and patient support solutions designed to connect diagnostic insight, clinical workflow, and patient engagement to help improve patient outcomes.

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. Our commercially available specialty oncology service is NavDx®, a blood-based test that detects and monitors human papillomavirus (HPV)-mediated cancers — including head, neck, and anal cancers — from diagnosis through post-treatment molecular residual disease (MRD) surveillance. Our post-transplant testing services and NavDx are collectively referred to as "the CLIA Tests". We have initiated several clinical studies to generate data on our existing and planned future testing services. From time to time, we partner with pharma and biopharma companies to use our technology and tests, often in clinical trials, to identify or screen for patients that may be appropriate candidates for their products. We also provide digital and patient solutions, including clinical practice management software, data and analytics tools, and patient support offerings.

Highlights for the Three Months Ended September 30, 2026

- Revenue of $139 million, an increase of 39% year-over-year
- Testing Services revenue of $119 million, an increase of 65% year-over-year
- Testing Services volume of approximately 75,900, an increase of 51% year-over-year, including contributions following our acquisition of NavDx
- Patient and Digital Solutions revenue of $20 million, an increase of 31% year-over-year
- Net income of $19 million, compared with net income of $2 million for the third quarter of 2025
- Cash flow from operations of $13 million

Financial Operations Overview

Revenue

We derive our revenue from testing services, product sales, and patient and digital solutions. 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 the CLIA Tests, which represented 86% and 80% of our total revenue for the three and nine months ended September 30, 2026, respectively, and 72% of our total revenue for each of the three and nine months ended September 30, 2025. 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

On June 30, 2026, we completed the sale of our lab products business, which included our kitted laboratory products, to Eurobio (see Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q).

Our product revenue was derived primarily from sales of kitted laboratory products. No product revenue was recognized for the three months ended September 30, 2026.

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 CareDx Pharmacy (formerly known as The Transplant Pharmacy, or TTP). Patient and digital solutions revenue represented 14% of our total revenue for each of the three and nine months ended September 30, 2026 and 15% of our total revenue for each of the three and nine months ended September 30, 2025.

Factors Affecting Our Performance

The Number of the CLIA Tests We Receive and Report

The growth of our testing services is tied to the number of patient samples for the CLIA Tests 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 pharmacy and software solutions, as well as continued support and maintenance of these products and services. Our software is currently implemented in multiple locations in the United States. The software implementation teams are based in Omaha, Nebraska. In addition, the CareDx Pharmacy is located mainly in Flowood, Mississippi and Atlanta, Georgia, and includes 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, 2026 and 2025

(In thousands)

	Three Months Ended September 30,			
	2026	2025	Change	Change (%)
Revenue:				
Testing services revenue	$ 119,191	$ 72,168	$ 47,023	65 %
Product revenue	—	12,478	(12,478)	(100)%
Patient and digital solutions revenue	20,171	15,409	4,762	31 %
Total revenue	139,362	100,055	39,307	39 %
Operating expenses:				
Cost of testing services	24,683	14,705	9,978	68 %
Cost of product	—	5,629	(5,629)	(100)%
Cost of patient and digital solutions	15,604	10,320	5,284	51 %
Research and development	21,324	16,769	4,555	27 %
Sales and marketing	31,650	24,449	7,201	29 %
General and administrative	37,989	28,429	9,560	34 %
Total operating expenses	131,250	100,301	30,949	31 %
Income (loss) from operations	8,112	(246)	8,358	(3,398)%
Other income:				
Interest income, net	2,208	2,013	195	10 %
Other income (expense), net	372	(107)	479	(448)%
Total other income	2,580	1,906	674	35 %
Income before income taxes	10,692	1,660	9,032	544 %
Income tax benefit	8,600	15	8,585	*
Net income	$ 19,292	$ 1,675	$ 17,617	1,052 %

*Percentage not meaningful

Testing services revenue

Testing services revenue increased by $47.0 million, or 65%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily driven by $12.5 million of revenue from NavDx tests performed following the Naveris Transaction and testing services volume growth of 20.8% (excluding NavDx tests) as compared to the same period in 2025. The variance between revenue growth and volume growth was primarily driven by $17.3 million of revenue recognized during the period associated with tests performed in prior periods under ASC 606, compared to $5.9 million in the same period in 2025, partially offset by a $2.6 million reduction in testing services revenue related to the recognition of refund reserves payable to third-party payers.

Product revenue

The decrease in product revenue was due to the sale of our lab products business, which was completed on June 30, 2026. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by $4.8 million, or 31%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily driven by higher pharmacy sales and growth in our digital solutions, particularly an expanded customer base from Ottr software.

Cost of testing services

Cost of testing services increased by $10.0 million, or 68%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributed to higher testing services volume, amortization of acquired intangible assets amounting to $2.7 million, and NavDx testing costs following the Naveris Transaction, partially offset by continued efficiency measures to lower laboratory expenses.

Cost of product

The decrease in cost of product was due to the sale of our lab products business, which was completed on June 30, 2026. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by $5.3 million, or 51%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily due to an increase in the cost of goods from our pharmacy business.

Research and development

Research and development expenses increased by $4.6 million, or 27%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $1.0 million in clinical trial and lab supplies expenses, $1.0 million in software-related expenses, $0.9 million in personnel-related costs, $0.8 million in amortization and impairment expense, $0.3 million in consulting and licensing expense, $0.3 million in equipment-related costs and $0.3 million in facilities-related costs.

Sales and marketing

Sales and marketing expenses increased by $7.2 million, or 29%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $7.0 million in personnel-related costs, $0.5 million in travel expenses, $0.4 million in marketing expenses and $0.2 million in software-related expenses, partially offset by a decrease of $0.9 million in stock-based compensation expense.

General and administrative

General and administrative expenses increased by $9.6 million, or 34%, for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $4.5 million in personnel-related costs, $2.3 million in stock-based compensation expense, $2.0 million in legal and consulting expenses and $1.8 million in software-related expenses, partially offset by a decrease of $1.0 million in facilities-related costs.

Interest income, net

Interest income, net increased by $0.2 million for the three months ended September 30, 2026, compared to the same period in 2025, primarily due to a higher average balance in cash and cash equivalents.

Other (expense) income, net

Other (expense) income, net increased by $0.5 million for the three months ended September 30, 2026, compared to the same period in 2025, primarily due to foreign exchange losses during the three months ended September 30, 2025.

Income tax benefit

Income tax benefit increased by $8.6 million for the three months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to a deferred income tax benefit of $9.8 million recognized related to the valuation allowance release in connection with the Naveris Transaction (see Notes 6 and 12 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information) which was partially offset by approximately $1.2 million related to federal and state income tax expense.

