Table of Contents

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# Form 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2025**

**OR**

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

**For the transition period from _____ to _____**

**Commission File Number 001-36536**

# 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**
**Brisbane, California 94005**
**(Address of Principal Executive Offices, Including Zip Code)**

**(415) 287-2300**
**(Registrant's Telephone Number, Including Area Code)**

**Securities Registered Pursuant to Section 12(b) of the Act:**

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

**Securities Registered Pursuant to Section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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, a 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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

If securities are registered pursuant to Section 12(b) of the Exchange Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b) of the Exchange Act. ☐

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, as reported by the Nasdaq Global Market on such date was approximately $1.0 billion. Shares of the registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of the registrant's Common Stock outstanding as of February 19, 2026 was 51,216,344.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement relating to the 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement, or an amendment to this Annual Report on Form 10-K, will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2025.

## TABLE OF CONTENTS

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K refer to CareDx, Inc. and its subsidiaries.

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

- our ability to generate revenue and increase the commercial success of our current and future testing services, products and patient and digital solutions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for our current and other future testing services, if any;
- our plans and ability to continue updating our testing services, products and patient and digital solutions to maintain our leading position in transplantation;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us; 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" included in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission, or the SEC, as exhibits to this Annual Report on Form 10-K 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

## ITEM 1. BUSINESS

### Company Overview

CareDx is a precision medicine company dedicated to improving outcomes for transplant patients and advancing organ health. We deliver solutions designed to empower clinicians and improve patient outcomes. The Company's integrated solutions include non-invasive molecular testing for heart, kidney, and lung transplants; laboratory products; digital health technologies; and patient solutions that support care before and after transplant. CareDx is the leading provider of genomics-based information for transplant patients. Our headquarters is located in Brisbane, California, and we have other primary operations in Omaha, Nebraska and Stockholm, Sweden.

We were originally incorporated in Delaware in December 1998 under the name Hippocratic Engineering, Inc. In April 1999, we changed our name to BioCardia, Inc., and in June 2002, we changed our name to Expression Diagnostics, Inc. In July 2007, we changed our name to XDx, Inc. and in March 2014, we changed our name to CareDx, Inc. Our principal executive offices are located at 8000 Marina Boulevard, Brisbane, California and our telephone number is (415) 287-2300. As of December 31, 2025, substantially all of our revenues came from the United States and Europe, and substantially all of our assets and operations were located in the United States and Sweden.

We are organized and operate as a single reportable segment. Refer to Note 13, *Segment Reporting,* of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

### Our Differentiated Approach

We aim to create life-changing solutions that enable transplant patients to thrive. Over the past 25 years, we have made considerable investments, bringing to market a portfolio of solutions that have significantly impacted the lives of hundreds of thousands of transplant patients globally.

At CareDx, we are incredibly passionate about the care of transplant patients and are deeply connected to this market, the patients we help, and the clinicians we serve. However, we still have a tremendous opportunity to unlock growth and innovation by driving greater value for transplant patients, clinicians, our employees, and shareholders.

CareDx is differentiated in the molecular diagnostics market because we innovated the go-to-market model for a laboratory developed test (LDT) business. Many LDT genomic products, like other medical technologies, fail to achieve a significant rate of adoption because clinicians use the products selectively. The cost of switching to a new diagnostic provider is low for clinicians, making it difficult for molecular diagnostic companies to grow in competitive markets. That market dynamic makes the cost of revenue acquisition high, which, coupled with high research and development spend on new products, makes the pursuit of profitability challenging. In fact, very few LDT laboratory companies have reached cash flow break even or become profitable enterprises.

In contrast, we are taking the approach of serving a concentrated market of transplant centers with a portfolio of solutions to improve health outcomes. We believe solutions selling into the same transplant center increases the adoption and adherence to our diagnostic products and allows us to lower our revenue acquisition costs over time. As we launch new products, we can cross-sell them to the same center, gaining leverage on our commercial channel. We also deeply understand the operational needs of these organizations. Our teams across the country provide staff augmentation services inside transplant centers, helping them operate efficiently. Additionally, through our digital business, we generate multiple terabytes of data on how transplant centers operate, which we expect will drive the next wave of innovation for the company by enabling us to build new products and solutions to help transplant centers operate more efficiently, do more transplants, and grow profitably.

We believe that this combination - remaining focused on a concentrated number of transplant centers, lowering our cost of revenue acquisition by cross-selling more solutions into the same institutions, and gaining leverage on our commercial channel – forms a clear and differentiated formula for profitable growth in the molecular diagnostics market. This is how CareDx intends to differentiate itself from other molecular diagnostic companies and competitors in the field.

### Our Growth Strategy

CareDx has four strategic priorities: (1) accelerate profitable growth; (2) drive operational excellence; (3) define TRANSPLANT+ and expand our total addressable market; and (4) elevate performance culture.

#### *Accelerate Profitable Growth*

We plan to accelerate profitable growth by first focusing on solutions-selling at transplant centers, with the goal of increasing the acquisition of new patients and improving patient adherence to our testing protocols. Second, we intend to fully integrate

our digital and patient solutions and laboratory products teams into a single go-to-market model designed to deliver comprehensive solutions that drive loyalty and maximize customer value. Third, we intend to focus on generating clinical evidence to gain optimal payer coverage and reimbursement for our products leading to revenue per test (RPT) appreciation. Finally, we intend to execute on our existing research and development pipeline, with the goal of generating incremental revenues from both in-line and new products that provide solutions to unmet medical needs in transplantation.

***Drive Operational Excellence***

A key objective of our growth strategy is to drive operational excellence, including scaling our organization efficiently while delivering a superior customer experience. We believe that operational excellence is critical to achieving profitable growth and margin expansion. This approach includes continual process improvement and strategic investments in enterprise applications, remote process automation, artificial intelligence, and business intelligence tools, along with investments in data security, privacy and secure communications with our patients, providers and payer community.

***Define TRANSPLANT+ and expand our total addressable market***

There are many adjacencies to our core solid organ transplant business that we could enter to grow our total addressable market. We collectively refer to these opportunities as a key strategic initiative called TRANSPLANT+.

TRANSPLANT+ is an initiative to expand our market by recognizing a broader definition of transplant that we believe unlocks significant long-term growth potential. By focusing on this initiative, we aim to pave the way to develop novel solutions that lie at the intersection of transplantation and immunology. We believe leveraging our core scientific and technological expertise in organ transplantation will enable an expansion into adjacent markets, such as pre- and peri-transplant areas of organ assessment, precursor disease areas that often lead to organ failure (such as autoimmune disorders, renal, hepatic, cardiovascular and lung diseases, and hematologic disorders), and cancer or other medical conditions that could require cell therapy or bone marrow transplant.

***Elevate Performance Culture***

We recognize that our people are the driving force behind our success, and we cannot unlock our full growth potential without engaging and inspiring the employees that deliver value to our patients and customers.

**Our Products and Services**

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, and AlloSure® Lung, a dd-cfDNA solution for lung transplant patients. We have initiated several clinical studies to generate data on our existing and planned future testing services. 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 offer high-quality products in the pre-transplant space that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Additionally, we provide digital transplant solutions and various offerings that help transplant centers with workflow and list management, outcomes quality and patient medication adhearance. Our software solutions are currently used in over 170 transplant centers in the U.S.

We also offer specialized pharmacy services for transplant patients. The pharmacy helps patients and caregivers access lifesaving medications by managing complex medication regimens, addressing side effects, and navigating the billing process.

***Testing Services***

We develop and provide diagnostic testing services for solid organ transplant recipients, hematopoietic stem cell transplant recipients and recipients of cell therapies. During 2025, we performed approximately 200,000 commercial tests from our Brisbane, California laboratory.

The care of organ transplant recipients is an intense and costly effort and requires life-long surveillance and management by highly specialized clinicians and other healthcare providers. Unsuccessful management of organ rejection can result in an additional transplant or worse, death of the patient.

The historical standard for transplant surveillance has been through functional tests and with invasive biopsies to identify histopathological signs of rejection. Both types of testing had (and have) significant limitations:

- Functional tests are recognized to be late indicators. Rejection is well known to occur even in the absence of clinical signs or symptoms and damage may occur before organ function is impacted to the extent it is measurable by a functional test; and
- Biopsies are invasive and risk damage to the organ and infection from exposure to a medical setting for the procedure itself. They also present risk of mechanical problems, pain, and anxiety to the patient. These risks present an impediment to the usage of biopsies on a routine basis. In addition, biopsies may be difficult to access for patients in more rural settings distant from a transplant center where the procedure would be performed. Importantly, diagnostic precision of biopsies is limited by sampling issues and interobserver variability. Finally, the interpretation of a biopsy relies on descriptive, empirically driven consensus classifications that change over time and frequently lack an etiologic basis.

There is a growing body of evidence that traditional tools do not fully address the dynamic nature of transplant and that rejection begins before clinical signs and symptoms can be observed. Molecular rejection is an active, dynamic process and AlloSure and AlloMap provide clinicians with early indicators of injury, as well as information to risk stratify patients and prognostic insights beyond traditional tools used for surveillance like serum creatnine and Donor-Specific Antibodies (DSA).

Improved post-transplant diagnostics are necessary to achieve further gains in the long-term care and health outcomes of heart, kidney and other organ transplant recipients. More effective solutions for the surveillance and risk assessment of recipients would improve the clinician's ability to individualize immunosuppression therapy and to detect and treat rejection earlier when the treatment is most effective.

***AlloMap Heart***

Our first product launched in 2005, AlloMap Heart is an innovative gene expression profiling test that is intended to aid clinicians in identification of heart transplant recipients with stable graft function who have a low probability of moderate-to-severe acute cellular rejection at the time of testing in conjunction with standard clinical assessment.

We believe the use of AlloMap Heart, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant, can improve patient care by helping healthcare providers avoid the use of unnecessary invasive surveillance biopsies, and may help to determine the appropriate dosage levels of immunosuppressants by measuring activity of the immune system. AlloMap Heart has 510(k) clearance from the U.S. Food and Drug Administration for marketing and sales as a test in heart transplant recipients who have stable graft function at the time of testing, to aid in the identification of those who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment.

***AlloSure Heart***

AlloSure Heart, our donor-derived cell-free DNA (dd-cfDNA) heart transplant solution, is a molecular diagnostic test intended for the early detection of heart allograft injury and rejection. AlloSure Heart helps provide peace-of-mind that injury is unlikely when dd-cfDNA levels are low. AlloSure Heart is validated to detect all types of clinical rejection, including antibody mediated rejection (AMR) and acute cellular mediated rejection (ACR).

AlloSure Heart was developed specifically for transplant patients and is a non-invasive blood test that analyzes Single Nucleotide Polymorphisms (SNPs) selected across all 22 somatic chromosomes to detect DNA released from a patient's heart allograft, known as dd-cfDNA.

A 2025 Surveillance HeartCare Outcomes Registry (SHORE) analysis published in JACC stated that heart failure established the largest prospective dataset on antibody-mediated rejection in heart transplantation and validated AlloSure Heart as a highly specific biomarker for AMR, enabling more precise, context-driven clinical decision-making.

***HeartCare***

HeartCare combines the gene expression profiling technology of AlloMap Heart with the dd-cfDNA technology of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap Heart – a measure of immune system status, and (ii) AlloSure Heart – a measure of graft injury. Each HeartCare test provides our proprietary Personalized Risk Report, combining measures of immune activation and graft injury for more precise risk assessment. The intersection of immune activation and graft injury reveals risk strata not seen with either test alone.

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, acute cellular rejection and antibody mediated rejection.

The International Society for Heart and Lung Transplantation, or ISHLT guidelines published online in 2022 reinforced the use of AlloMap Heart and referenced the combined use of AlloSure Heart and AlloMap Heart for surveillance purposes.

The SHORE is a landmark multicenter registry in heart transplant that has monitored over 2,700 transplant patients across 67 transplant centers in the United States since 2018. Our SHORE 3 publication demonstrates that HeartCare helps identify higher-risk patients more precisely than histology or dd-cfDNA alone.

A 2025 SHORE analysis published in the Journal of Heart and Lung Transplantation showed that positive HeartCare results—elevated AlloMap and AlloSure Heart—identified heart transplant recipients at significantly higher risk for graft dysfunction and cardiovascular death, even when biopsy results appeared normal. This analysis showed that patients with AlloMap (+) and AlloSure (+) positive results are approximately 6x more likely to have biopsy-confirmed ACR and approximately 2x more likely to experience poor outcomes than patients with AlloMap (-) and AlloSure (-) negative results.

In 2025, HeartCare expanded its indication to cover pediatric patients of all ages starting at birth.

***AlloSure Kidney***

AlloSure Kidney, our kidney transplant solution, is a molecular diagnostic test intended for the early detection of kidney allograft injury and rejection. AlloSure Kidney is validated to detect all types of clinical rejection including antibody mediated rejection (ABMR) and T-cell mediated rejection (TCMR). As published in Nature Medicine, AlloSure is a robust predictor of severity of rejection, with multiple thresholds enabling more precise risk assessment (low risk of rejection, likely graft injury and high risk of rejection). AlloSure testing is reported as a continuous score, and our relative change value (RCV) compares sequential tests to identify the percentage difference between them; RCV provides further risk stratification for patients whose levels are between 0.5% and 1.0%, and an RCV of ≥ 61% suggests rejection may be occurring.

AlloSure Kidney was developed specifically for transplant patients and is a non-invasive blood test that analyzes SNPs selected across all 22 somatic chromosomes to detect DNA released from a patient's kidney allograft, known as dd-cfDNA. AlloSure may identify patients who do not fit the criteria for AMR but may have significant underlying injury, and AlloSure Kidney is currently the only test proven to help identify patients with microvascular inflammation (MVI) who have DSA-negative and C4d-negative. MVI, DSA-negative and C4d-negative, has been recognized as a distinct rejection phenotype according to the Banff 2022 Classification, and is associated with a significant risk of graft failure.

A landmark 2025 study published in the American Journal of Transplantation demonstrated that AlloSure is a clinically actionable tool for kidney transplant surveillance that strongly predicted rejection, improved biopsy yield, and enabled earlier, more precise intervention.

AlloSure Plus is an artificial intelligence-driven diagnostic platform that integrates AlloSure® dd-cfDNA analysis with additional clinical inputs to provide a personalized assessment related to organ rejection risk in transplant recipients. AlloSure Plus is intended to support post-transplant surveillance and clinical evaluation in solid organ transplant patients.

In July 2025, we announced the presentation of multiple independent studies at the 2025 World Transplant Congress evaluating AlloSure Plus across solid organ transplant settings. These presentations included data from an international, prospective study led by the Paris Transplant Group that evaluated AlloSure Plus in renal transplant recipients using biopsy-correlated data.

***HistoMap Kidney***

HistoMap Kidney, our tissue-based molecular solution intended to identify allograft rejection and type of rejection in kidney transplant biopsy tissue. HistoMap Kidney uses gene expression profiling to characterize immune activity and rejection phenotypes, and is designed to complement histopathology by providing molecular information to enhance the clinical interpretation of biopsy results.

Biopsy is the standard of care for kidney transplant patients suspected of rejection, including patients identified through molecular surveillance methods such as AlloSure® Kidney or through clinical signs and symptoms of rejection. HistoMap Kidney is being developed for use on formalin-fixed kidney biopsy tissue to support rejection identification and typing, which may assist clinicians in clinical decision-making and therapy selection.

In 2023, a HistoMap validation study was published in the journal *Laboratory Investigation*, demonstrating its ability to accurately identify rejection and type as antibody mediated rejection, cellular rejection, mixed rejection, or no rejection.

***AlloSure Lung***

AlloSure Lung, our solution for lung transplant patients, is a leading indicator of injury and early rejection identification. AlloSure Lung may help guide physicians as to whether bronchoscopy and biopsy may be necessary. AlloSure Lung helps provide peace-of-mind that injury is unlikely when dd-cfDNA levels are low.

In April 2022, a multicenter study of 175 patients published in the Journal of Heart and Lung Transplantation demonstrated that AlloSure Lung reduced surveillance bronchoscopies by 82%, and that AlloSure Lung can identify subclinical acute lung allograft dysfunction in stable patients without clinical signs and symptoms.

AlloSure Lung was developed specifically for transplant patients and is a non-invasive blood test that analyzes SNPs selected across all 22 somatic chromosomes to detect DNA released from a patient's lung allograft, known as dd-cfDNA.

***AlloHeme***

AlloHeme™ is a minimally-invasive, next-generation sequencing (NGS)–based, and artificial intelligence-powered monitoring test designed to predict relapse in patients with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) following allogeneic hematopoietic cell transplant (HCT). AlloHeme is intended to enable the detection of emerging relapse signals earlier than traditional bone marrow-based or marker-specific methods through a universal, ultra-sensitive, blood-based surveillance approach.

The Assessing Chimerism and Relapse of Bone Marrow/HCT Transplant Using AlloHeme Testing (ACROBAT) study (NCT04635384) is a prospective, multi-center, observational trial conducted across U.S. transplant centers to evaluate the clinical performance of AlloHeme in patients following allogeneic HCT. The study generated pivotal clinical validation data presented at the Tandem Meeting in 2025, supporting the potential clinical value of AlloHeme in post-transplant relapse surveillance.

***AlloCell***

AlloCell, our solution for cell therapy such as CAR-T therapy, monitors the pharmacokinetics of engraftment and persistence of cells for patients who have received allogeneic cell therapy. AlloCell is currently being utilized in research partnerships with biopharma companies developing cell therapies. To date, we have executed multiple agreements with biopharma therapeutics companies to use AlloCell in research and clinical studies.

***Laboratory Products***

We access global markets through our RUO and CE-marked lab products. We develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a solid organ or stem cell donor and a recipient, and help provide post-transplant surveillance. Our laboratory product portfolio includes QTYPE, Olerup SSP and SBT, AlloSeq Tx, AlloSeq HCT, and AlloSeq cfDNA.

A 2025 study published in the American Journal of Transplantation showed that AlloSeq cfDNA delivered highly accurate detection of allograft injury and rejection across multiple organ types, demonstrating strong correlation with biopsy-proven rejection and supporting its use as a reliable, non-invasive surveillance tool.

***Distributed PCR Kits for HLA Typing***

QTYPE enables Human Leukocyte Antigen, or HLA, typing at a low to intermediate resolution for samples that require a fast turnaround time and uses real-time polymerase chain reaction, or PCR, methodology. QTYPE primarily focuses on typing where rapid typing results are required, such as for deceased donor typing. Typing with QTYPE requires one hour compared to the up to 2-3 hours that it takes to do traditional sequence specific primer, or SSP, typing and the 5-7 hours that it takes with sequence-specific oligonucleotides, or SSO.

Olerup SSP is used to type HLA alleles based on the SSP technology. The Olerup SSP product line comprises products for low to high-resolution HLA typing. The product line includes close to 170 different typing products. We offer one of the most up-to-date and comprehensive libraries of HLA typing kits based on SSP technology.

***Distributed NGS Kits for HLA Typing and Transplant Monitoring***

Our distributed NGS products include: AlloSeq Tx, a high-resolution HLA typing solution; AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect injury and active rejection in transplant recipients; and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients.

AlloSeq Tx is the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than other solutions on the market as well as non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx17 received CE mark authorization in May 2020. AlloSeq Tx9 is a high throughput version of AlloSeq Tx17 for HLA typing in high volume laboratories. AlloSeq Tx9 received CE mark authorization in August 2022.

We received CE mark authorization for AlloSeq cfDNA in January 2020. Further clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including product-specific evidence publications, local clinical education, customer laboratory technical proficiency, and levels of country-specific reimbursement.

AlloSeq HCT is an NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market. AlloSeq HCT received CE mark authorization in May 2022.

***Patient and Digital Solutions***

We deliver an ecosystem of tailored transplant management solutions designed to help centers grow volume, improve patient outcomes, drive efficiency and ease staff workload through: smarter referral management; personalized patient adherence and monitoring; streamlined operational workflows; quality insights and clinical intelligence; and supporting patients, clinicians, and centers across the entire transplant journey.

Workflow Solutions:

Our Ottr software consists of two unique offerings, Ottr Organ and Ottr Cellular, which provide comprehensive solutions for transplant patient management and enable integration with electronic medical records, or EMR, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

Referral Management:

TxAccess is a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs and closely follow and assist patients through the transplant waitlist process, and ultimately through transplantation.

Quality Solutions:

Our XynQAPI software simplifies transplant quality tracking and Scientific Registry of Transplant Recipients reporting, and our XynCare offering includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility. In 2025, we launched an IOTA module, or Increasing Organ Transplant Access, which represents an enhanced XynQAPI and is designed to project the center's performance based on the latest IOTA criteria.

Patient Adherence and Monitoring:

MedActionPlan helps centers address medication adherence challenges that increase graft-loss risk by targeting common barriers with patient-friendly, personalized medication management and education tools to help support better patient adherence.

Our CareDx pharmacy supports patients' medication management with expert transplant pharmacists with specialized knowledge who support patient adherence through dedicated care teams, proactive refill support and personalized, and dosed packaging.

AlloHome is a remote patient monitoring solution designed to drive patient engagement and timely interventions for patients pre- and post-transplant.

Lab Products Solutions:

Our HLA Data Systems software solutions, which include mTilda, VxMatch and VECTR, provide software and interoperability solutions for the histocompatibility and immunogenetics community.

**Reimbursement**

We have been successful in achieving reimbursement for our testing services.

Medicare

We are reimbursed by Medicare for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung tests. Tests performed on patients covered by Medicare represented 25%, 26% and 27% of all tests in 2025, 2024 and 2023,

respectively. Approximately 46%, 50% and 53% of all testing services revenue was derived from Medicare for the years ended December 31, 2025, 2024 and 2023, respectively.

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 (MAC), or Noridian. The Medicare reimbursement rate for AlloSure Kidney is $2,753, effective January 1, 2026.

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would have revised the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 16, 2024, the Centers for Medicare and Medicaid Services, or 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 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.

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On December 30, 2024, we received a CPT code (0540U) for our AlloSure tests: AlloSure Kidney, AlloSure Heart and AlloSure Lung, which subjects such tests to a repricing process. In June 2025, we recommended that CMS cross-walk our AlloSure tests to 0493U, another dd-cfDNA test already priced on the Medicare Fee Schedule at $2,753. On November 25, 2025 CMS issued a final determination to cross-walk AlloSure (0540U) to CPT code 0493U. The new reimbursement rate represents an $88 decrease to the previous pricing for our AlloSure Kidney test, and no change to the current pricing for AlloSure Heart and AlloSure Lung tests. AlloSure, PLA Code 0540U, was listed on the Clinical Laboratory Fee Schedule effective January 1, 2026 at approximately $2,753.

On July 17, 2025, MolDX and Noridian released a new Proposed Draft foundational LCD (DL40058, DL40060) for Solid Organ Allograft Rejection testing with a revised accompanying billing article (DA60146, DA60152). The Proposed LCD introduced new coverage criteria, utilization limitations, and a new bundled payment concept for certain CareDx testing in a “surveillance” setting, which could lead to fewer surveillance tests being reimbursed. MolDX and Noridian have 365 days from the date of issuance to finalize the Proposed LCD. We cannot predict the ultimate outcome of the LCD process, including as it relates to the Draft LCD, and whether it will produce changes in coverage, reimbursement practices, utilization limitations, or payment amounts, any of which could adversely affect our business, operating results and prospects.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently $3,240.

AlloSure Heart has been a covered service for Medicare beneficiaries since December 2020. In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MolDX to replace the former product-specific policies. The common policy LCD is titled “MolDX: Molecular Testing for Solid Organ Allograft Rejection” and the associated LCD numbers are L38568 (MolDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently $2,753.

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

Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the MolDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is $2,753.

Private Payers and Medicaid Payers

Due to End Stage Renal Disease, or ESRD, regulations by Medicare, most ESRD patients are covered by Medicare and Medicare Advantage plans and have access to AlloSure Kidney. Private payers that have adopted a positive coverage policy include BCBS payers as well as other regional payers. Most Medicaid payers have not yet adopted positive coverage policies for AlloSure Kidney.

AlloSure Heart and AlloSure Lung are covered by Medicare Advantage plans for beneficiaries who meet the coverage criteria. AlloSure Heart and AlloSure Lung are covered by several commercial payers.

We are reimbursed for a substantial portion of the AlloMap Heart tests we perform on patients covered by private payers. Coverage policies approving AlloMap Heart have approached nearly 90% of all covered lives and are published by many of the largest private payers, including Blue Cross Blue Shield, or BCBS payers as well as national payers and by more than half of the state Medicaid agencies in the U.S.

For all tests performed outside the scope of the payer's policy, and for tests performed where the payer has not adopted a coverage policy, we pursue reimbursement on a case-by-case basis. If a reimbursement claim is denied, we generally pursue payment through the particular payer's appeal process.

**Testing Services Laboratory Operations**

AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung testing is performed in our clinical laboratory, which is located in our Brisbane, California location. Our laboratory holds a certificate of accreditation under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and is accredited by the College of American Pathologists, or CAP. We believe that our laboratory capacity will be adequate to meet demand for AlloSure Kidney, AlloMap Heart and AlloSure Heart, HeartCare and AlloSure Lung and other tests in the development pipeline for the next few years.

There are two types of samples received at the laboratory. When AlloSure Kidney, AlloSure Heart or AlloSure Lung is ordered by a clinician, a blood sample is drawn and sent overnight to our laboratory. When a clinician orders AlloMap Heart, a blood sample is drawn, processed, and then sent via overnight courier to our laboratory. Regardless of the test requested, the test results are typically reported to the ordering clinician within two business days from receipt of the sample. Test samples that fail to meet quality control criteria and have enough remaining material are re-tested on the next available batch of samples, which may extend the turnaround time.

We rely solely on certain suppliers to provide some of the laboratory instruments and key reagents that we use to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung testing. These sole source suppliers include Thermo Fisher Scientific, Inc., or Thermo Fisher, which supplies us with instruments, laboratory reagents and consumables; Roche Molecular Systems, which supplies us with laboratory reagents and consumables; Hamilton Robotics, which supplies equipment and consumables; 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 equipment, reagents and consumables; and Qiagen N.V., which supplies us with a proprietary buffer reagent.

**Laboratory Products Manufacturing**

We have historically purchased many of the components and raw materials used in our product kits from numerous suppliers worldwide. For reasons of quality assurance, sole source availability or cost effectiveness, certain components and critical raw materials used in the manufacture of our products are available only from one supplier. We have worked closely with our suppliers to develop alternate backup plans to ensure continuity of supply while maintaining high quality and reliability, and in some cases, we have established long-term supply contracts with our suppliers. Due to the high standards and ISO/FDA requirements applicable to the manufacturing of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials.

In the event that we are unable to obtain sufficient quantities of raw materials or components on commercially reasonable terms or in a timely manner, our ability to manufacture our products on a timely and cost-competitive basis may be compromised, which may have a material adverse effect on our business, financial condition and results of operations.

Our manufacturing facility in Stockholm, Sweden is used to support the production, packaging and labeling of our proprietary test kits: Olerup SSP, QTYPE, AlloSeq Tx, AlloSeq cfDNA and HCT. The facility has a certified Quality Management System, or QMS, to the ISO 13485: 2016 standard and country specific MDSAP requirements. This standard includes a special set of requirements specifically related to the supply of medical devices and related services. ISO is an internationally recognized standard for QMS. Recertification is required every three years and we have been successfully recertified since obtaining our original ISO certification. The facility maintains valid EC certificates for compliance to Directive 98/79/EC Annex IV, excluding Sections 4 and 6, Full Quality Assurance System In Vitro Diagnostic Medical Devices and to IVDR (EU) 2017/746 under Annex IX Chapters I and III. Annual surveillance audits are also conducted by the site's notified body to ensure ongoing compliance.

In 2023, we added contract manufacturing in the U.S. and Europe to our global manufacturing capabilities to support our growth.

Additionally, we seek to manufacture to current Good Manufacturing Practice requirements and our QMS is implemented in accordance with FDA Quality System Regulations.

Our manufacturing facility in Fremantle, Australia, was used to support the production, packaging and labeling of our proprietary AlloSeq brand kits. In 2024, we decided to migrate manufacturing from Australia to the U.S. and Europe.

**Sales and Marketing**

We have organized our commercial sales and marketing teams to be customer-centric in a functional structure that is intended to unlock the potential of our synergistic portfolio of solutions and deliver the best experience for clinicians, patients, and administrators.

In the U.S., the organization and delivery of healthcare, including for transplantation, is highly local. To first and foremost empower local teams to devise effective tactical strategies for selling our solutions into each transplant center, we have created a regional structure. Each region consists of multiple territory account managers responsible for specific transplant centers. Each region is also supported by the dedicated expertise of individuals that specialize in our digital products, laboratory products, and clinical experts in medical science liaisons.

Outside of the U.S. we similarly have regional structure that includes country managers in Western Europe, and distributors we work with outside of Western Europe to service the needs of our transplant center customers globally.

**Competition**

With our comprehensive portfolio of surveillance testing services, diagnostic products and patient and digital solutions business offerings, we face different types of competition.

Testing Services

Our competition principally includes clinical reference laboratories and hospital laboratories using existing and routine clinical chemistry tests and biopsies. 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, Inc., or Natera, and Eurofins Transplant Genomics, Inc., or Eurofins, Devyser Diagnostics AB, or Devyser, and Insight Molecular Diagnostics, Inc, or iMDx, have commercially available molecular diagnostics tests.

We expect the competition for post-transplant surveillance to increase as there are several established and early-stage companies in the process of developing products and services for the transplant market that may directly or indirectly compete with AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, or our development pipeline. In addition, companies that have not historically focused on transplantation, but have knowledge of dd-cfDNA technology, have indicated they are considering this market.

We believe the principal competitive factors in our target markets include:

- quality and strength of clinical and analytical validation data;
- confidence in diagnostic results;
- technical performance and innovation to deliver new products that provide clinically actionable results;
- reputation among customers as a provider of high value transplant diagnostic tests and diagnostic test services;
- the extent of reimbursement;
- inclusion in practice guidelines;

- cost-effectiveness; and
- ease of use.

We believe we compete favorably on the factors described above.

Existing diagnostic methods for kidney transplant rejection include general, non-specific clinical chemistry tests, although biopsies are also a surveillance diagnostic tool. Existing diagnostic methods for heart transplant rejection generally involve evaluating biopsy samples to determine the presence or absence of rejection.

These practices have 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 tests to change clinical practice. Also, many transplant centers are located within hospitals that have their own laboratory facilities and have capacity to conduct various tests, and some hospitals may choose to rely on internally developed and/or internally performed surveillance and diagnostic tests.

Products

Our competitors within the HLA tissue typing markets comprise a diverse range of manufacturers servicing hospital and commercial reference testing laboratories. The market leader in HLA typing and third-party distributors is Thermo Fisher through its One Lambda business. In certain HLA tissue typing markets that incorporate a wide variety of technology test platforms, such as SSP, SSO and NGS, competitors include: Thermo Fisher, Omixon, GenDx, BAG, Qiagen, and Immucor. We also face competition from hospital and commercial reference laboratories that develop their own in-house testing solutions. We believe that our product line competes favorably with Thermo Fisher as a leading supplier of HLA test kits based on performance, reputation and service.

We expect future competition for post-transplant surveillance kitted solutions for AlloSeq cfDNA and AlloSeq HCT. There are several established and early-stage companies in the process of developing products and services for the transplant market that may directly or indirectly compete with our development pipeline. In addition, companies that have not historically focused on transplantation, but have knowledge of dd-cfDNA technology, have indicated they are considering the transplantation market.

Patient and Digital Solutions

Competition for our digital solutions includes various companies that develop application software and operate in the healthcare field. Our primary competitor for our patient management EMR solution is Phoenix, Epic's transplant application. Our referral application has two known competitors: T-REX and MedSleuth. 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. Competition for patient pharmacy solutions includes hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services.

**Intellectual Property**

Patents and Proprietary Technology

To remain competitive, we seek to develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, material and data transfer agreements and licenses to protect our intellectual property rights. We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We generally protect this information with confidentiality agreements and reasonable security measures.

As of December 31, 2025, we had seven 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.

We have developed trade secrets and know-how since our inception. These trade secrets and know-how are found particularly in technical areas such as optimized systems for making precise and reproducible q-PCR, measurements, and in the analysis of genomic data and algorithm development.

AlloMap, AlloSure, AlloSeq, AlloCell, AlloHeme, QTYPE, Ottr and CareDx are registered trademarks of ours in the United States.

License Agreements

We may in the future rely, at least in part, upon licensing agreements with third parties to obtain patent rights and transfers of technology, information and know-how that enable us to further our development of additional solutions for post-transplant surveillance. Of the seven existing U.S. patents related to transplant rejection and autoimmunity, four are exclusively licensed.

In May 2018, we entered into a license and commercialization agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's next generation sequencing product line for use in transplantation diagnostic testing. Six issued U.S. patents for HLA genotyping are licensed as part of this agreement.

In April 2020, we entered into a license agreement with Cornell University pursuant to which we were granted exclusive rights to four U.S. patents covering methods and technology for the 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 integrate AlloSure testing 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 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.

**Regulation**

Our business is subject to and impacted by frequently changing laws and regulations in the United States and internationally. These laws and regulations include regulations particular to our business and laws and regulations relating to conducting business generally (e.g., U.S. Foreign Corrupt Practices Act, Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and similar laws of other jurisdictions). We also are subject to inspections and audits by governmental agencies. Below are certain key regulations applicable to our business.

Clinical Laboratory Improvement Amendments of 1988

Having a clinical laboratory in California, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under the CLIA, administered by the Centers for Medical and Medicaid Services (CMS), we are required to hold a certificate applicable to the type of work we perform and to comply with standards covering personnel, facilities administration, quality systems, proficiency testing and performance. Most clinical laboratories are subject to regulation under the CLIA, which is designed to ensure that laboratory testing services performed on materials derived from the human body are accurate and reliable.

We have a certificate of accreditation under the CLIA to perform "high complexity" testing. Laboratories performing high complexity testing are required to meet more stringent personnel and quality system requirements than laboratories performing less complex tests. To renew our CLIA certificate, we are subject to inspection every two years to assess compliance with program standards. We were inspected as part of the customary College of American Pathologists audit and recertified in 2024 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2026.

California Laboratory Licensing

In addition to federal certification requirements of laboratories under the CLIA, licensure is required and maintained for our laboratory under California law. Such laws establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory. We are required to maintain compliance with California standards as a condition to continue operation of our laboratory in California.

Other States' Laboratory Testing

Other states require out-of-state laboratories that accept specimens for testing from those states to be licensed. We have obtained licenses in California, Florida, New York, Maryland, Pennsylvania and Rhode Island, and believe we are in compliance with applicable licensing laws.

Food and Drug Administration

The FDA regulates the design, testing, development, manufacture, safety, labeling, marketing, promotion, storage, sale and distribution of medical devices pursuant to its authority under the Federal Food, Drug and Cosmetic Act, or FFDCA. These

regulations apply to all of our products sold in the United States, as well as our facilities in Stockholm, Sweden, used to produce some of our products. The FDA has also asserted that it has the authority to regulate laboratory-developed tests, or LDTs, as medical devices under the FFDCA. An LDT is a test developed by a single laboratory for use only in that laboratory, such as our testing services, AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung.

The FDA has traditionally chosen not to exercise its authority to regulate LDTs because it regulates the primary components in most laboratory-developed tests and because laboratories, such as ours, certified as high complexity under the CLIA are regulated and reviewed by CMS to ensure that laboratory expertise and test procedures and correct analyses are followed.

In April 2025, the U.S. District Court for the Eastern District of Texas vacated the FDA's 2024 final rule under which the FDA intended to provide greater oversight of LDTs. In connection with this, the FDA proposed a rule that would amend its regulations to classify vitro diagnostic products as "medical devices" under the Federal Food, Drug and Cosmetic Act. The Court 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 limiting the FDA's authority over our testing services.

Health Insurance Portability and Accountability Act

Under the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, collectively, HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information, or PHI, and standardize data content, codes and formats used in healthcare transactions and the standardized identifiers used by healthcare providers, such as us, and health plans.

We have developed policies and procedures in view of these regulations. The requirements under these regulations may change periodically and could have an effect on our business operations if compliance becomes substantially more costly than under current requirements, business practices change or a significant breach to PHI occurs.