Results of Operations

Comparison of the Nine Months Ended September 30, 2026 and 2025

(In thousands)

	Nine Months Ended September 30,			
	2026	2025	Change	Change (%)
Revenue:				
Testing services revenue	$ 310,516	$ 196,122	$ 114,394	58 %
Product revenue	23,137	35,121	(11,984)	(34)%
Patient and digital solutions revenue	55,357	40,176	15,181	38 %
Total revenue	389,010	271,419	117,591	43 %
Operating expenses:				
Cost of testing services	57,698	45,224	12,474	28 %
Cost of product	9,176	16,196	(7,020)	(43)%
Cost of patient and digital solutions	42,008	26,307	15,701	60 %
Research and development	65,116	52,123	12,993	25 %
Sales and marketing	95,464	71,719	23,745	33 %
General and administrative	109,381	78,881	30,500	39 %
Gain on sale of lab products business	(112,966)	—	(112,966)	100 %
Litigation settlement expense	600	5,710	(5,110)	(89)%
Total operating expenses	266,477	296,160	(29,683)	(10)%
Income (loss) from operations	122,533	(24,741)	147,274	(595)%
Other income:				
Interest income, net	5,852	7,161	(1,309)	(18)%
Other (expense) income, net	(398)	260	(658)	(253)%
Total other income	5,454	7,421	(1,967)	(27)%
Income (loss) before income taxes	127,987	(17,320)	145,307	(839)%
Income tax benefit	4,750	74	4,676	*
Net income (loss)	$ 132,737	$ (17,246)	$ 149,983	(870)%

*Percentage not meaningful

Testing services revenue

Testing services revenue increased by $114.4 million, or 58%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily driven by $12.5 million of revenue from NavDx tests performed following the Naveris Transaction and testing services volume growth of 18.3% (excluding NavDx tests) as compared to the same period in 2025. The variance between revenue growth and volume growth was primarily driven by $52.9 million of revenue recognized during the period associated with tests performed in prior periods under ASC 606, compared to $1.0 million in the same period in 2025, partially offset by an $8.4 million reduction in testing services revenue related to the recognition of refund reserves payable to third-party payers.

Product revenue

The decrease in product revenue was due to the sale of our lab products business, which was completed on June 30, 2026, following which no product revenue was recognized. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by $15.2 million, or 38%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily driven by higher pharmacy sales and growth in our digital solutions, particularly an expanded customer base from Ottr software.

Cost of testing services

Cost of testing services increased by $12.5 million, or 28%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributed to higher testing services volume, amortization of acquired

intangible assets amounting to $2.7 million, and NavDx testing costs following the Naveris Transaction, partially offset by continued efficiency measures to lower laboratory expenses.

Cost of product

The decrease in cost of product was due to the sale of our lab products business, which was completed on June 30, 2026. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by $15.7 million, or 60%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily due to an increase in the cost of goods from our pharmacy business.

Research and development

Research and development expenses increased by $13.0 million, or 25%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $7.7 million in personnel-related costs, $1.3 million in consulting and licensing expense, $1.3 million in depreciation and impairment expenses, $1.1 million in clinical trial and lab supplies expenses, $1.0 million in facilities-related expenses, $0.7 million in software-related expenses and $0.2 million in equipment-related expenses, partially offset by a decrease of $0.3 million in stock-based compensation expense.

Sales and marketing

Sales and marketing expenses increased by $23.7 million, or 33%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $21.1 million in personnel-related costs, $2.9 million in marketing expenses, $1.5 million in travel expenses and $0.4 million in software-related expenses, partially offset by a decrease of $2.2 million in stock-based compensation expense.

General and administrative

General and administrative expenses increased by $30.5 million, or 39%, for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to increases of $13.9 million in personnel-related costs, $7.9 million in legal and consulting expenses, $6.6 million in stock-based compensation expense and $4.4 million in software-related expenses, partially offset by the absence of a $2.3 million one-time impairment charge related to an intangible asset and associated construction in progress recognized in the prior-year period.

Gain on sale of lab products business

Gain on sale of lab products business of $113.0 million in the current period reflects the gain on the sale of our lab products business. For details regarding the sale, see Note 1, Organization and Description of Business, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption “Sale of Lab Products Business,” which is incorporated herein by reference.

Litigation settlement expense

Litigation settlement expenses decreased by $5.1 million, or 89%, for the nine months ended September 30, 2026, compared to the same period in 2025. The decrease in litigation settlement expense was mainly due to the settlement of $5.4 million related to the Securities Class Action and additional litigation settlement expense of $0.4 million during the nine months ended September 30, 2025, which was partially offset by a $0.6 million settlement related to the Edelman Derivative Action and the Burns Derivative Action during the nine months ended September 30, 2026. For details regarding these lawsuits, see Note 9, Commitments and Contingencies, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption “Litigation and Indemnification Obligations”, which is incorporated herein by reference.

Interest income, net

Interest income, net decreased by $1.3 million for the nine months ended September 30, 2026, compared to the same period in 2025, primarily due to a decrease in average balance of cash, cash equivalents and marketable securities.

Other (expense) income, net

Other (expense) income, net decreased by $0.7 million for the nine months ended September 30, 2026, compared to the same period in 2025, primarily due to foreign exchange gain during the nine months ended September 30, 2025.

Income tax benefit

Income tax benefit increased by $4.7 million for the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to a deferred income tax benefit of $9.8 million related to the valuation allowance partial release in connection with the Naveris Transaction (see Note 6 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information) which was partially offset by the current tax expense of $4.6 million recognized on the taxable gain from the sale of our lab products business (see Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information) and approximately $0.5 million related to federal and state income tax expense.

Cash Flows for the Nine Months Ended September 30, 2026 and 2025

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

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 47,655	$ 20,669
Investing activities	143,761	37,071
Financing activities	(5,510)	(80,932)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	4	(96)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 185,910	$ (23,288)

Operating Activities

Net cash provided by operating activities consists of net income, 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, 2026 was $47.7 million. Net operating assets changed by $12.9 million. Our noncash items primarily included $113.0 million in gain on sale of lab products business, $30.1 million in stock-based compensation expense, $13.9 million of depreciation and amortization expense, $9.8 million of deferred income tax benefit in connection with the Naveris Transaction, $4.5 million of amortization of right-of-use assets, $1.4 million of amortization of premium on short-term marketable securities, net, and $0.2 million of loss on disposal of assets.

Cash provided by operating activities for the nine months ended September 30, 2025 was $20.7 million. Net operating assets changed 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.

Investing Activities

For the nine months ended September 30, 2026, net cash provided by investing activities of $143.8 million was primarily related to net proceeds from the sale of our lab products business of $164.8 million, sales of marketable securities of $114.6 million, and maturities of marketable securities of $59.7 million, partially offset by the acquisition of Naveris in the amount of $145.8 million, net of cash acquired, purchases of marketable securities of $39.9 million, $7.3 million related to additions of property and equipment and $2.5 million related to purchase of long-term investments.

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 property and equipment, and $0.7 million related to acquisition of an intangible asset.

Financing Activities

Net cash used in financing activities for the nine months ended September 30, 2026 of $5.5 million was primarily due to taxes paid related to net share settlements of restricted stock units of $13.1 million, repurchase and retirement of common stock of $12.2 million, and payment for contingent consideration of $1.5 million, partially offset by proceeds from exercise of stock options of $18.8 million and proceeds from issuances of common stock under our employee stock purchase plan of $2.5 million.

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.