In addition to federal privacy regulations, there are a number of state laws governing the confidentiality of health information that are applicable to our operations. New laws governing privacy may be adopted in the future as well. We have taken steps intended to address health information privacy requirements to which we are aware that we are subject.

Whether regulators may find our policies, procedures and other privacy initiatives to be compliant with HIPAA is subject to the regulator's assessment.

Federal and State Self-Referral Prohibitions

We are subject to the federal self-referral prohibitions, commonly known as the Stark Law, and to similar state restrictions such as California's Physician Ownership and Referral Act, or PORA. Where applicable, these restrictions generally prohibit us from billing patients or certain governmental or private payers for clinical laboratory testing services when the physician ordering the test, or any member of such physician's immediate family, has an investment interest in, or compensation arrangement with, us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and PORA contain exceptions for compensation paid to a physician for personal services rendered by the physician, provided that certain conditions are satisfied. We have compensation arrangements with a number of physicians for personal services, such as speaking engagements and clinical advisory boards. We have structured these arrangements with terms intended to address the requirements of the applicable exceptions to the Stark Law, PORA and other similar state laws. However, we cannot be certain that regulators would find these arrangements to be in compliance with the Stark Law, PORA or similar state laws.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law.

Federal and State Fraud, Abuse and Privacy Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal healthcare programs and across the healthcare system. Our business is subject to compliance with these laws.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or collectively, the Affordable Care Act, was enacted in the United States. The Affordable Care Act expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the Anti-Kickback Statute and the False Claims Act, to make it easier to bring a suit under these statutes. The Affordable Care Act also allocates additional resources and tools for the government to police healthcare fraud, with

expanded subpoena power for HHS, additional funding to investigate fraud and abuse across the healthcare system and expanded use of recovery audit contractors for enforcement.

There have previously been public announcements by President Trump and members of the U.S. Congress regarding their plans to repeal and replace the Affordable Care Act. We cannot predict whether future healthcare initiatives, including at the federal level, will be initiated or the effect any such initiatives could have on our business, financial condition or results of operations.

*The Eliminating Kickbacks in Recovery Act of 2018*

The Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal healthcare programs to include private insurance (i.e., it is an "all payer" statute). For purposes of EKRA, the term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to $200,000, up to 10 years in prison, or both, per violation. The law includes a limited number of exceptions, some of which closely align with corresponding Anti-Kickback Statute exceptions and safe harbors and others that materially differ.

*Information Blocking Prohibition*

On May 1, 2020, the Office of the National Coordinator for Health Information Technology promulgated final regulations under the authority of the 21st Century Cures Act to impose new conditions to obtain and maintain certification of certified health information technology and prohibit certain covered actors—developers of certified health information technology, health information networks / health information exchanges, and healthcare providers (including laboratories)—from engaging in activities that are likely to interfere with the access, exchange or use of electronic health information (information blocking). The final regulations further defined exceptions for activities that are permissible, even though they may have the effect of interfering with the access, exchange or use of electronic health information. Originally, the Office of the National Coordinator for Health Information Technology established an information blocking effective date of November 2, 2020; however, the agency subsequently issued an interim final rule to extend the effective date to April 5, 2021. Under the 21st Century Cures Act, healthcare providers that violate the information blocking prohibition will be subject to appropriate disincentives, which the U.S. Department of Health and Human Services has yet to establish through required rulemaking. Developers of certified information technology and health information networks / health information exchanges, however, may be subject to civil monetary penalties of up to $1 million per violation. The U.S. Department of Health and Human Services Office of Inspector General has the authority to impose such penalties and the final rule relating to such developers went into effect in August 2023. The U.S. Department of Health and Human Services Office of Inspector General began investigating health care providers for information blocking beginning on July 31, 2024, and declared it would exercise its enforcement discretion in relation to any determinations regarding conduct that occurred prior to July 31, 2024.

*Anti-Kickback Statutes*

The federal healthcare programs' Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual for the furnishing of or arranging for the furnishing of any good or service, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid, or the purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item payable under such programs.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute to mean that if any one purpose of remuneration is to induce or reward referrals of federal healthcare program payable business, the statute has been violated. The statute contains a number of statutory exceptions and the U.S. Department of Health and Human Services has created several regulatory "safe harbors." Arrangements that meet all of the conditions of an applicable exception or safe harbor are protected from liability under the Anti-Kickback Statute. However, the failure to fit an arrangement within an exception or a safe harbor does not necessarily mean that the statute has been violated or that the arrangement will be prosecuted. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Violations of the Anti-Kickback Statute are also actionable under the federal False Claims Act.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to items or services reimbursed by any third-party payer, including commercial insurers.

*Federal False Claims Act*

The federal False Claims Act, which includes "whistleblower" or "qui tam" provisions, imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by the federal government. The qui tam provisions of the federal False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the federal False Claims Act and to share in any monetary recovery.

In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the federal False Claims Act, and many of these state laws apply where a claim is submitted to any third-party payer and not merely the federal government.

The federal government has used the False Claims Act to assert liability on the basis of, among other things, causing physicians to order excessive or unnecessary services, providing false documentation in support of claims, kickbacks, off-label promotion of products, and Stark Law violations and other improper referrals, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. Our future activities relating to billing, compliance with certain regulations and Medicare reimbursement requirements, physician and other healthcare provider financial relationships and the sale and marketing of our products may be subject to scrutiny under these laws.

*State Privacy Laws*

U.S. state comprehensive consumer privacy laws, such as the California Consumer Privacy Act, or the CCPA, secure privacy rights for consumers and impose obligations on us, including providing specific disclosures in privacy notices and affording consumers with certain rights concerning their personal data. Over a third of U.S. states have similarly adopted comprehensive consumer privacy laws and similar laws are being considered in several other states, as well as at the federal and local levels.

Our business or financial results may be adversely impacted by adhering to these regulatory requirements and the related costs of ensuring and maintaining compliance. In addition, we cannot predict how future regulatory conditions will affect our business and may also have an adverse impact on our results of operations or financial condition.

Our business or financial results may be adversely impacted by adhering to these regulatory requirements and the related costs of ensuring and maintaining compliance. In addition, we cannot predict how future regulatory conditions will affect our business and may also have an adverse impact on our results of operations or financial condition.

Foreign Jurisdictions

Laws and regulations outside of the United States also apply to our products. We currently produce products, which are CE labeled and subject to the In Vitro Diagnostic Medical Devices Directive (98/79/EC), or IVDD, a European Union, or EU, directive. Some of our products are currently labeled by self-declaration based on their intended use or certified by a Notified Body for Compliance to the IVDD requirements. A product that is not CE marked is automatically considered to be non-compliant. Appointed national enforcement agencies monitor the market for violations and imported products are checked for compliance at customs offices.

No in vitro device or accessory may be placed on the market or put into service unless it satisfies the essential requirements set forth in the IVDD. Devices considered to meet the essential requirements must bear the CE marking of conformity, placed by the manufacturer, when introduced to the market. A manufacturer placing devices on the market in its name must notify its national competent authorities.

These CE-labeled products are also falling under the requirements of the In Vitro Diagnostic Regulation (2017/746) (IVDR). The IVDR requirements were applied starting May 26, 2022. The European Commission recently confirmed adoption of a proposal for a progressive rollout of the IVDR to prevent disruption in the supply of in vitro diagnostic products to the market. The proposal does not change any requirements of the IVDR or the implementation date but changes the transitional provisions to allow a progressive rollout based on the risk level of the device.

In accordance with these timelines, our current CE-marked products will remain available to customers throughout the transition period. There is currently no anticipated supply risk based on the implementation of the IVDR in May 2022. The certification for our products under the IVDR is in progress with our notified body and certification of these products to the IVDR shall be achieved within the transition timeframes. We also worked with our notified body to bring the quality management system at the sites to be compliant with IVDR requirements.

Certain of our products also comply with the CMDCAS, which is a system designed to implement Canadian regulations requiring some medical devices be designed and manufactured under a registered QMS. The SCC and Health Canada's Therapeutic Products Directorate developed this system. CMDCAS came into effect January 1, 2003.

*GDPR and UK GDPR*

The General Data Protection Regulation (EU) 2016/679, or the GDPR, is a regulation on data protection and privacy in the EU, and the European Economic Area, or the EEA. It also addresses the transfer of personal data outside the EU and EEA. The regulation contains provisions and requirements related to the processing of personal data of individuals, or data subjects, who reside in the EEA, and applies to any enterprise—regardless of its location—that is processing the personal data of data subjects inside the EEA. The UK GDPR imposes similar requirements for personal data about United Kingdom, or UK, data subjects.

Controllers and processors of EEA and UK personal data must have a legal basis to process personal data and put in place appropriate technical and organizational measures to implement the data protection principles. Business processes that handle personal data must be designed and built with consideration of the GDPR and UK GDPR principles and provide safeguards to protect personal data. Data controllers and processors must design information systems with privacy in mind.

Violators of the GDPR or UK GDPR may be fined up to €20 million (£17.5 million in the UK) or up to 4% of the annual worldwide turnover of the preceding financial year, whichever is greater.

Our business or financial results may be adversely impacted by adhering to these regulatory requirements and the related costs of ensuring and maintaining compliance.

**Employees and Human Capital Resources**

On December 31, 2025, we had 765 employees, of which 761 were full-time employees. We had 145 employees in manufacturing operations and support, 186 in research and development, 252 in sales and marketing and 182 in general and administrative positions. As of December 31, 2025, 706 employees were located in the U.S. and 59 were located outside of the U.S.

The diagnostics industry is characterized by rapid product development and technological advances, which require an adept and skilled workforce. We believe that it is critical to attract, develop and retain employees with the experience, knowledge, expertise and vision capable of not only operating, but also excelling, in this complex and competitive business environment, including competing against larger competitors and developing and commercializing new products, new and improved technologies and new applications for our existing technologies.

We consider our employees to be our greatest asset and therefore focus on attracting, developing, retaining and motivating our employees. Our recruitment and retention strategies include partnerships with external agencies to help hire top talent, onboarding processes, a leadership development program and a professional work environment that promotes innovation and rewards performance.

We believe employee career development is an investment in our employees' skills and our future. We offer our employees various training opportunities free of charge and during working hours. For example, we use the LinkedIn Learning platform, a learning library and repository for self-guided personal and professional learning opportunities for our employees.

In addition, we believe it is important to have regular engagement with our employees to understand their needs. Apart from regular scheduled meetings with managers, monthly town hall meetings and quarterly earnings reports and calls, we also conduct annual anonymous employee surveys to understand current employee sentiment, areas we are excelling in as well as areas for improvement.

Our total compensation for employees includes a variety of components that support sustainable employment and the ability to build a strong financial future, including competitive market-based pay and comprehensive benefits. In addition to earning a base salary, eligible employees are compensated for their contributions to our goals with both short-term cash incentives and long-term equity-based incentives. Through our global pay philosophy, principles and consistent implementation, we are committed to providing fair and equitable pay for employees. Eligible full-time employees in the U.S. also have access to medical, dental, and vision plans; savings and retirement plans; an employee stock purchase plan; and other resources. Programs and benefits differ internationally for a variety of reasons, such as local legal requirements, market practices, and negotiations with employee representative bodies.

From time to time, we also employ independent contractors, consultants and temporary employees to support our operations. Currently, our SSP production group in Sweden is represented by an IF Metall collective bargaining agreement. None of our other employees are represented by a union or are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good. See "*Risk Factors—General Risk Factors—Disputes with labor unions may adversely affect our ability to operate in our Sweden facility and may impact our financial results*."

We have a zero-tolerance policy for discrimination and have a Diversity, Equity, and Inclusion committee to engage, retain and develop talent from diverse backgrounds by facilitating diversity, equity and inclusion advocacy through event sponsorship, learning and client engagement. We have increased the diversity of our Board of Directors and leadership teams and continue to focus on maintaining a diverse organization. Our senior leadership team includes leaders with diverse skills, experience, racial backgrounds and genders. Our employees come from numerous countries and various backgrounds and we strive to provide a diverse and inclusive environment.

**Environmental Matters**

Our operations require the use of hazardous materials (including biological materials), which subjects us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, or holding a

party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. In addition, we could be subject to significant fines for failure to comply with applicable environmental, health and safety requirements. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

In addition, we look for ways to minimize our impact on the environment. Our main buildings headquartered in California are energy efficiency certified and meet stringent San Francisco Bay Area requirements for environmental impact, and several of our offices are in new energy efficient buildings. Our offices also provide recycling and use low flow fixtures to conserve water, and we take additional measures to conserve energy through LED fixtures, light timers/sensors, and thermostat regulation.

**Available Information**

Our website is www.caredx.com. Information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K, and you should not consider information on our website to be part of this report unless specifically incorporated herein by reference. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act, are available free of charge on our investor relations website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The SEC also maintains a website that contains our SEC filings. The address of the website is www.sec.gov.

## ITEM 1A. RISK FACTORS

**Summary of Risk Factors**

*Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K, or this Form 10-K, and our other filings with the SEC before making an investment decision regarding our common stock.*

- We have a history of losses, and we expect to incur net losses for the next several years.
- 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.
- Our financial results currently are largely dependent on sales of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung tests and products, and we will need to generate sufficient revenues from these and other solutions and tests we develop to grow our business.
- We 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.
- 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.
- The field of diagnostic testing in transplantation is evolving and is subject to rapid technological change. If we are unable to develop solutions to keep pace with rapid medical and scientific change, our operating results could be harmed.
- If clinicians, hospital administrators, medical centers and laboratories do not adopt our diagnostic solutions, we will not achieve future sales growth.
- 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.
- 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.
- If we cannot maintain existing clinical collaborations and enter into new ones, our efforts to commercialize and develop products could be delayed.

- If we are unable to successfully manage our growth and support demand for our tests, our business may suffer.
- Our past revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline.
- If our laboratory facility in the U.S. becomes inoperable, we will be unable to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung and future testing solutions, if any, and our business will be harmed.
- Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.
- 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.
- 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.
- 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.
- 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.
- We rely extensively on third-party service providers. Failure of these parties to perform as expected, or interruptions in our relationship with these providers or their provision of services or supplies to us, could interfere with our ability to provide test results for our testing services business and kits for our products business.
- 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 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.
- 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.
- Our operating results may be adversely affected by unfavorable economic and market conditions.
- Billing complexities associated with obtaining payment or reimbursement for our current and future solutions may negatively affect our revenue, cash flows and profitability.
- Healthcare reform measures could hinder or prevent the commercial success of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung.
- To operate our laboratory, we have to comply with the CLIA and federal and state laws and regulations governing clinical laboratories and laboratory-developed tests, including FDA regulations.
- We are subject to numerous fraud and abuse and other laws and regulations pertaining to our business, the violation of any one of which could harm our business.
- Our competitive position depends on maintaining intellectual property protection.
- Our business is dependent on licenses from third parties.
- Our operating results may fluctuate, which could cause our stock price to decrease.
- 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.

## 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 Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes, before investing in our common stock. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.*

### Risks Related to Our Business

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

We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the year ended December 31, 2025, our net loss was $21.4 million, and for the year ended December 31, 2024, our net income was $52.5 million. As of December 31, 2025, we had an accumulated deficit of $735.4 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of our testing services and product portfolio, and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC;
- ongoing litigation;
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

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

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

For the year ended December 31, 2025, revenue from Medicare for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung represented 46% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all. For example, on December 30, 2024, we

received a CPT code for our AlloSure Kidney, AlloSure Heart and AlloSure Lung tests (PLA Code 0540U), which subjects such tests to a repricing process.

On November 25, 2025, CMS issued a final determination to cross-walk 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 requires 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 would set the Medicare Clinical Laboratory Fee Schedule rate for certain of our tests in calendar years 2027 to 2029. We do not anticipate that the reporting will have a material impact on our current Medicare pricing.

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

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 16, 2024, CMS issued a press release entitled "MolDX Local Coverage Determination Statement," announcing that after careful consideration of the feedback received from interested parties, as well as the public comments and further review of evidence, the Medicare Administrative Contractors, or MACs, decided not to finalize the proposed LCD issued on August 10, 2023. CMS further stated that due to the importance of identifying solid organ allograft rejection early and to ensure the public has additional opportunities to comment on the policy, the MACs intend to issue a new LCD in the coming months. CMS stated that neither it nor the MACs have changed coverage for the blood tests that monitor for organ transplantation rejection when ordered by their physicians in medically appropriate circumstances, and explained that transplant patients would continue to have access to these blood tests, including: when there are signs or symptoms of rejection; after a physician-assessed pretest, including for surveillance testing; after an indeterminate biopsy; as a replacement for a biopsy when deemed clinically appropriate by the patient's qualified physician; and for evaluation of the adequacy of immunosuppression. On July 17, 2025, MolDX and Noridian released a new draft proposed revision to the existing foundational LCD (DL40058, DL40060) with a revised accompanying billing article (DA60146, DA60152), or the Proposed LCD. The Proposed LCD, which underwent public comment, may introduce new coverage criteria, utilization limitations, and a new bundled payment concept for certain CareDx testing, which could lead to lower rates of reimbursement. MolDX and Noridian have 365 days from the date of issuance to finalize the Proposed LCD. We cannot predict the ultimate outcome of the LCD process, including as it relates to the Proposed LCD, and whether it will produce changes in coverage, reimbursement practices, utilization limitations, or payment amounts, any of which could adversely affect our business, operating results and prospects.

If future reimbursement price 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. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the United States so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, or AlloSure Lung at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare or AlloSure Lung could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

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

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

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

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

Successful commercialization of AlloSure Kidney, AlloMap Heart and AlloSure Heart, HeartCare and AlloSure Lung depends, in large part, on the availability of coverage and adequate reimbursement from government and private payers. Favorable third-party payer coverage and reimbursement are critical to the commercial success of a diagnostic testing service, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected. Third-party payers have in the past disallowed, and may in the future disallow, in whole or in part, requests for reimbursement based on determinations that the member is not eligible for coverage, certain amounts are not reimbursable under plan coverage, were for services provided that were not medically necessary, were redundant or were not coupled with other specified tests or services or additional supporting documentation is necessary. Retroactive adjustments may change amounts realized from third-party payers. For example, we are currently involved in a dispute with a significant Medicare Advantage payer concerning payment of claims. We are seeking recovery of claims amounts that we believe were improperly denied, underpaid or recouped. The payer 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 and future solutions could be limited.