Liquidity and Capital Resources

We have historically incurred significant losses and negative cash flows from operations and had an accumulated deficit of $486.2 million at September 30, 2026. As of September 30, 2026, we had cash and cash equivalents of $250.5 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 April 28, 2026, we filed an automatic shelf registration statement on Form S-3ASR (File No. 333-295388), or the Registration Statement, which became effective upon filing. Pursuant to the Registration Statement, we may from time to time sell an indeterminate amount 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 May 30, 2025, our Board of Directors authorized a 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. There were no repurchases made during the three months ended September 30, 2026 under the May 2025 Repurchase Program. During the nine months ended September 30, 2026, we purchased an aggregate of 0.6 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of $12.2 million. As of September 30, 2026, no amounts remained available for future share repurchases under the May 2025 Repurchase Program.

Additionally, on April 24, 2026, our Board of Directors authorized the April 2026 Repurchase Program, which provides for the repurchase of up to $100.0 million in shares of our common stock over a period of up to two years, commencing on April 30, 2026. The April 2026 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. There were no repurchases made during the three and nine months ended September 30, 2026 under the April 2026 Repurchase Program. As of September 30, 2026, $100.0 million remained available under the April 2026 Repurchase Program.

Sale of Lab Products Business

On June 30, 2026, we completed the sale of our lab products business to Eurobio and received cash consideration of $171.7 million, subject to customary post-closing adjustments for working capital, cash and indebtedness. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Acquisition of Naveris

On July 1, 2026, we completed the acquisition of Naveris for total consideration of $203.3 million, consisting of $159.3 million in cash and contingent consideration with an acquisition-date fair value of $44.0 million. The cash consideration included $151.7 million paid to Naveris' securityholders, of which $5.0 million was deposited into an escrow account, and $7.6 million was paid to settle vested stock options. In connection with the closing, we also paid $9.7 million of Naveris' transaction expenses, which were assumed as liabilities in the acquisition, and acquired $13.5 million of cash. The purchase price remains subject to customary post-closing adjustments. Naveris' former securityholders are eligible to receive up to $100.0 million in additional cash consideration contingent upon the achievement of specified revenue-based milestones for the fiscal years ending December 31, 2026 and December 31, 2027; the portion attributable to the 2026 milestone, if earned, would be payable in the first half of 2027. See Note 6 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information.

Contractual Obligations

For a discussion regarding our significant contractual obligations as of September 30, 2026 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, refer to Note 9, *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

Prior to the sale of the lab products business on June 30, 2026, the accompanying unaudited condensed consolidated balance sheets contained certain recorded assets in foreign countries, namely in Stockholm, Sweden and Fremantle, Australia. These assets were transferred as part of the sale and are no longer reflected in the unaudited condensed consolidated balance sheet as of September 30, 2026. See Note 1 to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further information. To the extent we continue to sell our solutions internationally, foreign exchange transactions, export duties, government regulations or unanticipated events in foreign countries could continue to 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;
- Stock-based compensation; and
- Gain on sale of lab products business.

There have been no material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the year ended December 31, 2025, except for the accounting policies and estimates related to the Naveris Transaction and the sale of our lab products business.

Business Combination - Naveris Transaction

We account for acquired businesses using the acquisition method of accounting under ASC 805, Business Combinations. With respect to business combinations, we determine the purchase price, including contingent consideration, and allocate the purchase price of acquired businesses to the tangible and intangible assets acquired and liabilities assumed, based on estimated fair values. The excess of the purchase price over the identifiable assets acquired and liabilities assumed is recorded as goodwill. The allocation of the purchase price for the acquisition of Naveris is preliminary and subject to change during the measurement period, which will not exceed one year from the acquisition date.

We engaged a third-party professional service provider to assist in determining the fair values of the purchase consideration, assets acquired, and liabilities assumed. Such valuations require management to make significant estimates and assumptions,

especially with respect to contingent consideration and intangible assets, such as developed technology, trade names, and customer relationships. Critical estimates that we have used in valuing these elements include, but are not limited to, future expected cash flows using valuation techniques (e.g., Monte Carlo simulation models) and discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable.

The fair values of the developed technology and customer relationships were determined using income-based valuation methods, and the trade names were valued using a relief-from-royalty method. Significant inputs used in the intangible asset valuations included forecasted revenue and margins, an obsolescence factor reflecting the expected decline of the existing technology, expected research and development cost savings, contributory asset charges, customer attrition rates, royalty rates, long-term growth rates, and risk-adjusted discount rates.

The purchase price of Naveris included contingent consideration payable upon the achievement of specified revenue-based milestones in respect of fiscal years ending December 31, 2026 and December 31, 2027, with any payments expected to be made in 2027 and 2028, respectively. A portion of the contingent consideration is attributable to post-combination services and is recognized as compensation expense over the requisite service period. The fair value of the contingent consideration was estimated using a Monte Carlo simulation based on significant unobservable inputs, including projected NavDx revenue, revenue volatility, a revenue risk premium, an operational leverage ratio, a credit spread, and term-matched risk-free rates based on the U.S. Treasury yield curve. The valuation used a risk-neutral framework and a mid-period discounting convention. The contingent consideration is classified within Level 3 of the fair value hierarchy and is remeasured at fair value at each reporting date until settlement, with changes in fair value recognized in operating expenses in the condensed consolidated statements of operations.

The most significant assumption underlying the fair values of both the acquired intangible assets, principally the NavDx developed technology, and the contingent consideration is our forecast of NavDx revenue, including test volume growth and reimbursement per test. Because the contingent consideration is based on NavDx revenue for fiscal years 2026 and 2027 and is capped at $100.0 million, its fair value is particularly sensitive to near-term deviations from forecast and to the revenue volatility assumption. Our NavDx revenue forecast is subject to a number of risks and uncertainties, many of which are outside of our control, including changes in Medicare and commercial payer coverage and reimbursement, the pace of clinician adoption, competition from other circulating tumor DNA assays, and our ability to successfully integrate Naveris in a specialty oncology market in which we have limited operating experience, each of which is discussed further in Part II, Item 1A, "Risk Factors". The discount rates and credit spread used in these valuations are also significant assumptions that are affected by interest rates and conditions in the financial markets.

Accordingly, changes in these assumptions, particularly our forecast of NavDx revenue, could result in material adjustments to the contingent consideration liability and the amounts we ultimately pay, as well as impairment of goodwill or intangible assets, any of which could have a material impact on our results of operations in a given reporting period.

Sale of Lab Products Business

On June 30, 2026, we completed the sale of our lab products business to Eurobio and received cash proceeds of approximately $171.7 million, reflecting the base purchase price of $170.0 million, as adjusted for estimated working capital, cash, and other adjustments, subject to finalization of other customary post-closing purchase price adjustments, excluding transaction costs. During the nine months ended September 30, 2026, we recognized a gain on sale of lab products business of approximately $113.0 million, measured as the consideration received less the carrying amount of the net assets transferred to Eurobio or otherwise derecognized (including $4.4 million of goodwill allocated to the lab products business, which reduced the gain on sale), net of transaction costs of approximately $4.8 million. The reclassification of accumulated foreign currency translation adjustments related to the foreign entities sold was included in the gain on sale of lab products business. The gain on sale of lab products business was presented within operating expenses in the unaudited condensed consolidated statements of operations.

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 $250.5 million at September 30, 2026, which consisted of bank deposits. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $2.5 million on our unaudited condensed consolidated balance sheets.

Foreign Currency Exchange Risk

We had operations in Sweden and sell to other countries throughout the world. As a result, we were 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 was 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 was subject to foreign currency exchange risk. A portion of our operating expenses were incurred outside of the U.S. and were denominated in Swedish Krona, Australian Dollar and the Euro, which were also subject to fluctuations due to changes in foreign currency exchange rates. Following the sale of our lab products business, our exposure to foreign currency exchange risk is not significant. We do not enter into hedging transactions, and we do not believe a hypothetical 10% change in foreign currency exchange rates would have a material effect on our financial condition or results of operations.

ITEM 4. CONTROLS AND PROCEDURES

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of September 30, 2026, management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal accounting officer), performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2026, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

We are in the process of integrating Naveris into our internal control over financial reporting. As permitted by SEC guidance for newly acquired businesses, we intend to exclude Naveris from management's assessment of the effectiveness of our internal control over financial reporting for the year in which the acquisition was completed. Except as noted above, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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. These disclosures reflect management's beliefs and opinions as to factors that could materially and adversely affect the Company and our securities in the future. References to past events are provided by way of example only and are not intended to be a complete listing of such events or a representation as to whether or not such factors or similar events have occurred in the past or their likelihood of occurring in the future. 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 net losses, and we may not sustain profitability.

We have a history of substantial net losses since our inception, and we may incur net losses in future periods. For the three months ended September 30, 2026, our net income was $19.3 million and for the three months ended September 30, 2025, our net income was $1.7 million. As of September 30, 2026, we had an accumulated deficit of $486.2 million. Although we reported net income of $19.3 million for the three months ended September 30, 2026, we have not consistently achieved profitability and there can be no assurance that we will be able to sustain profitability on a quarterly or annual basis. 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 and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of our testing services and 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 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, 2026, revenue from Medicare for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and NavDx represented 37% of our testing services revenue and 31% of our total 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. On November 25, 2025, CMS issued a final determination to crosswalk AlloSure (0540U) to CPT code 0493U. As a result, PLA Code 0540U was listed on the Clinical Laboratory Fee Schedule effective January 1, 2026 at approximately $2,753. The new reimbursement rate represents an $88 decrease to the previous pricing for our AlloSure Kidney test, and no change to the pricing for AlloSure Heart and AlloSure Lung tests.

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.

On February 3, 2026, the "Consolidated Appropriations Act, 2026" was passed amending the PAMA law. The legislation required us, and other laboratories, to report private payor rates paid between January 1, 2025 and June 30, 2025 to CMS with a reporting period from May through July 2026. The volume-weighted median of the rates reported for each test will be used to set the CLFS rates for some of our tests in calendar years 2027 to 2029. On September 21, 2026, CMS released preliminary CLFS payment rates for calendar year 2027 based on the reported data. Under the preliminary rates, the AlloMap reimbursement rate would remain unchanged at $3,240 and the AlloSure reimbursement rate would increase from $2,753 to $2,840. The preliminary rates are subject to public comment and potential revision, and CMS has indicated that final rates will be published in November 2026 and become effective January 1, 2027. There can be no assurance that the final rates for our tests will not differ from the preliminary rates. In addition, the preliminary rates reflect reductions for a substantial majority of tests on the CLFS, and there can be no assurance that rates for our current or future tests will not be reduced in future pricing cycles.

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, Palmetto GBA's 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. On July 16, 2026, a final LCD (L40060) and billing article (A60152), or the Final LCD, were published, and the Final LCD became effective on August 30, 2026. The Final LCD affirms coverage across our transplant testing offerings in kidney, heart, and lung, including for-cause and surveillance testing, with defined coverage criteria. While the Final LCD affirms coverage for these offerings, changes in coverage criteria, utilization limitations, or payment amounts, including as a result of any future revisions to the LCD, could adversely affect our business, operating results and prospects.

NavDx has been a covered service for Medicare beneficiaries since August 2023 through an LCD issued by Palmetto GBA, and is priced nationally as an advanced diagnostic laboratory test, or ADLT, at $1,800 under CPT Code 0356U. In addition, NavDx coverage depends on a single LCD, and any revision or retirement of the LCD covering NavDx could restrict or eliminate coverage for NavDx and materially reduce the revenue we expect from our oncology business. As an ADLT, NavDx is subject to annual re-pricing based on a weighted median of private payer rates for the test, and any decline in the private payer rates we report could reduce the Medicare payment rate for NavDx more quickly than for our other tests.

If future reimbursement price or coverage levels are lower than the current prices or coverage level, 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. The MAC for North Carolina is Palmetto GBA. Our current Medicare coverage through Noridian and Palmetto GBA provides for reimbursement for tests performed for qualifying Medicare patients throughout the United States so long as the tests are performed in our California and North Carolina laboratories. We cannot predict whether Noridian, Palmetto GBA, or any future MAC will continue to provide coverage for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, or NavDx 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, AlloSure Lung, or NavDx could impact the coverage for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

Any decision by CMS or its local contractors to reduce or deny coverage for our tests 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, AlloSure Lung, and NavDx tests, 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 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 successfully develop and commercialize other solutions, tests or enhancements, or if we do not continue our Medicare reimbursement submissions for our testing at the same levels, 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, AlloSure Lung, and NavDx 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. In addition, third-party payers have imposed, and may in the future impose, administrative requirements as a condition of payment, including prior authorization and requests for medical records supporting medical necessity, certain of which can be satisfied only by the ordering healthcare provider or treating transplant center. Because satisfaction of these requirements may depend on the complete and timely response of these providers and may be outside of our control, claims may be delayed or denied, which could adversely affect our revenue and cash collections. 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 has also asserted entitlement to recoup additional previously paid claims pursuant to the provisions under the contract. 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, NavDx, 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 are currently, 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 9, *Commitments and Contingencies*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations," 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. Such matters may cause us to incur costly litigation and/or substantial settlement charges, divert management attention, result in adverse judgments, fines, penalties, injunctions or other relief, and may result in loss of customer or investor confidence regardless of their merit or ultimate outcome.

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 institutions;
- 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, NavDx, 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 fields of diagnostic testing in transplantation and specialty oncology are evolving and are 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. The market for oncology molecular testing is also subject to rapid technological change and substantial investment by competitors with significantly greater resources than ours. If competing assays obtain broader guideline inclusion, payer coverage or regulatory authorization than NavDx, or offer greater sensitivity, specificity or convenience, NavDx could become less competitive or obsolete and we may not realize the anticipated benefits of our acquisition of Naveris.