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

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail. See Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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 transplant centers;
- gain acceptance from ordering laboratories associated with transplant centers; and
- seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations.

We have included a discussion of a number of anticipated targets in this Annual Report on Form 10-K. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

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

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

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

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

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

of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical trial, which could harm our business.

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

The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations that could make AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and our other products and patient and digital solutions, including those in development, outdated. We must continually innovate, expand and update our test offerings to address unmet needs in monitoring transplant-related conditions. AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, and our other products and patient and digital solutions, including those in development, could become obsolete unless we continually innovate, enhance and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, or our other products and patient and digital solutions and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our tests, products and patient and digital solutions could decline, which would harm our business and financial results.

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

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

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

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

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

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

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

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

Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute rejection in kidney and heart transplant recipients by utilizing biopsies. Many clinicians

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The value of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung depends, in large part, on our ability to perform AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung tests on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new equipment or processes or hire new personnel could result in higher costs of processing or an inability to meet market demand in a timely manner. 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 or our future solutions, if any, on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand for our current and future solutions, our reputation could be harmed and our future prospects and our business could suffer.

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

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

From 2024 to 2025, our revenue increased from $333.8 million to $379.8 million, which represents an annual increase of 14%. In the future, our revenue may not grow at all and it may continue to decline. We believe that our future revenue will depend on, among other factors:

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

- general economic conditions and other factors.

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $201.4 million and an accumulated deficit of $735.4 million. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

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

Additional capital, if needed, may not be available on satisfactory terms, or at all, and might include the issuance of equity securities, debt, cash from collaboration agreements or a combination of these. 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 the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-competes, may lead to increased uncertainty in hiring and competition for talent.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- reduced or varied protection for intellectual property rights in some countries.

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

In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities, which could result in the disruption of our distribution and sales activities.

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

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

We currently use artificial intelligence, or AI, in certain of our internal processes to increase employee efficiency and productivity and to optimize software and algorithm development process, and we may decide to expand our use of AI in the future. As with many new and emerging technologies, AI presents numerous risks and challenges that could adversely affect our business. If we fail to keep pace with rapidly evolving AI technological developments, especially in the healthcare sector, our competitive position and business results may suffer. Additionally, our competitors and other third parties may incorporate AI into their operations 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 recently become the subject of significant media attention and political debate. While we do not currently use AI in any of our products, the introduction and use of AI technologies, particularly generative AI, into new or existing offerings may result in new or expanded risks and liabilities, including 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. For example, AI technologies can generate content that is, or is alleged to be, factually inaccurate, deficient, misleading, or otherwise flawed, or that results in unintended biases and discriminatory outcomes, which could negatively impact our customers and affect our product offerings, harm our reputation and business, and expose us to liability. Laws, regulations or industry standards that develop in response to the use of AI may be burdensome or may restrict our ability to use, develop or deploy AI, particularly generative AI technologies, in our products or processes to the extent we may choose to do so in the future, or our efforts to expand our business. Legislation governing the development and use of AI has been passed or is under consideration in the U.S. at the federal, state and local level, as well as internationally, including the EU AI Act.

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.

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

Our production group in Sweden is represented by an IF Metall collective bargaining agreement. Our failure to successfully renegotiate this labor agreement as it expires could lead to work stoppages or other disputes with labor unions. Our

manufacturing facility in Sweden is used to support the production, packaging and labeling of our proprietary test kits: Olerup SSP, QTYPE, AlloSeq cfDNA and HCT. Disruptions to our manufacturing facility through various forms of labor disputes could adversely affect us. Any strike, work stoppage, or other dispute with a labor union distracts management from operating the business, may displace employees from ordinary job positions to fill in vacant positions, may affect our reputation, and could materially adversely affect our business, results of operations, and financial condition.

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

Many of the countries in which we operate, including the U.S. and several of the members of the European Union, 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 recently enacted the One Big Beautiful Bill Act, or the OBBBA, which includes significant provisions, including tax cut extensions and modifications to the international tax framework, 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 contained in this Annual Report on Form 10-K. 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 Ottr, XynManagement, TransChart, MedActionPlan, TTP, HLA Data Systems, or any other businesses or assets that we may acquire.***

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

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

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

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

**Risks Related to Billing and Reimbursement**

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

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

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

- disputes among payers regarding which party is responsible for payment;
- disparity in coverage among various payers;
- different process, information and billing requirements among payers; and

- incorrect or missing billing information, which is required to be provided by the prescribing clinician.

Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized from these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. In addition, we are subject to and expect to continue to be subject to one or more audits under the CMS Recovery Audit Contractor, or RAC, program, the CMS Targeted Probe and Educate, or TPE, program, the Unified Program Integrity Contractors, or UPIC, program and other federal and state audits. Following two rounds of TPE audit in 2022 in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us in the first quarter of 2023 it was making a referral to CMS given disagreement as to the interpretation of the applicable LCDs. We appealed claims which had a basis for appeal. Ultimately, 100% of claims which were appealed were resolved in our favor. We have also met with CMS to discuss the difference in interpretation and intend to continue this dialogue regarding our position that the Noridian interpretation is inconsistent with the LCD, MolDX's and Noridian's prior associated responses to public comments, and medical necessity. In addition, in the second quarter of 2023, we received a record request from UPIC. UPIC has the authority to implement Medicare payment suspensions during the pendency of an audit and the ability to refer billing matters to other regulatory agencies. In the third quarter of 2023, the UPIC provided us with notice that we had received Medicare payments in error, resulting in an overpayment of $38,975.02. The UPIC further stated that going forward it wished to support our efforts to remedy the billing issues and it would continue to monitor our Medicare claim submission patterns. 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 and AlloSure Lung.***

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

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

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

PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests), private payer payment rates and volumes for

their tests. The PAMA rules use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests.

There have been public announcements by President Trump and members of the U.S. Congress regarding plans to repeal and replace the Affordable Care Act. We cannot predict the ultimate form or timing of any repeal, replacement or expansion of the Affordable Care Act or the effect such repeal, replacement or expansion would have on our business. Regardless of the impact of any repeal, replacement or expansion of the Affordable Care Act on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could decrease the amount of reimbursement available from governmental and other third-party payers. On April 1, 2013, cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including AlloSure Kidney and AlloMap Heart, and is expected to remain in effect through at least 2032. The OBBBA, which was recently signed into law, reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly for Medicaid programs. Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung and our future diagnostic solutions, increase costs, divert management's attention and adversely affect our ability to generate revenue and achieve profitability.

In addition to the Affordable Care Act 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 laboratory, we have to comply with the CLIA and federal and state laws and regulations governing clinical laboratories and laboratory-developed tests, including FDA regulations.***

We are subject to the CLIA, a federal law that regulates clinical laboratories that perform testing on specimens taken from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. If our laboratory is out of compliance with the CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as a direct plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain the CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found to be out of compliance with the CLIA program requirements and subjected to sanction, our business could be materially harmed.

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

Finally, we may be subject to regulation in foreign jurisdictions where we offer our test. Failure to maintain certification in those states or countries where it is required could prevent us from testing samples from those states or countries, could lead to the suspension or loss of licenses, certificates or authorizations, and could have an adverse effect on our business. We were inspected as part of the customary College of American Pathologists audit and recertified in 2024 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2026.

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

The FDA has traditionally chosen not to exercise its authority to regulate laboratory developed tests, or LDTs, because it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as “in vitro diagnostic multivariate index assays,” or IVDMIAs.

In October 2023, the FDA proposed a new policy under which the FDA intends to provide greater oversight of LDTs, through a phase-out of its general enforcement discretion approach to LDTs. In connection with this, the FDA proposed a rule that would amend its regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug and Cosmetic Act. 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, this proposed policy and/or rule will be adopted or as to the content of any policies or rule that may eventually be adopted.

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

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

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

If the FDA or the U.S. Congress decides to regulate LDTs and other future solutions under development as medical devices, we could be required to conduct additional premarket analytical studies and clinical testing subsequent to continued commercialization in the case of AlloSure LDTs and/or conduct premarket clinical and analytical testing prior to submitting a regulatory application for commercial sales for future products not yet developed. If we are required to conduct premarket analytical studies and clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of analytical or clinical testing could significantly increase our development costs and delay test commercialization and also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient blood or tissue samples or insufficient data regarding the associated clinical outcomes. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials and reduce our control over such activities. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, applicable regulatory requirements, or for other reasons, our clinical trials may have to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our solutions under development and our ability to be profitable.

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

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

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

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

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

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

- federal and state laws and regulations regarding billing and claims payment applicable to clinical laboratories and/or regulatory agencies enforcing those laws and regulations;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented to the government, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or making a false statement material to a false or fraudulent claim;
- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return

for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services, including clinical laboratory services, reimbursed by Medicare if the physician (or a member of the physician's family);
- has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- HIPAA, as amended by 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. On September 25, 2023, we reported that by letter dated September 19, 2023, we were notified by the staff of the SEC that the SEC has concluded its investigation as to our company and does not intend to recommend an enforcement action by the SEC against us. We previously received a request for information from a separate state regulatory agency and we may receive additional requests for information from the DOJ or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the prior SEC subpoena, or the state regulatory agency information request raises or raised any issues regarding the safety or clinical utility of any of our products or services and are cooperating fully with the investigations and the request for information. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of the DOJ investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, if any governmental body, such as the DOJ or SEC, determines that we have not complied with applicable securities or other laws, such governmental body could initiate a proceeding against us, which may ultimately lead to significant penalties and other relief assessed against us, including monetary fines. We may expend significant financial and managerial resources in connection with responding to the CID and other information requests. Any of the foregoing consequences could seriously harm our business and our financial results.

In addition, we have implemented and strive to continuously develop, implement and improve compliance policies and procedures intended to train our sales, billing, marketing and other personnel regarding compliance with state and federal laws applicable to our business. Our efforts to implement appropriate monitoring of compliance with such policies and procedures are likewise ongoing. We may need to supplement and amend our current policies and procedures and implement additional

policies and procedures in the future. In addition, despite our compliance policies and procedures, and related training and monitoring, we may experience situations in which employees may fail to fully adhere to our policies and procedures. Such failures may subject us to administrative, civil, and criminal actions, penalties, damages, fines, exclusion from participation in federal healthcare programs, refunding of payments received by us and curtailment of our operations.

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

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

**Risks Related to Our Intellectual Property**

***Our competitive position depends on maintaining intellectual property protection.***

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

As of December 31, 2025, we had seven 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.

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 do 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 USPTO, and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO 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 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K under the caption "Litigation and Indemnification Obligations", which is incorporated herein by reference, for a discussion of our recently completed and ongoing litigation with Natera.

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

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 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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 comprised 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 who 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, Olerup SSP, QTYPE, Ottr and CareDx are registered trademarks of our company in the United States. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This process can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

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

As is commonplace in our industry, we employ individuals who were previously employed at other diagnostics, medical device, life sciences or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information of others in the course of their work for us and no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. We may also be forced to bring claims against third parties or defend against third-party claims in order to determine the ownership of our intellectual property. An adverse result in the prosecution or defense of any such claims could require us to pay substantial monetary damages and could result in the loss of valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Our business is dependent on licenses from third parties.***

We license technology from third parties necessary to develop and commercialize our products. On May 4, 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization

rights to Illumina's NGS product line for use in transplantation diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients.

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

In June 2021, we entered into a strategic agreement, which was amended in April 2022, with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX 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.

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 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 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. In 2025, our closing stock price ranged from $11.57 to $25.07 per share. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

- demand by clinicians and recipients for our current and future solutions, if any;
- coverage and reimbursement decisions by third-party payers and announcements of those decisions;
- clinical trial results and publication of results in peer-reviewed journals or their presentation at medical conferences;
- the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others;
- new or less expensive tests and services or new technology introduced or offered by our competitors or us;
- the level of our development activity conducted for new solutions, and our success in commercializing these developments;
- our ability to efficiently integrate the business of our acquisitions;
- the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development;
- changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities;
- changes in recommendations of securities analysts or lack of analyst coverage;
- failure to meet analyst expectations regarding our operating results;
- additions or departures of key personnel;
- public health emergencies;
- share repurchases completed by us; and
- general market conditions.

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

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

Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to

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

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

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, our Board of Directors authorized a new share repurchase program of up to $50.0 million in shares of our common stock over a period of up to two years, commencing on May 30, 2025, or the May 2025 Repurchase Program. The May 2025 Repurchase Program may be carried out, subject to approval by a committee of our Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the year ended December 31, 2025, we purchased an aggregate of 2.8 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of $37.8 million. As of December 31, 2025, $12.2 million was available for future share repurchases under the May 2025 Repurchase Program.

During the year ended December 31, 2025, we purchased an aggregate of 5.8 million shares of our common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of $87.8 million.

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

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

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

Based on a review of our equity transactions since inception, a portion of our NOLs have been limited due to the equity financings that we have completed. Future equity transactions may result in further substantial annual limitations on the

utilization of our NOLs due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.

Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. 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 December 31, 2025, 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" below, 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.

Despite our efforts to improve our internal control over financial reporting, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. If we or otherwise fail to maintain an effective system of internal controls in the future, 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 us and, as a result, the value of our common stock. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business and results of operations and could adversely impact our business, operating results, and financial condition.

If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, we could lose investor confidence in the accuracy and completeness of our financial reports.

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

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

If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting or otherwise fail to maintain or implement effective controls and procedures for financial reporting, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control, investors may lose confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline. If we experience additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately and timely report our financial position, results of operations, and cash flows or key operating metrics, or prevent fraud, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our consolidated financial statements or other corrective disclosures, a decline in our stock price, suspension or delisting of our common stock from the Nasdaq Global Market, SEC investigations, civil or criminal sanctions, an inability to access the capital and commercial lending markets, defaults under our debt and other agreements or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. We believe that our securities have in the past been, and may continue to be, the subject of short selling. Reports and information have been published about us that we believe are mischaracterized or incorrect, and which have in the past been followed by a decline in our stock price.
It is not clear what additional effects the negative publicity will have on us, if any, other than potentially affecting the market price of our common stock. If we continue to be the subject of unfavorable allegations, we may have to expend a significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 1C. CYBERSECURITY

Our Board of Directors, or the Board, is responsible for overseeing our risk management program and cybersecurity is a critical element of this program. Management is responsible for the day-to-day administration of our risk management program and our cybersecurity policies, processes, and practices. Our cybersecurity policies, standards, and controls are based on SOC2 Type 2 security criteria as defined by American Institute of Certified Public Accountants, periodic assessments using recognized National Institute of Standards and Technology's Cybersecurity Framework, and other applicable industry standards. Our cybersecurity program is fully integrated into our overall risk management system and processes. In general, we seek to address material cybersecurity threats through a company-wide approach that addresses the confidentiality, integrity, and availability of our information systems or the information that we collect and store, by assessing, identifying, and managing cybersecurity issues as they occur.

### Cybersecurity Risk Management and Strategy

Our cybersecurity risk management strategy focuses on several areas:

- **Identification and Reporting:** We have implemented a cross-functional approach to assessing, identifying, and managing material cybersecurity threats and incidents. Our program includes controls and procedures to identify, classify, and escalate certain cybersecurity incidents to provide management visibility and obtain direction from management as to the public disclosure and reporting of material incidents in a timely manner.
- **Technical Safeguards:** We implement technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, and access controls, which are evaluated and improved through routine vulnerability assessments and cybersecurity threat intelligence, as well as outside audits and certifications.
- **Incident Response and Recovery Planning:** We have established and maintain an incident response plan designed to address our response to a cybersecurity incident, and a business continuity and disaster recovery plan. We conduct annual tabletop exercises to test these plans.
- **Third-Party Risk Management:** We maintain a risk-based approach to identifying and overseeing material cybersecurity threats presented by third parties, including vendors, service providers, as well as the systems of third parties that could adversely impact our business in the event of a material cybersecurity incident affecting those third-party systems, including any outside auditors or consultants who advise on our cybersecurity systems. We collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes. These third parties include cybersecurity assessors, consultants and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks.
- **Education and Awareness:** We provide quarterly, regular, mandatory training for all employees regarding cybersecurity threats as a means to equip our employees with tools to make employees aware of and to address cybersecurity threats, as well as to communicate our evolving information security policies, standards, processes, and practices.

We conduct quarterly assessments and testing of our policies, standards, processes, and practices in a manner designed to address cybersecurity threats and events. The results of such assessments, audits, and reviews are evaluated by management and reported to the Audit and Finance Committee of the Board, or the Audit and Finance Committee, on a quarterly basis, and we adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by these assessments, audits, and reviews.

### Governance

The Board, in coordination with the Audit and Finance Committee, oversees our risk management program, including the management of cybersecurity threats. The Board and the Audit and Finance Committee each receive regular presentations and reports on developments in the cybersecurity space, including risk management practices, recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technological trends, and information security issues encountered by our peers and third parties. The Board and the Audit and Finance Committee also

receive prompt and timely information regarding any cybersecurity risk that meets pre-established reporting thresholds. Annually, the Board and the Audit and Finance Committee discuss our approach to overseeing cybersecurity threats with our Chief Technology Officer, or CTO, and other senior management members.

The CTO, in coordination with senior management including the Chief Executive Officer, Chief Financial Officer, and General Counsel, works collaboratively across our company to implement a program designed to protect our information systems from cybersecurity threats and to promptly respond to any material cybersecurity incidents in accordance with our incident response and recovery plans. To facilitate the success of our cybersecurity program, cross-functional teams have been established to address cybersecurity threats and respond to cybersecurity incidents. Through ongoing communications with these teams, the CTO and senior management are informed about and monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents, and report such threats and incidents to the Audit and Finance Committee when appropriate.

The CTO has served in various roles in information technology and information security for over 25 years. The CTO holds undergraduate and graduate degrees in Management Information Systems and Masters in Business Administration. Our Chief Executive Officer, Chief Financial Officer, and General Counsel each hold undergraduate and graduate degrees in their respective fields. Collectively, they have several decades of experience managing risk at our company and in similar organizations or settings and assessing cybersecurity threats.

**Material Effects of Cybersecurity Incidents**

Except as described in the section entitled "Risk Factors" included in Part I, Item 1A, including, without limitation, the risk factor above titled "*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*" risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition. In this instance, materiality is defined as an adverse impact to our critical information, which could result in significant legal and financial exposure.