If we are unable to demonstrate the effectiveness of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, NavDx, 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 and patient and digital solutions, and demonstrate the clinical and diagnostic benefits of these services and patient and digital solutions. We believe that clinicians, transplant centers and laboratories may not use our services 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 and patient and digital solutions provide accurate, reliable and cost-effective information that is useful to their patients. The acceptance of our services and patient and digital solutions will depend upon our ability to demonstrate the safety and efficacy, advantages, short and long-term clinical performance and cost-effectiveness of our services and patient and digital solutions.

If clinicians, hospital administrators and laboratories do not adopt or continue to use our tests 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, heart, and lung 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, iMDx, 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 and Bio-Rad. In addition, Eurobio Scientific S.A., which acquired our lab products business, may offer post-transplant surveillance kits that compete with our solutions outside of North America.

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 have 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, Eurofins and iMDx have commercially available molecular diagnostics tests.

Competition for NavDx comes from conventional surveillance methods for HPV-driven cancers, including imaging, clinical examination, endoscopy and tissue biopsy, as well as from other circulating tumor DNA, or ctDNA, assays, including tests offered by Natera, NeoGenomics, Guardant Health and others. Several of these competitors are significantly larger than we are, offer broader oncology testing menus, have established relationships with oncologists and payers, and have substantially greater resources, and they may develop or market tests for HPV-driven or other viral-mediated cancers that are viewed by clinicians or payers as equivalent or superior to NavDx. If we are unable to compete successfully in specialty oncology, we may not realize the anticipated benefits of our acquisition of Naveris.

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 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 patient and digital solutions on a timely basis, our ability to attract and retain transplant center 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 patient and digital solutions. To compete successfully, we must continually update our software, including maintaining interoperability with the electronic health record systems used by transplant centers. The failure to maintain the quality of our solutions or inability to keep pace with this innovation could render our existing or future solutions obsolete or less attractive to transplant centers. 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, AlloSure Lung, and NavDx depends, in large part, on our ability to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and NavDx 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. In addition, changes in the funding of the FDA or other government agencies or comparable foreign regulatory authorities could hinder, prevent or delay their regulatory review and approval processes or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely.

There can be no assurance that we will be able to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, NavDx, 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, we may not grow at all, and revenue may decline.

From 2024 to 2025, our revenue increased from $333.8 million to $379.8 million, which represents an increase of 14%. From the three months ended September 30, 2025 to the three months ended September 30, 2026, our revenue increased from $100.1 million to $139.4 million, which represents an increase of $39.3 million or 39%. In the future, our revenue may not grow at all and it may decline. We believe that our future revenue will depend on, among other factors:

- the continued usage and acceptance of our current and future solutions;
- demand for our testing services 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, AlloSure Lung, and NavDx 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 facilities in the United States become inoperable, we will be unable to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, NavDx and future testing solutions, if any, and our business will be harmed.

We perform our testing services for the United States in laboratories located in Brisbane, California, Waltham, Massachusetts and Durham, North Carolina. While we operate multiple laboratory facilities, our testing operations are not fully redundant, and not all of our tests can be readily performed at each laboratory location. Certain tests, including our AlloSure, AlloMap and NavDx offerings, rely on specialized equipment, workflows, personnel training, quality systems, regulatory approvals, and laboratory-specific validations that would require significant time, expense and regulatory review to replicate or transfer to another facility.

Brisbane, California is situated on or near earthquake fault lines. The Durham facility is subject to risks associated with hurricanes, tropical storms, severe weather, flooding and prolonged power disruptions that may impact our operations, supply chain, workforce availability and transportation networks. The Waltham facility is subject to risks associated with severe winter storms, extreme precipitation, flooding and other weather-related events that may disrupt operations, transportation networks and utility services.

Our facilities 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. Although our multiple laboratory locations may provide some operational flexibility, a disruption at a facility performing a specific test may materially affect our ability to provide that test until operations can be transferred, validated and scaled at another location. Any inability to perform our tests may result in the loss of customers, delays in patient testing, harm to our reputation and reduced revenue, and we may be unable to regain affected customers in the future. Although we maintain 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.

While we may seek to expand testing capabilities across existing or additional laboratory facilities, doing so would require considerable time and expense, including securing adequate space, installing and qualifying equipment, recruiting and training personnel, conducting analytical and clinical validation activities, obtaining any required regulatory approvals, and establishing the operational and administrative infrastructure necessary to support testing services. Any new clinical laboratory facility established by us in the United States would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and would also be required to secure and maintain applicable state licenses, including in states such as California, Massachusetts, Maryland, New York, Rhode Island and Pennsylvania.

Obtaining and maintaining such certifications and licenses may be time-consuming and could delay our ability to commence operations or offer specific testing services at a facility.

If we fail to secure or maintain any required certifications or licenses, we may be unable to process samples from certain states or offer particular tests from specific laboratory locations. In addition, we expect that it would be difficult, time-consuming and costly to qualify, train, equip and oversee a third party to perform tests on our behalf. Even though multiple CLIA-certified laboratories exist, only laboratories with the necessary certifications, state licenses, technical capabilities, validated methods and quality systems could perform our tests following appropriate technology transfer, validation and other required procedures. We cannot be certain that we would be able to successfully transfer testing to another laboratory, whether internal or external, within an acceptable timeframe, or that any such laboratory would be willing or able to perform our tests in compliance with applicable quality, regulatory and commercial requirements. As a result, disruptions affecting one or more of our laboratories could materially adversely affect our business, financial condition and results of operations.

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. At the same time, an increasing number of stakeholders, regulators and lawmakers have expressed or pursued contrary views, including the proposal or enactment of "anti-ESG" policies, legislation, executive orders or initiatives or issued related legal opinions. Conflicting regulations and a lack of harmonization of ESG legal and regulatory environments across the jurisdictions in which we operate may create enhanced compliance risks and costs.

Further, we have in the past and may continue to communicate certain initiatives, including goals, regarding environmental matters, responsible sourcing, and social investments. We could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could fail in fully and accurately reporting our progress on such initiatives and goals. In addition, we could be criticized for the scope of such initiatives or goals or perceived as not acting responsibly in connection with these matters.

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. 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. In 2026, the SEC proposed to rescind the climate-related disclosure rules in their entirety. The ultimate outcome and timing of any rescission remain uncertain. In addition, we are or may become subject to state-level and non-U.S. climate-related disclosure requirements, which may impose additional reporting obligations and cause us to incur increased costs.

If we are not effective in addressing ESG matters affecting our business, or setting and meeting relevant ESG goals, our reputation and financial results may suffer.

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 laboratories 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 laboratories. Our business will suffer if these service providers do not support AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, NavDx 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, 2026, we had cash and cash equivalents of $250.5 million and an accumulated deficit of $486.2 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 patient and digital solutions or enhancements to those tests, 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. In addition, rules and regulations of the SEC may restrict our ability to conduct certain types of financing activities or may affect the timing of and the amounts we can raise by undertaking such activities. 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 we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. 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.

We have experienced changes in our executive leadership and we may experience further changes in executive leadership in the future. Changes to strategic or operating goals, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. If we do not integrate new executives successfully, we may be unable to manage and grow our business, and our financial condition and profitability may suffer as a result. If we are unable to attract and retain qualified management personnel, our business could suffer.

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 state laws restricting or prohibiting the use of non-competition agreements and increased scrutiny of such agreements by the Federal Trade Commission, 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, NavDx 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 testing services, assays or software could result in voluntary corrective actions or agency enforcement actions, as well as harm our reputation, decrease market acceptance of our solutions and expose us to product liability or professional liability claims, which could exceed our resources.

Our testing services, assays, algorithms and software may contain undetected errors or defects that are not identified until after they are first introduced or deployed. Disruptions or other performance problems with our offerings, or the perception of disruption or performance problems, may require us to issue corrected test reports, suspend or revalidate an assay, notify clinicians, patients or payers, or withdraw or modify a software release, 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 offerings. A material liability claim, corrective action or similar occurrence may cause us to incur significant expense, decrease market acceptance of our solutions 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, NavDx 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.

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 perform reliable services.

We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use 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 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 supply us with cell preparation tubes; Beckman Coulter, which provides laboratory reagents and consumables; Takara, which supplies us with reagents; IDT, which supplies us with reagents; Avantor, which supplies us with consumables; Qiagen N.V., which supplies us with proprietary reagents and reagent kits; Bio-Rad, which supplies us with instruments, laboratory reagents and consumables; and Promega, which supplies us with instruments, laboratory reagents and consumables. We do not have guaranteed supply agreements for all products and reagents used in our testing services with Thermo Fisher, Becton, Dickinson and Company, Bio-Rad 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, the Israel-Hamas war, and ongoing conflicts in Iran and the Middle East, 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 Canada. 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;
- 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 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. Although in February 2026 the U.S. Supreme Court held that the International Emergency Economic Powers Act does not authorize the imposition of tariffs, the U.S. government has since imposed or announced tariffs under other statutory authorities, and certain other countries have imposed retaliatory tariffs. The scope, duration and ultimate impact of these tariffs remain uncertain, and additional tariffs or trade restrictions may be imposed or expanded. 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, artificial intelligence, or AI, technologies into some of our internal processes and certain products and solutions. These technologies may present business, compliance, product and reputational risks.

We currently use artificial intelligence, or AI, in certain of our products and solutions and in certain internal processes to increase employee efficiency and productivity and to optimize software and algorithm development, and we may further expand our use of AI, including in additional products, 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. Additionally, our competitors and other third parties may incorporate AI into their operations, products and processes more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations.

At the same time, use of AI has become the subject of significant media attention and political debate. As we integrate or consider integrating AI—including generative AI—into new or existing offerings, we may face new or expanded risks and liabilities, including 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, our business, operating results and financial condition. AI-enabled features may not perform as intended, may produce inaccurate, deficient, misleading or otherwise flawed outputs, or may reflect unintended biases and discriminatory outcomes. In a healthcare context, such issues could negatively impact clinicians, patients and our customers, require additional validation, human oversight and post-market monitoring, result in product complaints or recalls, and expose us to product liability and professional liability claims. In addition, laws, regulations or industry standards governing AI use are evolving and may be burdensome or restrict our ability to develop, deploy or update AI in our products or processes, including potential frameworks for AI/ML-enabled medical device software in the United States and the EU AI Act, as well as emerging U.S. federal, state and local rules.

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 alternative 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. Changes to or disruptions with third-party AI providers, including model deprecation, performance issues or restrictive terms, could also disrupt, degrade or increase the cost of offerings that incorporate such technologies.

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

Many of the countries in which we operate, including the U.S., 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; the imposition of trade barriers such as tariffs (and judicial uncertainty about their enforceability), quotas, trade wars, preferential bidding or import or export licensing requirements; increased inflation globally and in the U.S. in particular; 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 U.S. federal government to shut down for periods of time. Continued adverse political conditions or a severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our tests and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

Our 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. 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 enacted the One Big Beautiful Bill Act, or the OBBBA, in July 2025, which includes significant provisions, including tax cut extensions and modifications to the international tax framework, and the restoration of the immediate deductibility of domestic research and development expenditures beginning with our 2025 taxable year.

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.

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. We may not be able to successfully complete any acquisitions or successfully integrate any acquired business. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisition targets. 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 Naveris, Ottr, XynManagement, TransChart, MedActionPlan, TTP, HLA Data Systems, or any other businesses or assets that we may acquire, or from the sale of our lab products business.

The integration of any businesses or assets we may acquire, including our recently completed acquisition of Naveris, 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 Naveris, its specialty oncology testing business, including minimal residual disease and recurrence monitoring, 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.

Our acquisition of Naveris also expands our business beyond our historical focus on transplant diagnostics and related patient and digital solutions into specialty oncology testing, a market in which we have limited operating experience and which may involve different clinical adoption, reimbursement, regulatory, commercial and competitive dynamics. We may not be successful in integrating Naveris' operations, technology, personnel, laboratory processes, quality systems, payer relationships, compliance programs, financial reporting and internal control processes, and we may fail to retain key personnel, customers, collaborators or commercial relationships.

In addition, we may not realize the anticipated benefits of the June 2026 sale of our lab products business to Eurobio Scientific S.A., or Eurobio, and we remain subject to post-closing obligations, including transition services and indemnification of Eurobio for certain matters, as well as our reliance on Eurobio to supply certain products that we distribute in North America.

If we are not able to achieve the anticipated strategic benefits of any strategic 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.

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. In addition, commercial payers, Medicare Advantage plans and contractors administering government healthcare programs are increasingly using artificial intelligence, algorithms and other automated tools to review claims, make prior authorization and medical necessity determinations and select claims for audit. These tools may result in higher rates of claim denials, requests for additional documentation or audits, may apply coverage criteria in ways that we believe are inconsistent with applicable coverage policies, and may be difficult to challenge, which could increase our appeals volume and administrative costs and delay or reduce our collections and revenue. 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. Four claims remain subject to appeal with the rest being resolved in our favor.

In the first quarter of 2025, we received a second UPIC records request with which we complied. In the second quarter of 2025, the UPIC notified us that it had received the medical records we provided in connection with such request and concluded that no further information was necessary at that time. The UPIC identified no overpayment in connection with the second request and thanked us for our cooperation.

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

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 2032. The OBBBA, which was signed into law in July 2025, 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, AlloSure Lung, NavDx, 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 and the OBBBA, 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 laboratories, 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 any of our laboratories are out of compliance with the CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of that laboratory's 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 CLIA compliance and certification at each laboratory 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 laboratories under California and Massachusetts law in order to conduct testing. Each state's laws establish standards for day-to-day operation of our clinical laboratories, 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 and Massachusetts certifications, we currently hold licenses in 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 received a successful inspection in March 2026.

If we were to lose the CLIA accreditation or applicable state law license for any of our laboratories, whether as a result of a revocation, suspension or limitation, we would no longer be able to perform the tests conducted at that laboratory, which may include AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung or NavDx, 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.