## ITEM 2. PROPERTIES

Our headquarters are located in Brisbane, California. We lease facilities in North America, Europe, and Australia. The following is a summary of the locations, functions and approximate square footage of those facilities as of December 31, 2025:

| Location | Function | Square Footage |
|---|---|---|
| **United States** | | |
| Brisbane, California | Corporate headquarters | 26,506 |
| Brisbane, California | Research & development and clinical laboratories | 61,444 |
| West Chester, Pennsylvania | Sales office and distribution | 6,336 |
| Omaha, Nebraska | Digital solutions office | 24,984 |
| Flowood, Mississippi | Transplant pharmacy | 4,800 |
| **Europe** | | |
| Stockholm, Sweden | Research & development and product manufacturing | 24,940 |
| **Australia** | | |
| Fremantle | Research & development | 5,199 |

We do not own any real property. We believe that our leased facilities are adequate to meet our current needs and that additional facilities are available for lease to meet future needs.

## ITEM 3. LEGAL PROCEEDINGS

The information set forth in Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K under the caption "Litigation and Indemnification Obligations" is incorporated herein by reference.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information

Our common stock has been trading on the Nasdaq Global Market under the symbol "CDNA" since July 22, 2014. The daily market activity and closing prices of our common stock can be found at www.nasdaq.com.

### Holders of Record

As of February 19, 2026, there were approximately 55 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

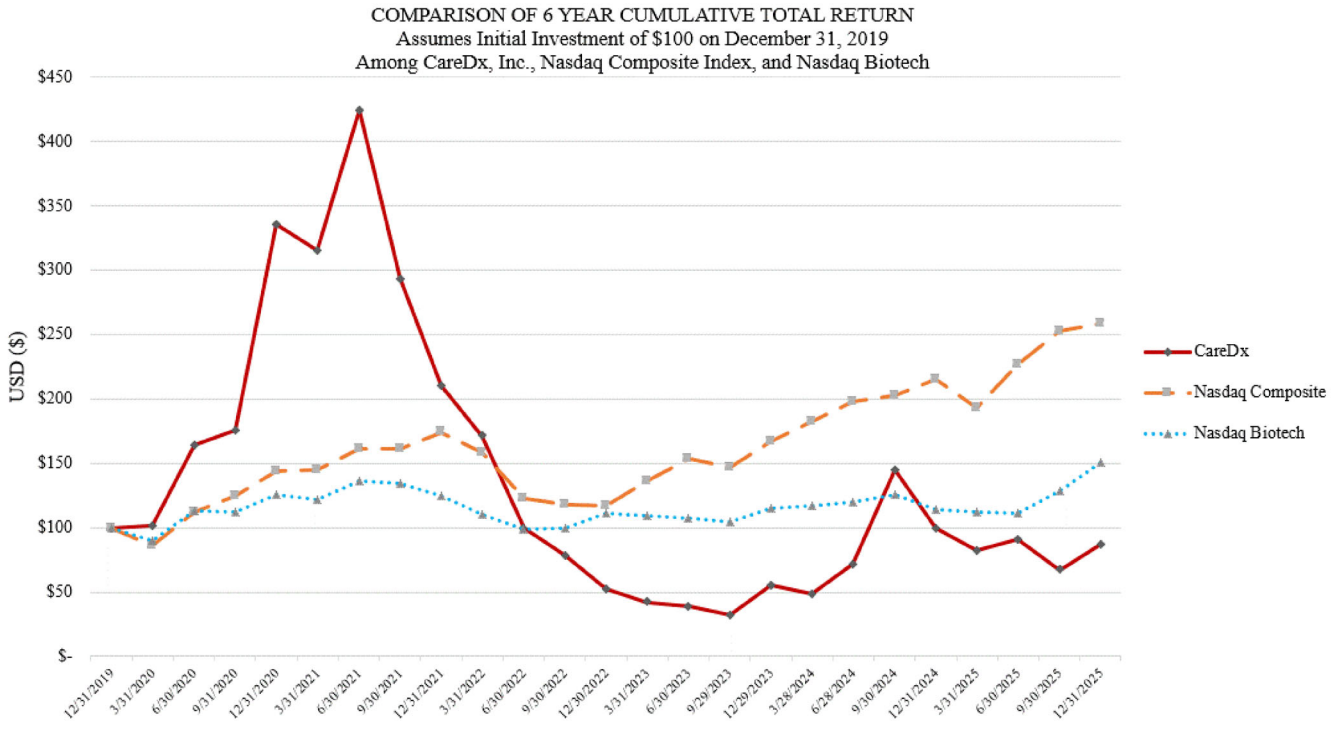
### Dividend Policy

We have never declared or paid cash dividends on our common stock, and currently do not have any plans to do so in the foreseeable future.
Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements and other factors deemed relevant by our Board of Directors and will be at the discretion of our Board of Directors.

### Stock Performance Graph

The following stock performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following stock performance graph compares total stockholder returns for CareDx, Inc. from December 31, 2019 through December 31, 2025 against the Nasdaq Market Composite Index and Nasdaq Biotech Index, assuming a $100 investment made on December 31, 2019. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.




### Sales of Unregistered Securities

There were no sales of unregistered securities by us during the fourth quarter of 2025.

**Securities Authorized for Issuance Under Equity Compensation Plans**

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

**Issuer Repurchases of Equity Securities and Withholding of Equity Securities**

We satisfied certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. Shares repurchased by us or withheld to satisfy tax withholding obligations during each month of the quarter ended December 31, 2025 were as follows:

| | Total Number of Shares Purchased or Withheld | 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) |
|---|---|---|---|---|
| October 1, 2025 - October 31, 2025 | | | | |
| Stock Repurchase Program [1] | — | $ — | — | $ 24.4 |
| Employee Transactions [2] | 13,345 | $ 14.93 | N/A | N/A |
| November 1, 2025 - November 30, 2025 | | | | |
| Stock Repurchase Program [1] | 772,856 | $ 15.79 | 772,856 | $ 12.2 |
| Employee Transactions [2] | 58,152 | $ 14.96 | N/A | N/A |
| December 1, 2025 - December 31, 2025 | | | | |
| Stock Repurchase Program [1] | — | $ — | — | $ 12.2 |
| Employee Transactions [2] | 28,140 | $ 19.10 | N/A | N/A |
| Total | — | | | |
| Stock Repurchase Program [1] | 772,856 | $ 15.79 | 772,856 | $ 12.2 |
| Employee Transactions [2] | 99,637 | $ 16.13 | N/A | N/A |

(1) See Part II, Item 8 of this Annual Report on Form 10-K under the heading “Stockholders' Equity” 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 6. [RESERVED]**

Not applicable.

## ITEM 7. 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 our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains certain forward-looking statements that involve risk and uncertainties. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the Section entitled "Risk Factors" in Item 1A, and other documents we file with the SEC. Historical results are not necessarily indicative of future results.*

*A discussion regarding our financial condition and results of operations for fiscal 2025 compared to fiscal 2024 is presented under Results of Operations of this Form 10-K. Discussions regarding our financial condition and results of operations for fiscal 2024 compared to 2023 have been omitted from this Annual Report on Form 10-K, but can be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 28, 2025, which is available without charge on the SEC's website at www.sec.gov and on our investor relations website at caredx.com.*

### Overview

We are a precision medicine company dedicated to improving outcomes for transplant patients and advancing organ health. We deliver solutions designed to empower clinicians and improve patient outcomes. Our integrated solutions include non-invasive molecular testing for heart, kidney, and lung transplants; laboratory products; digital health technologies; and patient solutions that support care before and after transplant. CareDx is the leading provider of genomics-based information for transplant patients.

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

See Part I, Item 1 (Business) of this Annual Report on Form 10-K for further information about our business.

### Fourth Quarter Business Highlights

- Revenue of $108 million, an increase of 25% year-over-year
- Testing services revenue of $78 million, an increase of 23% year-over-year, and testing services volume of approximately 53,000, an increase of 17% year-over-year
- Patient and digital solutions revenue of $16.8 million and product revenue of $13.3 million, representing year-over-year growth of 47% and 17%, respectively
- Average revenue per test of approximately $1,480 including approximately $5 million in prior period revenue
- Net loss of $4 million, compared to net income of $88 million for the fourth quarter of 2024
- Cash flow from operations of $21.4 million
- Share repurchases of $12 million during the quarter of 773,000 shares at an average price of $15.79 per share

### Full Year 2025 Financial Highlights

- Revenue of $380 million, an increase of 14% year-over-year
- Testing services revenue of $275 million, an increase of 10% year-over-year, and testing services volume of approximately 200,000, an increase of 14% year-over-year
- Patient and digital solutions revenue of $57 million and product revenue of $48 million, representing year-over-year growth of 31% and 19%, respectively
- Net loss of $21 million
- Cash flow from operations of $42 million
- Cash, cash equivalents and marketable securities of approximately $200 million as of December 31, 2025
- Share repurchases of $88 million during the year of 5.8 million shares at an average price of $15.16 per share

**Factors Affecting Our Performance**

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

The growth of our testing services is tied to the number of AlloSure Kidney, AlloMap Heart and AlloSure Heart, HeartCare and AlloSure Lung patient samples we receive and patient results we report. We incur costs in connection with collecting and shipping all samples and a portion of the costs when we cannot ultimately issue a report. As a result, the number of patient samples received largely correlates directly to the number of patient results reported.

Continued Growth of Patient and Digital Sales

The growth of our patient and digital revenues is tied to the continued successful implementation of our pharmacy solutions, Ottr, MedActionPlan and XynQAPI software businesses, as well as continued support and maintenance of existing pharmacy, MedActionPlan, Ottr and XynManagement customers. The Ottr software, TransChart, Tx Access and XynQAPI are currently implemented in multiple locations in the United States. The Ottr software implementation and XynQAPI implementation and support teams are based in Omaha, Nebraska. In addition, patient solutions offered by TTP in Flowood, Mississippi include hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. Additionally, with of 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 Years Ended December 31, 2025 and 2024

(In thousands)

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| | 2025 | 2024 | Change | Change % |
| Revenue: | | | | |
| Testing services revenue | $ 274,495 | $ 249,381 | $ 25,114 | 10 % |
| Product revenue | 48,377 | 40,783 | 7,594 | 19 % |
| Patient and digital solutions | 56,933 | 43,621 | 13,312 | 31 % |
| Total revenue | 379,805 | 333,785 | 46,020 | 14 % |
| Operating expenses: | | | | |
| Cost of testing services | 62,045 | 55,611 | 6,434 | 12 % |
| Cost of product | 22,953 | 23,381 | (428) | (2)% |
| Cost of patient and digital solutions | 38,241 | 30,704 | 7,537 | 25 % |
| Research and development | 71,429 | 72,510 | (1,081) | (1)% |
| Sales and marketing | 102,643 | 81,975 | 20,668 | 25 % |
| General and administrative | 107,565 | 125,139 | (17,574) | (14)% |
| Litigation expense | 5,710 | (96,300) | 102,010 | (106)% |
| Total operating expenses | 410,586 | 293,020 | 117,566 | 40 % |
| (Loss) income from operations | (30,781) | 40,765 | (71,546) | (176)% |
| Other income: | | | | |
| Interest income, net | 9,174 | 11,765 | (2,591) | (22)% |
| Other income, net | 524 | 329 | 195 | 59 % |
| Total other income | 9,698 | 12,094 | (2,396) | (20)% |
| (Loss) income before income taxes | (21,083) | 52,859 | (73,942) | (140)% |
| Income tax expense | (271) | (310) | 39 | (12)% |
| Net (loss) income | $ (21,354) | $ 52,549 | $ (73,903) | (141)% |

Testing services revenue

Testing services revenue increased by $25.1 million, or 10%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily driven by testing services volume growth of approximately 14% as compared to the year ended December 31, 2024. This increase was partially offset by an increase in the refunds reserve of $3.5 million, and a decrease of $7.8 million in collections during the year ended December 31, 2025, as compared to the year ended December 31, 2024, under ASC 606 related to specific tests performed in prior periods.

Product revenue

Product revenue increased by $7.6 million, or 19%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily due to higher sales of our commercial NGS-based kitted solutions resulting from growth in our existing business including conversions of targeted customers.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by $13.3 million, or 31%, during the year ended December 31, 2025, compared to the year ended December 31, 2024. 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 $6.4 million, or 12%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily attributed to higher testing services volume, partially offset by the continuous efficiency measures to lower laboratory expenses.

Cost of product

Cost of product decreased by $0.4 million, or 2%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The decrease was primarily due to certain cost reduction efforts offset by an increased sales of our commercial NGS-based kitted solutions.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by $7.5 million, or 25%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily due to an increase in the cost of goods from our pharmacy business resulting from higher sales.

Research and development

Research and development expenses decreased by $1.1 million, or 1%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The decrease was primarily attributable to decreases of $4.7 million in clinical trial expenses, $2.0 million in consulting and licensing expense and $1.5 million in stock-based compensation expense, partially offset by increases of $5.5 million in personnel-related costs and $1.6 million in software-related expenses.

Sales and marketing

Sales and marketing expenses increased by $20.7 million, or 25%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase was primarily attributable to increases of $15.4 million in personnel-related costs, $4.5 million in marketing expenses, $3.2 million in consulting expenses and $0.5 million in travel expenses, partially offset by a decrease of $2.9 million in stock-based compensation expense.

General and administrative

General and administrative expenses decreased by $17.6 million, or 14%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The decrease was primarily attributable to decreases of $25.7 million in stock-based compensation expense and $2.4 million in legal and consulting expenses, partially offset by increases of $3.7 million in software-related costs, $2.9 million in personnel-related costs, $2.3 million in a one-time impairment charge related to an intangible asset and associated construction in progress, $1.0 million in equipment related expenses and $0.6 million in travel expenses.

Litigation expense

The change in litigation settlement expense was mainly due reversal of litigation expense in 2024 related to the favorable outcome of patent infringement claims filed by Natera against us where the District Court ruled that the patents asserted against us were invalid, which was partially offset by settlement of the Securities Class Action lawsuit during 2025. See Note 8, *Commitments and Contingencies*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K under the caption “Litigation and Indemnification Obligations”, which is incorporated herein by reference.

Interest income, net

Interest income, net, decreased by $2.6 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to a decrease in cash, cash equivalents, and marketable securities.

Other income, net

Other income, net increased by $0.2 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to an increase in foreign exchange gains.

Income tax expense

For the year ended December 31, 2025, we recorded an income tax expense of $0.3 million on a loss before income taxes of $21.1 million. The effective tax rate for year ended December 31, 2025 differs from the federal statutory tax rate mainly due to the change in unrecognized tax benefits, non-deductible executive compensation and stock-based compensation.

**Liquidity and Capital Resources**

We have incurred significant losses and negative cash flows from operations and had an accumulated deficit of $735.4 million at December 31, 2025. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $201.4 million, and no debt outstanding.

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

*Shelf Registration Statement*

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

*Stock Repurchase Programs*

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

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, our Board of Directors authorized a new share repurchase program of up to $50.0 million in shares of our common stock over a period of up to two years, commencing on May 30, 2025, or the May 2025 Repurchase Program. The May 2025 Repurchase Program may be carried out, subject to approval by a committee of our Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the year ended December 31, 2025, we purchased an aggregate of 2.8 million shares of our common stock under the May 2025 Repurchase Program for an aggregate purchase price of $37.8 million. As of December 31, 2025, $12.2 million was available for future share repurchases under the May 2025 Repurchase Program.

During the year ended December 31, 2025, we purchased an aggregate of 5.8 million shares of our common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of $87.8 million.

**Cash Flows**

The following table summarizes our cash flows for the years ended December 31, 2025, 2024 and 2023:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| | (in thousands) | | |
| Net cash provided by (used in): | | | |
| Operating activities | $ 42,032 | $ 38,048 | $ (18,388) |
| Investing activities | 2,158 | (483) | 40,446 |
| Financing activities | (93,394) | (5,606) | (29,606) |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | (90) | 532 | (112) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (49,294) | $ 32,491 | $ (7,660) |

**Cash Flows from Operating Activities**

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

Net cash provided by operating activities for the year ended December 31, 2025 was $42.0 million. Net operating assets increased by $3.8 million. Our noncash items included $34.9 million in stock-based compensation expense, $15.0 million of depreciation and amortization expense, $5.4 million of amortization of right-of-use assets, $2.3 million of impairment of

intangible asset and associated construction in progress, $1.3 million of amortization of premium on marketable securities, net, and revaluation of contingent consideration to estimated fair value of $0.7 million.

Net cash provided by operating activities for the year ended December 31, 2024 was $38.0 million. Net operating assets decreased by $102.3 million. Our noncash items included $66.4 million in stock-based compensation expense, $14.2 million of depreciation and amortization expense, $5.6 million of amortization of right-of-use assets, $0.6 million of amortization of premium on marketable securities and revaluation of contingent consideration to estimated fair value of $0.9 million.

**Cash Flows from Investing Activities**

For the year ended December 31, 2025, net cash provided by investing activities was $2.2 million and primarily related to maturities of marketable securities of $154.7 million, partially offset by purchase of marketable securities of $145.9 million, additions of capital expenditures of $5.9 million and $0.7 million related to acquisition of an intangible asset.

For the year ended December 31, 2024, net cash used in investing activities was $0.5 million and primarily related to purchase of marketable securities of $160.3 million, additions of capital expenditures of $6.5 million and purchase of corporate equity securities of $0.6 million, offset by maturities of marketable securities of $166.9 million.

**Cash Flows from Financing Activities**

Net cash used in financing activities for the year ended December 31, 2025 was $93.4 million and primarily related to repurchase and retirement of common stock of $87.8 million, taxes paid related to net share settlements of restricted stock units of $12.1 million and payments of contingent consideration of $1.5 million. These payments were partially offset by the proceeds from exercises of stock options of $5.7 million and proceeds from issuances of shares of common stock under our employee stock purchase plan of $2.3 million.

Net cash used in financing activities for the year ended December 31, 2024 was $5.6 million and primarily related to repurchase and retirement of common stock of $0.5 million, taxes paid related to net share settlements of restricted stock units of $10.1 million and payments of contingent consideration of $5.3 million. These payments were partially offset by the proceeds from exercises of stock options of $8.9 million and proceeds from issuances of shares of common stock under our employee stock purchase plan of $1.4 million.

For a discussion regarding our cash flows for the year ended December 31, 2023, please refer to the discussion under the heading “Results of Operations—Liquidity and Capital Resources” in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on February 28, 2025.

**Contractual Obligations**

For a discussion regarding our significant contractual obligations as of December 31, 2025 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, refer to Note 8, *Commitments and Contingencies*, of the consolidated financial statements, and “Results of Operations—Liquidity and Capital Resources”, respectively, included elsewhere in this Annual Report on Form 10-K.

**Foreign Operations**

The accompanying consolidated balance sheets contain certain recorded assets in foreign countries, namely Stockholm, Sweden, and Fremantle, Australia. Although these countries are considered economically stable and we have experienced no notable burden from foreign exchange transactions, export duties, government regulations, or unanticipated events in foreign countries could have a material adverse effect on our operations.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these 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. 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*, of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. 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 consolidated financial statements.

**Revenue Recognition**

We recognize revenue from testing services, product sales and patient and digital solutions revenue in the amount that reflects the consideration which it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

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

The healthcare providers that order the tests and on whose behalf we provide testing services are generally not responsible for the payment of these services. The first criterion, identify the contract(s) with a customer, and the second criterion, identify the performance obligations in the contract, of revenue recognition are satisfied when we receive a test requisition form with payer information from the healthcare provider. Generally, we bill third-party payers upon delivery of an AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare or AlloSure Lung test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer.

We have used the portfolio approach, a practical expedient under Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, to identify financial classes of payers. Revenue recognized for Medicare and other contracted payers is based on the agreed current reimbursement rate per test, adjusted for historical collection trends where applicable. We estimate revenue for non-contracted payers and self-payers using transaction prices determined for each financial class of payers using history of reimbursements. This includes analysis of an average reimbursement per test and a percentage of tests reimbursed. This estimate requires significant judgment.

We monitor revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Changes in transaction price estimates are updated quarterly based on actual cash collected or changes made to contracted rates, our discussions with payers, and other pertinent information. In addition, consistent with *ASC 606-10-25-1*, we continue to assess whether it is probable that we will collect substantially all of the consideration to which we will be entitled when determining if a contract with a customer exists.

Refunds Reserve

With respect to revenue recognized related to testing services whereby consideration is expected to be received from third-party payers, we recognized a constraint to the estimated variable consideration such that it is not probable that a significant revenue reversal will occur. When assessing the total consideration expected to be received from third-party payers, a certain percentage of revenues is further constrained for estimated refunds.

Certain refunds were recognized in accrued liabilities until they are either paid to the respective third-party payers or it is determined the refund will not ultimately be paid, at which time the related accrual is reduced with a corresponding increase to testing services revenue. During the year ended December 31, 2025, the refunds reserve to third-party payers were recognized and testing services revenue decreased by $3.5 million for amounts we estimated that would be refunded to third-party payers.

Product Revenue

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. We generally have a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable in the contract. The products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligation related to a contract and revenue is recognized at the point of shipment or delivery consistent with the terms of the contract or purchase order.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue is primarily derived from software as a service, or SaaS, agreements entered into with various transplant centers, which are our customers for this class of revenue. Digital revenue in connection with software license agreements is recognized at the point in time when control of the license is transferred and made available for the customer's use and benefit. The PCS is recognized ratably over the term of the arrangement beginning on the date when access to the subscription is made available to the customer in accordance with ASC 606.

Software license agreements typically require advance payments from customers upon the achievement of certain milestones. We record deferred revenue in relation to these agreements when cash payments are received for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met, and generally recognize revenue over the contractual term, as performance obligations are fulfilled.

In addition, we derive patient revenue from medication sales. The medication sales revenue is recognized based on the negotiated contract price with the governmental, commercial and non-commercial payers with any applicable patient co-pay. Based on the individual agreement, we recognize revenue from medication sales when prescriptions are shipped or delivered.

**Stock-based Compensation**

We use the Black-Scholes Model, which requires the use of estimates such as stock price volatility and expected option lives, to value employee stock options. We estimate the expected option lives using historical data, estimate volatility using our own historical stock prices, estimate risk-free rates using the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected option lives, and estimate dividend yield using our expectations and historical data. Compensation expense for stock options issued to nonemployees is calculated using the Black-Scholes Model and is recorded over the service performance period using the straight-line attribution method. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period. The fair value of each restricted stock unit is calculated based upon the closing price of our common stock on the date of the grant.

Our stock-based compensation arrangements vest over a three to four year vesting schedule. We expense our stock-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant. Compensation expense is recognized on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on our historical experience.

**Business Combinations**

We determine and allocate the purchase price of an acquired business to the assets acquired and liabilities assumed based on their estimated fair values as of the business combination date, including separately identifiable intangible assets, which are separable from goodwill. We base the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management’s best estimates of inputs and assumptions that a market participant would use. We allocate any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, royalty rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In those circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under Accounting Standard Codification, or ASC, Topic 480, *Distinguishing Liabilities from Equity*, we recognize a liability equal to the fair value of the contingent payments that we expect to make as of the acquisition date. We remeasure this liability each reporting period and record changes in the fair value as a component of operating expenses.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in our operating results from the date of acquisition.

**Acquired Intangible Assets**

Amortizable intangible assets include customer relationships, developed technology, commercialization rights, trademarks and trade names and in-process technology assets acquired as part of a business combination or asset acquisition. Intangible assets subject to amortization are amortized over their estimated useful lives. Acquired in-process technology assets and a favorable license agreement are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

**Impairment of Goodwill, Intangible Assets and Long-lived Assets**

*Goodwill*

Goodwill recorded in a business combination is not subject to amortization. Instead, it is tested for impairment on an annual basis and whenever events or changes in circumstances indicate its carrying amount may not be recoverable. We have a single reporting unit and consequently evaluate goodwill for impairment based on an evaluation of the fair value of our company as a whole.

Our annual impairment test date is December 1st. During the goodwill impairment review, we assess qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and the market considerations, and our overall financial performance. If, after assessing the totality of these qualitative factors, we determine that it is not more likely than not that the fair value of the reporting unit is less than the carrying amount, then no additional assessment is deemed necessary. Otherwise, we proceed to compare the estimated fair value of the reporting unit with the carrying value, including goodwill. If the carrying amount of the reporting unit exceeds the fair value, we record an impairment loss based on the difference.

When necessary, to determine the reporting unit's fair value under the quantitative approach, we use a combination of income and market approaches, such as estimated discounted future cash flows of that reporting unit, multiples of earnings or revenues, and analysis of recent sales or offerings of comparable entities. We also consider our market capitalization on the date of the analysis to ensure the reasonableness of the reporting unit's fair value.

In connection with our annual goodwill assessment on December 1, 2025, we performed a qualitative assessment taking into consideration past, current and projected future earnings, recent trends and market conditions, and our market capitalization. Based on this analysis, we concluded that it was more likely than not that the fair value of the reporting unit exceeded its carrying amount. As such, it was not necessary to perform the quantitative goodwill impairment assessment at that time. As of December 31, 2025, no impairment of goodwill has been identified.

*Intangible assets not subject to amortization*

We evaluate the carrying value of intangible assets not subject to amortization, related to acquired in-process technology assets and a favorable license agreement.

During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, as well as between annual tests if we become aware of any events occurring or changes in circumstances that would indicate that the fair values of the acquired in-process technology assets are less than their carrying amounts. An impairment loss would be recorded when the fair value of an acquired in-process technology asset is less than its carrying value. If and when development is complete, which generally occurs when the products are made commercially available, the associated acquired in-process technology asset will be deemed finite-lived and will then be amortized based on its estimated useful life.

As of December 31, 2025, no impairment of acquired in-process technology assets has been identified.

*Intangible assets and long-lived assets subject to amortization*

We evaluate our finite-lived intangible assets and our long-lived assets for indicators of possible impairment when events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. We then compare the carrying amounts of an asset group with the future net undiscounted cash flows expected to be generated by such asset group. If an impairment exists, we measure the impairment based on the excess carrying value of the asset group over the asset group's fair value determined using discounted estimates of future cash flows. Intangible assets subject to amortization are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of testing services, cost of product, cost of patient and digital solutions, research and development expenses and sales and marketing expenses in the consolidated statements of operations.

**Recently Issued Accounting Standards**

Refer to Note 2, *Summary of Significant Accounting Policies - Recent Accounting Pronouncements*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. We had cash, cash equivalents and marketable securities of $201.4 million at December 31, 2025, which consisted of bank deposits, money market funds, corporate debt securities and U.S government securities. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $2.0 million on our consolidated balance sheets.

Foreign Currency Exchange Risk

We have operations in Sweden and sell to other countries throughout the world. As a result, we are subject to foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in U.S. dollars and the Euro. Our patient and digital solutions revenue is primarily denominated in U.S. dollars. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona, Australian Dollar and the Euro, which are also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at December 31, 2025, would have negatively impacted our consolidated balance sheets for the year ended December 31, 2025 by $0.2 million and would have negatively impacted our product and patient and digital solutions revenue by $1.9 million for the year ended December 31, 2025. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility but may do so in the future if our exposure to foreign currencies should become more significant. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**CareDx, Inc.**
**Index to Consolidated Financial Statements**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of CareDx, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CareDx, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2026, expressed an unqualified opinion on the Company's internal control over financial reporting.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

**Testing Services Revenue (non-Medicare) — Refer to Note 2 to the consolidated financial statements**

*Critical Audit Matter Description*

The Company’s testing services revenue is recognized when the results of the test are provided to the healthcare provider, at which time the Company generally bills for its services. The Company estimates revenue for non-Medicare payers using transaction prices determined for each financial class of payers using their history of reimbursements.

The transaction price estimate includes an analysis of the average reimbursement per test and a percentage of tests reimbursed. This estimate requires significant judgment. The Company monitors revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Changes in transaction price estimates are updated quarterly based on actual cash collected. The Company also considers whether historical collections per test are indicative of future collections or if there are any current or expected developments or changes that could affect reimbursement rates.

We identified management’s estimation of the transaction price for transaction services billed to non-Medicare payers as a critical audit matter due to the significant judgments required by management to estimate how coverage practices and policies of payers might affect the amounts received. This required a high degree of auditor judgment and an increased extent of effort, including the involvement of more experienced engagement team members, when performing audit procedures to evaluate the estimated transaction prices.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to management’s estimation of transaction prices for testing services revenue (non-Medicare), included the following, among others:

- We tested the effectiveness of controls over the Company’s testing services revenue, including those over the estimation of transaction prices.
- We tested the assumptions used by management to estimate transaction prices by:
  - Testing the mathematical accuracy of management’s calculation.
  - Testing the historical cash receipts from non-Medicare payers used in the estimate of transaction prices by making selections and agreeing the selected information to source documents.
  - Testing management’s ability to estimate transaction prices accurately by comparing recorded revenue to cash receipts received through December 2025.
  - Evaluating trends in revenue and accounts receivable compared to previous periods to identify evidence inconsistent with management’s estimated transaction prices.
- We tested the accuracy and completeness of the lab billing report by tracing to source documents, including the test requisition form, fax support, proof of insurance, and payment support.

/s/ Deloitte & Touche LLP

San Francisco, California
February 25, 2026

We have served as the Company's auditor since 2018.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of CareDx, Inc.

### Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of CareDx, Inc. and subsidiaries (the "Company") as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2025, of the Company and our report dated February 25, 2026, expressed an unqualified opinion on those financial statements.

### Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

San Francisco, California
February 25, 2026

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

| | As of December 31, | |
|---|---|---|
| | **2025** | **2024** |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 65,429 | $ 114,689 |
| Marketable securities | 111,779 | 145,964 |
| Accounts receivable | 42,628 | 64,605 |
| Inventory | 26,705 | 19,503 |
| Prepaid and other current assets | 10,591 | 7,071 |
| Total current assets | 257,132 | 351,832 |
| Property and equipment, net | 32,971 | 33,552 |
| Operating lease right-of-use assets | 22,760 | 24,340 |
| Marketable securities, non-current | 24,165 | — |
| Intangible assets, net | 31,960 | 38,184 |
| Goodwill | 40,336 | 40,336 |
| Restricted cash | 551 | 585 |
| Other assets | 3,353 | 2,221 |
| Total assets | $ 413,228 | $ 491,050 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,988 | $ 7,686 |
| Accrued compensation | 38,107 | 38,333 |
| Accrued and other liabilities | 41,754 | 43,352 |
| Total current liabilities | 89,849 | 89,371 |
| Deferred tax liability | 181 | 164 |
| Contingent consideration | 161 | 174 |
| Operating lease liabilities, less current portion | 19,679 | 22,263 |
| Other liabilities | 257 | 645 |
| Total liabilities | 110,127 | 112,617 |
| Commitments and contingencies (Note 8) | | |
| Stockholders' equity: | | |
| Preferred stock: $0.001 par value; 10,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024 | — | — |
| Common stock: $0.001 par value; 100,000,000 shares authorized at December 31, 2025 and 2024; 50,916,644 shares issued and outstanding at December 31, 2025; 54,771,203 shares issued and outstanding at December 31, 2024 | 50 | 51 |
| Additional paid-in capital | 1,043,925 | 1,013,193 |
| Accumulated other comprehensive loss | (5,515) | (8,569) |
| Accumulated deficit | (735,359) | (626,242) |
| Total stockholders' equity | 303,101 | 378,433 |
| Total liabilities and stockholders' equity | $ 413,228 | $ 491,050 |

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Revenue: | | | |
| Testing services revenue | $ 274,495 | $ 249,381 | $ 209,685 |
| Product revenue | 48,377 | 40,783 | 33,517 |
| Patient and digital solutions revenue | 56,933 | 43,621 | 37,122 |
| Total revenue | 379,805 | 333,785 | 280,324 |
| Operating expenses: | | | |
| Cost of testing services | 62,045 | 55,611 | 57,642 |
| Cost of product | 22,953 | 23,381 | 18,379 |
| Cost of patient and digital solutions | 38,241 | 30,704 | 26,045 |
| Research and development | 71,429 | 72,510 | 82,421 |
| Sales and marketing | 102,643 | 81,975 | 84,062 |
| General and administrative | 107,565 | 125,139 | 118,838 |
| Litigation settlement expense | 5,710 | (96,300) | 96,300 |
| Total operating expenses | 410,586 | 293,020 | 483,687 |
| (Loss) income from operations | (30,781) | 40,765 | (203,363) |
| Other income: | | | |
| Interest income, net | 9,174 | 11,765 | 11,867 |
| Other income, net | 524 | 329 | 1,353 |
| Total other income | 9,698 | 12,094 | 13,220 |
| (Loss) income before income taxes | (21,083) | 52,859 | (190,143) |
| Income tax expense | (271) | (310) | (141) |
| Net (loss) income | $ (21,354) | $ 52,549 | $ (190,284) |
| Net (loss) income per share (Note 3): | | | |
| Basic | $ (0.40) | $ 1.00 | $ (3.54) |
| Diluted | $ (0.40) | $ 0.93 | $ (3.54) |
| Weighted-average shares used to compute net (loss) income per share: | | | |
| Basic | 53,287,546 | 52,773,247 | 53,764,705 |
| Diluted | 53,287,546 | 56,620,590 | 53,764,705 |

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

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

| | Year ended December 31, | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Net (loss) income | $ (21,354) | $ 52,549 | $ (190,284) |
| Other comprehensive income (loss): | | | |
| Foreign currency translation adjustment, net of tax | 3,054 | (1,606) | 540 |
| Comprehensive (loss) income | $ (18,300) | $ 50,943 | $ (189,744) |

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

**CareDx, Inc.**
**Consolidated Statements of Stockholders' Equity**
***(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, 2022 | 53,533,250 | $ 52 | $ 898,806 | $ (7,503) | $ (460,444) | $ 430,911 |
| Issuance of common stock under employee stock purchase plan | 190,841 | — | 1,495 | — | — | 1,495 |
| Repurchase and retirement of common stock | (2,942,997) | (3) | — | — | (27,541) | (27,544) |
| RSU settlements, net of shares withheld | 669,283 | — | (3,059) | — | — | (3,059) |
| Issuance of common stock for services | 21,965 | — | 216 | — | — | 216 |
| Issuance of common stock for cash upon exercise of stock options | 27,903 | — | 120 | — | — | 120 |
| Issuance of common stock upon exercise of warrants | 3,132 | — | 26 | — | — | 26 |
| Employee stock-based compensation expense | — | — | 48,907 | — | — | 48,907 |
| Foreign currency translation adjustment | — | — | — | 540 | — | 540 |
| Net loss | — | — | — | — | (190,284) | (190,284) |
| Balance at December 31, 2023 | 51,503,377 | 49 | 946,511 | (6,963) | (678,269) | 261,328 |
| Issuance of common stock under employee stock purchase plan | 159,019 | — | 1,397 | — | — | 1,397 |
| Repurchase and retirement of common stock | (55,500) | | — | — | (522) | (522) |
| RSU settlements, net of shares withheld | 2,620,716 | 2 | (10,092) | — | — | (10,090) |
| Issuance of common stock for services | 16,582 | — | 174 | — | — | 174 |
| Issuance of common stock for cash upon exercise of stock options | 527,009 | — | 8,936 | — | — | 8,936 |
| Employee stock-based compensation expense | — | — | 66,267 | — | — | 66,267 |
| Foreign currency translation adjustment | — | — | — | (1,606) | — | (1,606) |
| Net income | — | — | — | — | 52,549 | 52,549 |
| Balance at December 31, 2024 | 54,771,203 | 51 | 1,013,193 | (8,569) | (626,242) | 378,433 |
| Issuance of common stock under employee stock purchase plan | 150,981 | 1 | 2,271 | — | — | 2,272 |
| Repurchase and retirement of common stock | (5,790,952) | (5) | — | — | (87,763) | (87,768) |
| RSU settlements, net of shares withheld | 1,424,235 | 1 | (12,121) | — | — | (12,120) |
| Issuance of common stock for services | 4,794 | 1 | 88 | — | — | 89 |
| Issuance of common stock for cash upon exercise of stock options | 356,383 | 1 | 5,722 | — | — | 5,723 |
| Employee stock-based compensation expense | — | — | 34,772 | — | — | 34,772 |
| Foreign currency translation adjustment | — | — | — | 3,054 | — | 3,054 |
| Net loss | — | — | — | — | (21,354) | (21,354) |
| Balance at December 31, 2025 | 50,916,644 | $ 50 | $ 1,043,925 | $ (5,515) | $ (735,359) | $ 303,101 |