In October 2023, the FDA proposed a 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. In April of 2025, the U.S. District Court for the Eastern District of Texas found that the FDA's authority to promulgate rules over "medical devices" does not extend to "laboratory services." In September 2025, the FDA issued a final rule reverting the text of the regulation as it existed prior to this change and limiting the FDA's authority over our testing services. Following the decision, the current administration reverted the policy to suggest it would not exercise authority to regulate LDTs. There is no assurance whether, or when, the FDA may again seek to regulate LDTs, 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, NavDx, 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 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. For violations assessed after July 3, 2025, the minimum FCA penalty increased from $13,946 to $14,308 per claim and the maximum penalty increased from $27,894 to $28,619 per claim. 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. As previously reported, the SEC has concluded its investigation and does not intend to recommend an enforcement action against us, and the DOJ declined to intervene in the related qui tam action and has closed its investigation with no finding of wrongdoing. On April 23, 2026, the private relator who had continued to pursue the qui tam action filed a notice of voluntary dismissal, the DOJ informed the court that it consented to dismissal of the action, and the District Court dismissed the case. We previously received a request for information from a separate state regulatory agency and may receive additional requests for information from the DOJ, the SEC 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 raised any issues regarding the safety or clinical utility of any of our products or services. Although the DOJ and SEC investigations have concluded, we cannot predict the outcome of 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. 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.

If and to the extent we market our solutions in foreign jurisdictions in the future, we would be subject to rules and regulations in those jurisdictions. In some foreign countries, including countries in the EU, the reimbursement of our diagnostic tests is subject to governmental control, and 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 related to our products and services.

As of September 30, 2026, we owned or exclusively licensed eight issued U.S. patents related to diagnosing transplant rejection and autoimmune disease, which will expire between August 2027 and May 2035. In addition, we had four U.S. patents related to organ function recovery and allograft preservation, which will expire between July 2038 and June 2041. In addition, through the acquisition of Naveris on July 1, 2026, we acquired exclusive license rights to six additional U.S. patents related to HPV-driven cancer detection and monitoring, which will expire between September 2039 and September 2041.

The patent applications that we own or exclusively license from others may fail to result in issued patents with claims that protect our products and services in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Further, if we encounter delays in regulatory approvals, the period during which we could market our products and services under patent protection could be reduced. Even if patents do successfully issue and even if such patents cover our products or services, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held 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 does not infringe 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 and other countries. 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 and other countries 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office, or the PTO, and other foreign patent agencies in several stages over the lifetime of the patent. The PTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products and services, our competitors might be able to enter the market, which would have an adverse effect on our business.

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 9, *Commitments and Contingencies*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations," which is incorporated herein by reference, for a discussion of our recently completed litigation with Natera.

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

Third parties may challenge the patentability, validity, scope, and/or enforceability of the patents and patent applications in administrative proceedings at the USPTO and patent offices in other countries. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights. The costs of defending our patents or enforcing our proprietary rights in these administrative proceedings and related litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or

invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products and services without infringing third-party patent rights. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party.

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 9, *Commitments and Contingencies*, to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q under the caption "Litigation and Indemnification Obligations," 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 the substantial amount of discovery required in connection with intellectual property litigation results in our confidential information being compromised by disclosure during the litigation;
- 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, inter partes review 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.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications may, upon grant of a patent, become a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC may be opted out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries that are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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, NavDx, 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.

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 are developing advanced analytics that are expected to 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.

In addition, Naveris has an exclusive license with the University of North Carolina to five U.S. patents related to HPV-driven cancer detection and monitoring.

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 Information Technology, Cybersecurity, and Data Privacy

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

We store sensitive intellectual property and other proprietary business information, including that of our customers, employees, payers and collaboration partners. We manage applications and data across on-site, managed, and cloud-based environments, which include business critical research and development, commercial, business, and financial information. We also use a third-party billing software to collect and store sensitive data, including protected health information, or PHI, credit card information and personal data 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 are highly dependent on information technology, or IT, networks and systems for significant elements of our operations, including our laboratory information management system and certain software provided by Epic Systems Corporation. These IT systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation and general administrative activities. A significant risk in implementing these systems includes the integration and communication between separate IT systems, and any failure to integrate these systems effectively, or any significant disruptions to these systems, could adversely affect various aspects of our operations. 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. Despite significant security measures, our information technology networks and those of our vendors remain vulnerable to evolving threats (including physical and electronic intrusions, malware and viruses, ransomware, phishing and social engineering, system failures, and insider error or malfeasance) that could disrupt systems or result in unauthorized access, use, or alteration of confidential information. There can be no assurance our controls, monitoring, and testing will prevent or timely detect a cyberattack or other security incident.

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. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personal data, such as PHI) 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.

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 data, 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.

We are subject to changing laws, regulations, standards, and contractual obligations related to privacy, data protection and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions, fines, sanctions, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

The interpretation and application of consumer protection (e.g., Section 5 of the Federal Trade Commission, or FTC, Act), 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, we obtain health information (including from TTP) that is subject to privacy and security requirements under HIPAA, as amended by HITECH, which imposes, among other things, certain requirements relating to the privacy, security, transmission, and breach of individually identifiable health information. If we violate HIPAA, depending on the specific facts and circumstances, we could be subject to significant fines, penalties or regulatory inquiries or actions.

Over a third of U.S. states have adopted comprehensive privacy and security laws and regulations, which govern the privacy, processing and protection of personal data, including certain specific requirements and laws with respect to health-related information. For example, Washington state has passed the My Health My Data Act, which focuses on the collection of consumer health data, and has a broader scope than HIPAA and includes a private right of action. Nevada has also passed a similar law with respect to the collection and processing of consumer health information. Additionally, state legislation continues to be a driving force behind the changing privacy law landscape in the U.S. Over a third of U.S. states have passed comprehensive consumer privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels, some of which we are or may become subject to. In California, for example, the CCPA requires, among other things, covered companies to provide disclosures to California consumers concerning the collection and sale of personal data, and gives consumers the right to opt-out of certain sales of personal data. The FTC has also stepped-up enforcement of data privacy with several significant settlements (including settlements concerning the downstream sharing of personal information and use and disclosure of personal health data) and there has been a material increase in class-action lawsuits linked to the collection and use of biometric data and use of tracking technologies, such as web cookies.

Internationally, we are subject to the GDPR, which applies to personal data (including health-related data) obtained from individuals within the EEA, and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. The GDPR imposes strict obligations on businesses, including requirements and limitations on data processing, establishing a legal basis for processing personal data, notification of data processing obligations, notification of

security incidents to appropriate data protection authorities or data subjects, protecting the security and confidentiality of the personal data, and establishing means for data subjects to exercise rights in relation to their personal information. The GDPR subjects noncompliant companies to fines of up to the greater of 20 million Euros (17.5 million GBP in the UK) or 4% of their global annual revenues, potential bans on processing of personal data, and private litigation.

Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico and Australia, have also implemented laws relating to data privacy and protection. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. Changes in international legislation may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, and could result in increased compliance costs or changes in business practices. Compliance with domestic and foreign privacy, data security and data protection laws, regulations and contractual and other obligations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. The actual or perceived failure to comply with domestic and foreign privacy, data security and data protection laws and regulations could result in government enforcement actions, private litigation or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with privacy, data security and data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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, 2026 to September 30, 2026, our closing stock price ranged from $16.05 to $65.00 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 earnings 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 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 May 30, 2025, our Board of Directors authorized the May 2025 Repurchase Program, which provides for the repurchase 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. Additionally, on April 24, 2026, our Board of Directors authorized the April 2026 Repurchase Program, which provides for the repurchase of up to $100.0 million in shares of our common stock over a period of up to two years, commencing on April 30, 2026. The May 2025 Repurchase Program and April 2026 Repurchase Program may be carried out at the discretion of a committee of our Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. Any repurchase of shares of our common stock under the May 2025 Repurchase Program or April 2026 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% on the fair market value of net stock repurchases. 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.

There were no repurchases made during the three months ended September 30, 2026 under the May 2025 Repurchase Program. During the nine months ended September 30, 2026, we purchased an aggregate of 0.6 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of $12.2 million. As of September 30, 2026, no amounts remained available for future share repurchases under the May 2025 Repurchase Program.

There were no repurchases made during the three and nine months ended September 30, 2026 under the April 2026 Repurchase Program. As of September 30, 2026, $100.0 million remained available under the April 2026 Repurchase Program.

In the event we make any additional stock repurchases in the future, our ability to finance any material expansion of our business, including through acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our Board of Directors may modify or amend our existing repurchase programs, 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. Our ability to use these NOLs could also be limited if the tax laws are amended or otherwise changed. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs.

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.

If we fail to maintain an effective system of internal controls, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, 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. 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. While we were able to determine that our disclosure controls and procedures and internal control over financial reporting were effective as of September 30, 2026, we anticipate that we will continue to expend resources, including accounting-related costs and significant management oversight to continue to improve our internal control over financial reporting.

As discussed in Item 9A "Controls and Procedures" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, a material weakness existed in our internal control over financial reporting as of December 31, 2024. A material weakness is a deficiency or combination of deficiencies in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. As previously disclosed, we did not fully maintain components of the COSO framework, including elements of the control environment, risk assessment, control activities, and monitoring activities components, that resulted in immaterial corrected errors in the reporting of stock-based compensation expense for the year ended December 31, 2024 and determined that this control deficiency constituted a material weakness in our internal control over financial reporting. We successfully remediated the material weakness during the year ended December 31, 2025.

If we experience additional material weaknesses, are otherwise unable to maintain an effective system of internal control over financial reporting in the future, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, we may not be able to accurately or timely report our financial condition or results of operations or prevent fraud, which may adversely affect investor confidence in the accuracy and completeness of our financial reports and, as a result, the value of our common stock.

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.

Any such failure 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, 2026:

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, 2026 - July 31, 2026				
Stock Repurchase Program [1]	—	—	—	$ 100.0
Employee Transactions [2]	33,885	$ 29.04	N/A	N/A
August 1, 2026 - August 31, 2026				
Stock Repurchase Program [1]	—	$ —	—	$ 100.0
Employee Transactions [2]	44,332	$ 46.02	N/A	N/A
September 1, 2026 - September 30, 2026				
Stock Repurchase Program [1]	—	$ —	—	$ 100.0
Employee Transactions [2]	30,273	$ 51.35	N/A	N/A
Total				
Stock Repurchase Program [1]	—	$ —	—	$ 100.0
Employee Transactions [2]	108,490	$ 42.21	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

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2026, 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, modified 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 August 3, 2026, Jeffrey A. Novack, our General Counsel and Secretary, 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 68,075 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 26, 2027, subject to early termination for certain specified events set forth in the plan.

On August 4, 2026, the Richard Bryan Riggsbee Revocable Trust, of which Richard Bryan Riggsbee, a member of our Board of Directors, is a trustee, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Mr. Riggsbee’s plan is for the sale of up to 10,570 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 May 16, 2027, subject to early termination for certain specified events set forth in the plan.

On August 6, 2026, Keith Kennedy, our Chief Operating Officer and Chief Financial Officer, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Mr. Kennedy's plan is for the sale of up to 141,678 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 19, 2027, subject to early termination for certain specified events set forth in the plan.

On August 13, 2026, the Michael D. Goldberg Family Trust, of which Michael D. Goldberg, a member of our Board of Directors, is a trustee, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Mr. Goldberg's plan is for the sale of up to 13,800 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 26, 2027, subject to early termination for certain specified events set forth in the plan.

On August 26, 2026, John W. Hanna, our President and Chief Executive Officer, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Mr. Hanna's plan is for the sale of up to 190,036 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 April 21, 2027, subject to early termination for certain specified events set forth in the plan.

On August 28, 2026, Jessica Meng, our Chief Commercial Officer, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Ms. Meng's plan is for the sale of up to 111,918 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 26, 2027, subject to early termination for certain specified events set forth in the plan.

Compensatory Arrangements of Certain Officers

On October 26, 2026, the Compensation and Human Capital Committee (the "Compensation Committee") of our Board of Directors approved one-time, discretionary cash bonuses (the "Transaction Bonuses") for certain of our executive officers in recognition of their efforts in connection with the completion of the sale of our lab products business to Eurobio on June 30, 2026 and our acquisition of Naveris on July 1, 2026. The Transaction Bonuses approved for our named executive officers are as follows:

- John W. Hanna, President and Chief Executive Officer: $750,000
- Keith Kennedy, Chief Operating Officer and Chief Financial Officer: $500,000
- Jessica Meng, Chief Commercial Officer: $125,000
- Jeffrey Novack, General Counsel and Secretary: $100,000

The Transaction Bonuses are expected to be paid on or about December 11, 2026, subject to the executive officer's continued employment with us through the payment date. The Transaction Bonuses were not granted pursuant to any plan adopted by us or our stockholders and are in addition to any annual cash incentive for which the executive officers are eligible with respect to fiscal year 2026.

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 of CareDx, Inc. effective December 12, 2025.
4.1(5)	Form of Registrant's common stock certificate.
10.1#*	Amendment No. 1 to the CareDx, Inc. 2025 Inducement Equity Incentive Plan.
31.1*	Certification of Periodic Report by Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Periodic Report by Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)
(1)	Incorporated by reference to Exhibit 3.1 to the Registrant's Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 28, 2014.
(2)	Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on June 21, 2021.
(3)	Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on June 20, 2023.
(4)	Incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed with the SEC on December 15, 2025.
(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.

CAREDX, INC.
(Registrant)

Date: October 29, 2026

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

By: /s/ KEITH KENNEDY
Keith Kennedy
Chief Operating Officer and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

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

I, 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: October 29, 2026

By: /s/ JOHN W. HANNA

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

Exhibit 31.2

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

I, Keith Kennedy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CareDx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 29, 2026

By: /s/ KEITH KENNEDY

Keith Kennedy
Chief Operating Officer and Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of CareDx, Inc. (the "Company") for the period ended September 30, 2026 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: October 29, 2026

By: /s/ KEITH KENNEDY
Keith Kennedy
Chief Operating Officer and Chief Financial Officer
(Principal Accounting and Financial Officer)
Date: October 29, 2026

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.