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| **Operating activities:** | | | |
| Net (loss) income | $ (21,354) | $ 52,549 | $ (190,284) |
| Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities: | | | |
| Stock-based compensation | 34,864 | 66,406 | 49,086 |
| Asset impairments and write-downs | — | — | 1,000 |
| Impairment of intangible asset and associated construction in progress | 2,258 | — | — |
| Depreciation and amortization | 15,018 | 14,194 | 14,386 |
| Amortization of right-of-use assets | 5,398 | 5,563 | 5,438 |
| Realized gain on sale of long-term marketable equity securities, net | — | — | (284) |
| Loss on disposal of asset | 48 | 91 | 44 |
| Gain on settlement of obligation and recovery of written-off investment | — | — | (2,109) |
| Revaluation of common stock warrant liability to estimated fair value | — | — | (10) |
| Revaluation of contingent consideration to estimated fair value | 703 | 931 | 2,677 |
| Amortization of premium and accretion of discount on marketable securities, net | 1,273 | 621 | (4,927) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 22,521 | (13,741) | 16,016 |
| Inventory | (4,959) | (1,018) | 54 |
| Prepaid and other assets | (4,413) | 606 | 1,767 |
| Accounts payable | 808 | (5,110) | 2,904 |
| Accrued compensation | (845) | 18,667 | 2,655 |
| Accrued and other liabilities | (3,308) | (95,661) | 89,608 |
| Accrued royalties | — | — | (1,557) |
| Operating lease liabilities, net | (5,997) | (5,863) | (5,418) |
| Deferred taxes | 17 | (187) | 566 |
| Net cash provided by (used in) operating activities | 42,032 | 38,048 | (18,388) |
| **Investing activities:** | | | |
| Maturities of marketable securities | 154,671 | 166,921 | 256,038 |
| Purchases of marketable securities | (145,925) | (160,286) | (201,165) |
| Purchase of corporate equity securities | — | (634) | (965) |
| Sale of corporate equity securities | — | — | 2,460 |
| Additions of capital expenditures | (5,913) | (6,484) | (8,344) |
| Acquisition of intangible assets | (675) | — | (896) |
| Acquisition of business, net of cash acquired | — | — | (6,682) |
| Net cash provided by (used in) investing activities | 2,158 | (483) | 40,446 |
| **Financing activities:** | | | |
| Payment of contingent consideration | (1,500) | (5,325) | (625) |
| Repurchase and retirement of common stock | (87,768) | (522) | (27,541) |
| Proceeds from exercise of warrants | — | — | 4 |
| Proceeds from exercise of stock options | 5,723 | 8,936 | 120 |
| Proceeds from issuance of common stock under employee stock purchase plan | 2,272 | 1,397 | 1,495 |
| Taxes paid related to net share settlement of restricted stock units | (12,121) | (10,092) | (3,059) |
| Net cash used in financing activities | (93,394) | (5,606) | (29,606) |
| Effect of exchange rate changes on cash and cash equivalents | (90) | 532 | (112) |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (49,294) | 32,491 | (7,660) |
| Cash, cash equivalents, and restricted cash at beginning of period | 115,274 | 82,783 | 90,443 |
| Cash, cash equivalents, and restricted cash at end of period | $ 65,980 | $ 115,274 | $ 82,783 |
| **Supplemental disclosures of cash information** | | | |
| Cash paid for income taxes | $ 284 | $ 317 | $ 738 |
| **Supplemental disclosures of non-cash operating, investing and financing information** | | | |
| Shares issued in lieu of payment | $ 88 | $ 174 | $ 216 |
| Operating lease right-of-use assets | $ 3,368 | $ 195 | $ 607 |
| Purchases of capital expenditures in accounts payable and accrued liabilities | $ 3,209 | $ 633 | $ 647 |
| Employee stock purchase plan shares included in accrued compensation | $ 1,140 | $ 975 | $ 556 |
| Contingent consideration | $ — | $ — | $ 3,499 |

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

**CareDx, Inc.**
**NOTES TO 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 improving outcomes for transplant patients and advancing organ health. The Company delivers solutions designed to empower clinicians and improve patient outcomes.The Company's integrated solutions include non-invasive molecular testing for heart, kidney, and lung transplants; laboratory products; digital health technologies; and patient solutions that support care before and after transplant. CareDx is the leading provider of genomics-based information for transplant patients. The Company's headquarters are in Brisbane, California and it has other primary operations in Omaha, Nebraska; and Stockholm, Sweden.

The Company's commercially available post-transplant testing services consist of AlloSure® Kidney, a donor-derived cell-free DNA, 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. The Company has initiated several clinical studies to generate data on its existing and planned future testing services. The Company has signed multiple biopharma research partnerships for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. The Company also offers high-quality products in the pre-transplant space that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. The Company also provides digital technologies solutions and various offerings that help transplant centers with patient management, outcomes quality and operational support.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP, and include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated.

Certain reclassifications have been made to prior period amounts to conform to current period presentations.

Use of Estimates

The preparation of 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 consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to transaction price estimates used for testing services revenue; accrued expenses for clinical studies; inventory valuation; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and marketable securities. The Company's policy is to invest its cash and cash equivalents in money market funds, obligations of U.S. government agencies and government-sponsored entities, commercial paper, corporate debt securities and various bank deposit accounts. The counterparties to the agreements relating to the Company's investments consist of financial institutions of high credit standing. The Company is exposed to credit risk in the event of default by the financial institutions to the extent of amounts recorded on the balance sheets that may be in excess of insured limits.

The Company is also subject to credit risk from its accounts receivable, which are primarily derived from revenue earned from AlloSure Kidney, AlloSure Heart, AlloMap Heart, HeartCare and AlloSure Lung tests provided for patients located in the U.S. and Canada, and billed to various third-party payers, from sales of products to distributors, strategic partners and transplant laboratories in Europe, Asia, the Middle East, Africa, the U.S., Latin America and other geographic regions, and from sales of patient and digital solutions. The Company has not experienced any significant credit losses and does not require collateral on receivables. For the years ended December 31, 2025, 2024 and 2023, approximately 34%, 38% and 40%, respectively, of total revenue was billed to Medicare. No other payers represented more than 10% of total revenue for the years ended December 31, 2025, 2024 and 2023.

As of December 31, 2025 and 2024, approximately 21% and 27%, respectively, of accounts receivable was due from Medicare. No other payer or customer represented more than 10% of accounts receivable at either December 31, 2025 or 2024.

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consist primarily of amounts invested in money market funds.

Restricted Cash

As a condition of the lease agreements for certain facilities, the Company must maintain letters of credit and certain minimum collateral requirements. The cash used to support these arrangements of $0.6 million is classified as long-term restricted cash on the accompanying consolidated balance sheets.

Marketable Securities

The Company considers all highly liquid investments in securities with a maturity of greater than three months at the time of purchase to be marketable securities. As of December 31, 2025, the Company's marketable securities consisted of corporate debt securities and U.S government securities. Those with maturities of greater than three months but less than 12 months from the balance sheet date were classified as current assets, while investments with maturities of one year or beyond one year from the balance sheet date are classified as non-current assets on the consolidated balance sheet.

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

Inventory

Inventories are stated at the lower of actual purchased cost, determined on an average cost basis, on a first-in, first-out basis, or at net realizable value. Excess and obsolete inventories are determined primarily based on expiration dates and future demand forecasts, and write-downs of excess and obsolete inventories are recorded as a component of cost of product.

Property and Equipment, net

Property and equipment are stated at historical cost, less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. The estimated useful life is generally three to five years for computer, office and laboratory equipment, and seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remaining lease term.

The Company capitalizes certain costs incurred for software developed or obtained for internal use, including hosting arrangements. These costs include software licenses and consulting services, as well as employee payroll and payroll-related costs. Capitalized internal-use software costs are usually amortized over a period of three to seven years.

Business Combinations

The Company determines and allocates the purchase price of an acquired business to the assets acquired and liabilities assumed based on their estimated fair values as of the business combination date, including separately identifiable intangible assets, which are separable from goodwill. The Company bases the estimated fair value of identifiable intangible assets acquired in a business combination on independent valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, royalty rates, cash flows, discount rates, estimated useful lives and probabilities surrounding the achievement of contingent milestones could result in different purchase price allocations and amortization expense in current and future periods.

In those circumstances where an acquisition involves a contingent consideration arrangement that meets the definition of a liability under Accounting Standard Codification, or ASC, Topic 480, *Distinguishing Liabilities from Equity*, the Company recognizes a liability equal to the fair value of the contingent payments that the Company expects to make as of the acquisition date. The Company remeasures this liability each reporting period and records changes in the fair value as a component of operating expenses.

Transaction costs associated with acquisitions are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

Acquired Intangible Assets

Amortizable intangible assets include customer relationships, developed technology, commercialization rights, trademarks and tradenames and in-process technology assets acquired as part of a business combination or asset acquisition. Intangible assets subject to amortization are amortized over their estimated useful lives. Acquired in-process technology assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

Impairment of Goodwill, Intangible Assets and Long-lived Assets

*Goodwill*

Goodwill recorded in a business combination is not subject to amortization. Instead, it is tested for impairment on an annual basis and whenever events or changes in circumstances indicate its carrying amount may not be recoverable. The Company has a single reporting unit and consequently evaluates goodwill for impairment based on an evaluation of the fair value of the Company as a whole.

The Company's annual impairment test date is December 1st. During the goodwill impairment review, the Company assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than the carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and the market considerations, and the Company's overall financial performance. If, after assessing the totality of these qualitative factors, the Company determines that it is not more likely than not that the fair value of the reporting unit is less than the carrying amount, then no additional assessment is deemed necessary. Otherwise, the Company proceeds to compare the estimated fair value of the reporting unit with the carrying value, including goodwill. If the carrying amount of the reporting unit exceeds the fair value, the Company records an impairment loss based on the difference.

When necessary, to determine the reporting unit's fair value under the quantitative approach, the Company uses a combination of income and market approaches, such as estimated discounted future cash flows of that reporting unit, multiples of earnings or revenues, and analysis of recent sales or offerings of comparable entities. The Company also considers its market capitalization on the date of the analysis to assess the reasonableness of the reporting unit's fair value.

*Indefinite-lived intangible assets*

The Company evaluates the carrying value of indefinite-lived intangible assets, related to acquired in-process technology assets and a favorable license agreement.

During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, as well as between annual tests if the Company becomes aware of any events or changes in circumstances that would indicate that the fair value of the acquired in-process technology assets and the favorable license agreement are less than their carrying amounts. An impairment loss would be recorded when the fair value of an acquired in-process technology asset and the favorable license agreement are less than the carrying value. If and when development is complete, which generally occurs when the products are made commercially available, the associated acquired in-process technology asset and the favorable license agreement will be deemed finite-lived and will then be amortized based on the estimated useful life.

*Finite-lived intangible assets and long-lived assets*

The Company evaluates its finite-lived intangible assets and its long-lived assets for indicators of possible impairment when events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. The Company then compares the carrying amounts of the asset group with the future net undiscounted cash flows expected to be generated by such asset group. If an impairment exists, the Company measures the impairment based on the excess carrying value of the asset group over the asset group's fair value determined using discounted estimates of future cash flows. Intangible assets subject to amortization are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of testing services, cost of product, cost of patient and digital solutions, research and development expenses and sales and marketing expenses in the consolidated statements of operations.

Fair Value of Financial Instruments

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 carrying amounts of certain financial instruments of the Company, including accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their short maturities. The carrying amount of the contingent consideration liability also represents its fair value.

Leases

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

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

Revenue

The Company recognizes revenue from testing services, product sales, and patient and digital solutions revenue in the amount that reflects the consideration that it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

*Testing Services Revenue*

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

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

The Company monitors revenue estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Changes in transaction price estimates are updated quarterly based on actual cash collected or changes made to contracted rates, the Company's discussions with payers, and other pertinent information. In addition,

consistent with ASC 606-10-25-1, the Company continues to assess whether it is probable that it will collect substantially all of the consideration to which it will be entitled when determining if a contract with a customer exists.

For the years ended December 31, 2025 and 2024, the Company recognized $9.6 million and $17.4 million respectively, in revenue for the tests performed in prior periods, as all performance obligations were satisfied at the time the contract was established.

*Refunds Reserve*

With respect to revenue recognized related to testing services whereby consideration is expected to be received from third-party payers, the Company recognized a constraint to the estimated variable consideration such that it is not probable that a significant revenue reversal will occur. When assessing the total consideration expected to be received from third-party payers, a certain percentage of revenues is further constrained for estimated refunds.

Certain refunds were recognized in accrued liabilities until they are either paid to the respective third-party payers or it is determined the refund will not ultimately be paid, at which time the related accrual is reduced with a corresponding increase to testing services revenue. During the year ended December 31, 2025, the refunds reserve to third-party payers were recognized and testing services revenue decreased by $3.5 million for amounts the Company estimated that would be refunded to third-party payers.

*Product Revenue*

Product revenue is recognized from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. The Company generally has a contract or a purchase order from a customer with the specified required terms, including the number of products ordered. Transaction prices are determinable in the contract. The products are delivered and control is transferred to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of shipment or delivery consistent with the terms of the contract or purchase order.

*Patient and Digital Solutions Revenue*

Patient and digital solutions revenue is primarily derived from software as a service, or SaaS, agreements entered into with various transplant centers, which are the Company’s customers for this class of revenue. Digital revenue in connection with software license agreements is recognized at the point in time when control of the license is transferred and made available for the customer's use and benefit. The PCS is recognized ratably over the term of the arrangement beginning on the date when access to the subscription is made available to the customer in accordance with ASC 606.

Software license agreements typically require advance payments from customers upon the achievement of certain milestones. The Company records deferred revenue in relation to these agreements when cash payments are received for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met, and generally recognizes revenue over the contractual term, as performance obligations are fulfilled.

In addition, the Company derives patient revenue from medication sales. The medication sales revenue is recognized based on the negotiated contract price with the governmental, commercial and non-commercial payers with any applicable patient co-pay. Based on the individual agreement, the Company recognizes revenue from medication sales when prescriptions are shipped or delivered.

Cost of Testing Services

Cost of testing services reflects the aggregate costs incurred in delivering the Company’s testing services. The components of cost of testing services primarily consist of materials and service costs, direct labor costs, stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples, and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Royalties for licensed technology, calculated as a percentage of testing services revenues, are recorded as license fees in cost of testing services at the time the testing services revenues are recognized.

Cost of Product

Cost of product reflects the aggregate costs incurred in delivering the Company’s products to customers. The components of cost of product primarily consist of materials costs, manufacturing and kit assembly costs, direct labor costs, equipment and infrastructure expenses associated with preparing kitted products for shipment, shipping, and allocated overhead including rent, information technology, equipment depreciation and utilities. Cost of product also includes amortization of acquired developed technology and adjustments to inventory values, including write-downs of excess or obsolete inventory.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions primarily consists of personnel-related costs associated with developing, installing and maintaining software, depreciation of servers and equipment, amortization of acquired intangible assets, support of the functionality of the software's platforms, including stock-based compensation expenses, cost of medications and allocated costs of facilities and information technology.

Research and Development Expenses

Research and development expenses, including clinical operations, represent costs incurred to develop diagnostic products and services, high-quality evidence to support the use of the Company’s tests, as well as continued efforts related to improving the Company’s existing products and patient and digital solutions offerings. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, clinical studies and certain allocated expenses as well as amounts incurred under certain collaborative agreements. Research and development costs are expensed as incurred. The Company records accruals for estimated clinical study costs comprised of work performed by contract research organizations based on measure of progress.

Stock-based Compensation

The Company uses the Black-Scholes Model, which requires the use of estimates such as stock price volatility and expected option lives, to value employee stock options. The Company estimates the expected option lives using historical data, estimates volatility using its own historical stock prices, estimates risk-free rates using the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected option lives, and estimates dividend yield using the Company’s expectations and historical data. Compensation expense for stock options issued to nonemployees is calculated using the Black-Scholes Model and is recorded over the service performance period using the straight-line attribution method. Options subject to vesting are required to be periodically remeasured over their service performance period, which is generally the same as the vesting period.

The fair value of each restricted stock unit is calculated based upon the closing price of the Company’s common stock on the date of the grant.

The Company's stock-based compensation arrangements vest over a three to four year vesting schedule. The Company expenses its stock-based compensation under the ratable method, which treats each vesting tranche as if it were an individual grant. Compensation expense is recognized on awards ultimately expected to vest and reduced for forfeitures that are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on the Company's historical experience.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. The Company’s assessment of an uncertain tax position begins with the initial determination of the position’s sustainability and is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit may change as new information becomes available.

Foreign Currency Translation

The functional currency of the Company’s foreign subsidiaries is the local currency for each entity, including the Swedish Krona and Australian dollar. The revenue and expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. Foreign currency translation gains and losses on revenue and expenses are recognized in the consolidated statements of operations. Assets and liabilities have been translated at the rates of exchange on the balance sheet date. The resulting cumulative translation adjustments are reported in other comprehensive income (loss).

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other income and losses affecting stockholders' equity that, under U.S. GAAP, are excluded from net income or loss. For the Company, such items consist of foreign currency income and losses on the translation of foreign assets and liabilities.

Recent Accounting Pronouncements

*Adopted in the current period*

In December 2023, the FASB issued Accounting Standards Update, or ASU, No. 2023-09, *Income Taxes (Topic 340): Improvements to Income Tax Disclosures*, which requires annual disclosures in the rate reconciliation table to be presented using both percentages and reporting currency amounts, and this table must include disclosure of specific categories. Additional information is required for reconciling items that meet a quantitative threshold. The new guidance also requires enhanced disclosures of income taxes paid, including the amount of income taxes paid disaggregated by federal, state and foreign taxes and the amount of income taxes paid disaggregated by individual jurisdictions that exceed a quantitative threshold. The Company adopted this ASU on a prospective basis effective January 1, 2025. Refer to Note 12, Income Taxes.

*Effective in Future Periods*

In December 2025, the Financial Accounting Standards Board, or 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 and does not expect to have a material impact on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*, or ASU 2025-12. 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. The Company is currently evaluating the provisions of this ASU and does not expect to have a material impact on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*. This standard requires entities to disaggregate certain costs and expenses into specific categories and by relevant expense caption in the statement of operations. This guidance will be effective for the Company's annual disclosures for the fiscal year ending December 31, 2027 and for interim period disclosures beginning in the fiscal year ending December 31, 2028. The Company is currently evaluating the potential impact of the new standard on its 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 and does not expect to have a material impact on its consolidated financial statements.

## 3. NET (LOSS) INCOME PER SHARE

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

For the years ended December 31, 2025, and 2023 common share equivalents have been excluded from the calculation of diluted net loss per share, as their effect would be antidilutive.

For the year ended December 31, 2024, all common share equivalents have been included in the calculation of diluted net income per share.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Numerator:** | | | |
| Net (loss) income used to compute basic and diluted net (loss) income per share | $ (21,354) | $ 52,549 | $ (190,284) |
| **Denominator:** | | | |
| Weighted-average shares used to compute basic net (loss) income per share | 53,287,546 | 52,773,247 | 53,764,705 |
| Weighted-average shares used to compute diluted net (loss) income per share | 53,287,546 | 56,620,590 | 53,764,705 |
| **Net (loss) income per share:** | | | |
| Basic | $ (0.40) | $ 1.00 | $ (3.54) |
| Diluted | $ (0.40) | $ 0.93 | $ (3.54) |

The following potentially dilutive securities have been excluded from diluted net (loss) income per share because their effect would be antidilutive:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Shares of common stock subject to outstanding options | 2,478,871 | 2,496,063 | 3,055,208 |
| Restricted stock units | 3,930,939 | 543,479 | 5,001,370 |
| Employee stock purchase plan | 61,866 | 66,747 | 73,759 |
| Total common stock equivalents | 6,471,676 | 3,106,289 | 8,130,337 |

## 4. FAIR VALUE MEASUREMENTS

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

| | 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 |

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

The following table presents the exercise, changes in estimated fair value, additions, deduction 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 at December 31, 2023 | $ 7,930 |
| Change in estimated fair value of contingent consideration from business combination | 931 |
| Change in estimated fair value of contingent consideration from asset acquisition | (448) |
| Deduction from contingent consideration | (500) |
| Payment related to contingent consideration | (5,325) |
| Balance at December 31, 2024 | 2,588 |
| Change in estimated fair value of contingent consideration from business combination | 704 |
| Change in estimated fair value of contingent consideration from asset acquisition | (14) |
| Payment related to contingent consideration | (1,500) |
| Balance at December 31, 2025 | $ 1,778 |

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. At December 31, 2025 and 2024, money market funds were included as cash and cash equivalents in the consolidated balance sheets.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met based on management's estimate of the probability of success and projected revenues for revenue-based considerations at discounted rates of 7% at December 31, 2025 and 7% to 12% at December 31, 2024. The significant input in the Level 3 measurement that is not supported by market activity is the Company's probability assessment of the achievement of the milestones. The value of the liability is subsequently remeasured to fair value at each reporting date, and the change in estimated fair value is recorded as income or expense within operating expenses in the consolidated statements of operations until the milestones are paid, expire or are no longer achievable. Increases or decreases in the estimation of the probability percentage result in a directionally similar impact on the fair value measurement of the contingent consideration liability. The carrying amount of the contingent consideration liability represents its fair value.

## 5. CASH AND MARKETABLE SECURITIES

Cash, Cash Equivalents and Restricted Cash

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

| | December 31, 2025 | December 31, 2024 | December 31, 2023 |
|---|---|---|---|
| Cash and cash equivalents | $ 65,429 | $ 114,689 | $ 82,197 |
| Restricted cash | 551 | 585 | 586 |
| Total cash, cash equivalents, and restricted cash at the end of the period | $ 65,980 | $ 115,274 | $ 82,783 |

Marketable Securities

All marketable securities were considered held-to-maturity at December 31, 2025 and 2024. The Company determined that it had the positive intent and ability to hold until maturity all marketable securities. The Company assesses whether the decline in value of marketable securities is temporary or other-than-temporary. In making its assessment, the Company evaluates the current market and interest rate environment as well as specific issuer information. There has been no recognition of any other-than-temporary impairment at December 31, 2025 and 2024.

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

| | December 31, 2025 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Holding Gains | Fair Value |
| Marketable securities: | | | |
| U.S. agency securities | $ 81,196 | $ 595 | $ 81,791 |
| Corporate debt securities | 54,748 | 57 | 54,805 |
| Total marketable securities | $ 135,944 | $ 652 | $ 136,596 |

| | December 31, 2024 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Holding Gains | Fair Value |
| Marketable securities: | | | |
| U.S. agency securities | $ 90,918 | $ 1,648 | $ 92,566 |
| Corporate debt securities | 55,046 | 718 | 55,764 |
| Total marketable securities | $ 145,964 | $ 2,366 | $ 148,330 |

As of December 31, 2025, $24.2 million of marketable securities had maturities of more than one year and less than two years and are classified as non-current assets.

## 6. GOODWILL AND INTANGIBLE ASSETS

Goodwill

On December 1, 2025, the Company performed a qualitative assessment of its reporting unit taking into consideration past, current and projected future earnings, recent trends and market conditions, and its market capitalization. Based on this analysis, the Company concluded that it was more likely than not that the fair value of the reporting unit exceeded its carrying amount. As such, it was not necessary to perform the quantitative goodwill impairment assessment at this time. As of December 31, 2025, 2024 and 2023, there has been no impairment of goodwill.

Intangible Assets

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 | |

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

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

As of December 31, 2025, 2024 and 2023, other than the $1.7 million intangible asset that was impaired and written off under general and administrative expenses during the year ended December 31, 2025, the Company did not identify any impairment indicators suggesting that the carrying value of the intangible assets was not recoverable.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Cost of testing services | $ 1,388 | $ 1,316 | $ 1,316 |
| Cost of product | 1,751 | 1,660 | 1,655 |
| Cost of patient and digital solutions | 610 | 850 | 1,039 |
| Sales and marketing | 2,602 | 2,520 | 2,457 |
| Total | $ 6,351 | $ 6,346 | $ 6,467 |

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2025 (in thousands):

| Years Ending December 31, | Total |
|---|---|
| 2026 | $ 5,332 |
| 2027 | 5,319 |
| 2028 | 5,319 |
| 2029 | 4,604 |
| 2030 | 3,535 |
| Thereafter | 4,358 |
| Total future amortization expense | $ 28,467 |

## 7. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Finished goods | $ 9,804 | $ 4,819 |
| Work in progress | 3,740 | 3,793 |
| Raw materials | 13,161 | 10,891 |
| Total inventory | $ 26,705 | $ 19,503 |

Property and Equipment, Net

Property and equipment consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Internally developed software | 23,016 | 13,843 |
| Machinery and equipment | $ 19,110 | $ 18,771 |
| Leasehold improvements | 18,171 | 18,106 |
| Construction in progress | 8,280 | 11,937 |
| Computer and office equipment | 1,676 | 5,650 |
| Furniture and fixtures | 1,569 | 2,187 |
| Property and equipment | 71,822 | 70,494 |
| Less: Accumulated depreciation and amortization | (38,851) | (36,942) |
| Property and equipment, net | $ 32,971 | $ 33,552 |

Depreciation expense was $8.7 million, $7.8 million and $7.9 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Accrued and Other Liabilities

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

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Clinical studies | $ 12,356 | $ 16,166 |
| Short-term lease liability | 6,515 | 6,103 |
| Professional fees | 4,988 | 5,971 |
| Deferred revenue | 4,653 | 4,848 |
| Refunds reserve | 3,500 | — |
| Laboratory processing fees and materials | 2,425 | 3,184 |
| Other accrued expenses | 7,317 | 7,080 |
| Total accrued and other liabilities | $ 41,754 | $ 43,352 |

## 8. COMMITMENTS AND CONTINGENCIES

### Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in Brisbane, California; West Chester, Pennsylvania; Flowood, Mississippi; Omaha, Nebraska; Fremantle, Australia; and Stockholm, Sweden.

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

As of December 31, 2025, the carrying value of the ROU asset was $22.8 million. The related current and non-current lease liabilities as of December 31, 2025 were $6.5 million and $19.7 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 consolidated balance sheets.

The following table summarizes the lease cost for the years ended December 31, (in thousands):

| | 2025 | 2024 | 2023 |
|---|---|---|---|
| Operating lease cost | $ 7,340 | $ 7,717 | $ 7,936 |
| Total lease cost | $ 7,340 | $ 7,717 | $ 7,936 |

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Other information: | | |
| Weighted-average remaining lease term - Operating leases (in years) | 4.02 | 4.61 |
| Weighted-average discount rate - Operating leases (%) | 7.0 % | 7.1 % |

Supplemental cash flow information related to leases for the years ended December 31, are as follows (in thousands):

| | 2025 | 2024 | 2023 |
|---|---|---|---|
| **Cash paid for amounts included in the measurement of lease liabilities** | | | |
| Operating cash flows used for operating leases | $ 6,055 | $ 5,339 | $ 5,454 |
| Total | $ 6,055 | $ 5,339 | $ 5,454 |

Maturities of operating lease liabilities as of December 31, 2025, are as follows (in thousands):

| Years ending December 31, | Operating Leases |
|---|---|
| 2026 | $ 7,905 |
| 2027 | 8,248 |
| 2028 | 7,573 |
| 2029 | 2,581 |
| 2030 | 1,768 |
| Thereafter | 1,715 |
| Total lease payments | 29,790 |
| Less imputed interest | 3,596 |
| Present value of future minimum lease payments | 26,194 |
| Less operating lease liability, current portion | 6,515 |
| Operating lease liability, long-term portion | $ 19,679 |

As of December 31, 2025, the Company's leases had remaining terms of 0.41 years to 7.09 years, some of which include options to extend the lease term.

**Royalty Commitments**

Illumina

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

Other Royalty Commitment

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

**Other Commitments**

Effective as of July 2023, the Company entered into a license and collaboration agreement with a private entity, 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 consolidated financial statements indicates that it is probable that a liability had been incurred at the date of the 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. The Company did not record a receivable or a gain from the judgment as the amount has not yet been 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 expires in September 2026. Following trial, Natera moved for an injunction on the Company's prior AlloSure process and the parties engaged in motion practice regarding the jury's verdict and discovery as to whether the Company's current AlloSure process infringes Natera's U.S. Patent 11,111,544. On September 11, 2024, Natera informed the Court that it was abandoning claims of ongoing infringement. On January 3, 2025, the Court issued an order denying Natera's motion to set aside the jury's finding that the Company did not infringe Natera's U.S. Patent 10,655,180. On February 24, 2025, the Court issued an order concluding that Natera's U.S. Patents 11,111,544 and 10,655,180 were invalid for lack of written description thereby overturning the jury verdict. On February 25, 2025, the Court issued an order denying Natera's motion for an injunction as moot. Natera has appealed the Court's invalidation of the three patents it asserted against CareDx. The Company intends to defend these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail.

In addition, Natera's U.S. Patent 10,597,724 is currently subject to an ex parte reexamination before the United States Patent and Trademark Office, or PTO. On December 17, 2025, a PTO examiner issued a non-final office action rejecting Claims 1 and 4-6 of the patent. 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 United States Securities and Exchange Commission, or 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 denies the allegations in the qui tam action and intends to vigorously defend itself.

The Company may receive additional requests for information from the DOJ, the SEC, or other regulatory and governmental agencies regarding similar or related subject matters. Although the Company remains committed to compliance with all applicable laws and regulations, it cannot predict the outcome of, or any other requests or investigations that may arise, in the future.

Securities Class Action

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

On August 25, 2022, the court appointed an investor group led by the Oklahoma Police Pension and Retirement System as lead plaintiffs and appointed Saxena White P.A. and Robbins Geller Rudman & Dowd LLP as lead counsels. Plaintiffs filed an amended complaint on November 28, 2022. On January 27, 2023, defendants moved to dismiss all claims and to strike certain allegations in the amended complaint.

On May 24, 2023, the court granted the Company's motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against the Company, Reginald Seeto, Ankur Dhingra, and Peter Maag. Under a briefing schedule ordered by the court on June 12, 2023, defendants' motion to dismiss and motion to strike the second amended complaint was filed on July 26, 2023, plaintiffs' opposition was filed on August 30, 2023, and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 2023.

On September 18, 2024, the court granted the Company's motion to dismiss the second amended complaint without prejudice, providing plaintiffs leave to file a third amended complaint by no later than October 2, 2024 (a deadline which was subsequently extended by stipulation). On October 18, 2024, plaintiffs filed a third amended complaint, which again alleges that the Company and the individual defendants made materially false and/or misleading statements and/or omissions in violation of Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. Among other things, plaintiffs removed former Chief Financial Officer, Ankur Dhingra, as a named defendant. The third amended complaint reiterates many of the same factual allegations as in prior complaints, but purports to add new allegations based on, among other things, a recently unsealed qui tam action filed by a former employee. On November 15, 2024 the defendants filed a motion to dismiss the third amended complaint and on December 13, 2024, plaintiffs filed an opposition brief. On January 10, 2025, defendants filed their reply brief and a hearing was held on January 28, 2025. On February 18, 2025, the court denied the defendant's motion to dismiss the third amended complaint.

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

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

In accordance with the Court's July 23, 2025 order, plaintiffs filed a motion for final approval and a motion for an award of attorneys' fees and expenses on September 30, 2025. On December 4, 2025, the Court 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, or the Edelman Derivative Action. The Edelman Derivative Action asserts claims against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra, and other current and former members of the Company's Board of Directors alleging, among other things, breaches of fiduciary duty and various state and federal claims based on the factual allegations of the Securities Class Action.

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

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

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

On April 21, 2025, plaintiffs in the Edelman Derivative Action submitted a letter motion to the Court seeking to have the Court lift the discovery stay provided by the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4, or 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, or the Burns Derivative Action. Prior to filing the complaint, the Company produced documents to the plaintiff in response to a books and records inspection demand made pursuant to Section 220 of the Delaware General Corporation Law. The plaintiff purports to incorporate those documents in the complaint. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, unjust enrichment, waste of corporate assets, and aiding and abetting breaches of fiduciary duty. The suit seeks declaratory relief, recovery of alleged damages sustained by the Company as a result of the alleged violations, equitable relief, restitution, and plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. On April 11, 2024, the Court entered an order staying the Burns Derivative Action pursuant to a stipulation filed by the parties.

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

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

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

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

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

On December 9, 2025, the Court issued an order preliminarily approving the parties' settlement, subject to resolution of the plaintiffs' request for attorney's fees.

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

## 9. STOCKHOLDERS' EQUITY

Shelf Registration Statement

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

Stock Repurchase Programs

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

Following the completion of the February 2025 Repurchase Program, on May 30, 2025, the Company’s Board of Directors authorized a new share repurchase program of up to $50.0 million in shares of its common stock over a period of up to two years, commencing on May 30, 2025, or the May 2025 Repurchase Program. The May 2025 Repurchase Program may be carried out, subject to approval by a committee of the Company's Board of Directors, through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. During the year ended December 31, 2025, the Company purchased an aggregate of 2.8 million shares of its common stock under the May 2025 Repurchase Program for an aggregate purchase price of $37.8 million. As of December 31, 2025, $12.2 million was available for future share repurchases under the May 2025 Repurchase Program.

During the year ended December 31, 2025, the Company purchased an aggregate of 5.8 million shares of its common stock under the February 2025 and May 2025 Repurchase Programs, for a total purchase price of $87.8 million.

These shares were retired upon repurchase. The Company's policy related to repurchase of its common stock is to charge the excess of cost over par value to accumulated deficit.

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.

Preferred Stock

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

## 10. 401(K) PLAN

The Company sponsors a 401(k) defined contribution plan covering all U.S. employees under the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. The Company incurred expenses related to contributions to the plan of $3.8 million, $2.3 million and $1.7 million for the years ended December 31, 2025, 2024 and 2023, respectively.

## 11. STOCK INCENTIVE PLANS

2025 Inducement Equity Incentive Plan

On November 4, 2025, the Company adopted the 2025 Inducement Equity Incentive Plan, or the 2025 Plan, that allows for the issuance of stock options, restricted stock units, or RSUs, and other stock awards of up to a total of 350,000 shares of common stock to new employees of the Company. The 2025 Plan was adopted to accommodate a reserve of additional shares of common stock for issuance to new employees hired by the Company. There were 68,745 shares of common stock reserved for future issuance under the 2025 Plan as of December 31, 2025.

2024 Equity Incentive Plan

The Company grants stock-based awards under the 2024 Equity Incentive Plan, or the 2024 Plan, that allows for the issuance of stock options, RSUs and other stock awards to the Company's employees, directors, and consultants.

On November 4, 2025, the Company increased the shares available under the 2024 Plan by 1,600,000 shares.There were 3,047,496 shares of common stock reserved for future issuance under the 2024 Plan as of December 31, 2025.

2019 Inducement Equity Incentive Plan

The Company grants stock-based awards under the 2019 Inducement Equity Incentive Plan, or the 2019 Plan, that allows for the issuance of stock options, RSUs and other stock awards to new employees of the Company. There were 57,204 shares of common stock reserved for future issuance under the 2019 Plan as of December 31, 2025.

2016 Inducement Plan

On April 21, 2016, the Company adopted the 2016 Inducement Equity Incentive Plan, or the 2016 Plan, that allows for the issuance of stock options, RSUs and other stock awards of up to a total of 155,500 shares of common stock to new employees of the Company. The 2016 Plan was adopted to accommodate a reserve of additional shares of common stock for issuance to new employees hired by the Company from Allenex AB. There were 15,495 shares of common stock reserved for future issuance under the 2016 Plan as of December 31, 2025.

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

| | December 31, | |
|---|---|---|
| | 2025 | 2024 |
| Common stock options outstanding | 2,478,871 | 3,409,912 |
| RSUs and PSUs outstanding | 3,930,939 | 4,842,670 |
| 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 | 3,188,940 | 4,559,101 |
| Shares reserved under the Employee Stock Purchase Plan | 541,706 | 558,787 |
| Total | 10,140,456 | 13,370,470 |

Stock Options

There were no stock options granted to employees during 2025.

The following table summarizes stock option activity during the year ended December 31, 2025:

| | Number of Shares | | Weighted-Average Exercise Price |
|---|---|---|---|
| Stock options outstanding at December 31, 2024 | 3,409,912 | $ | 22.63 |
| Exercised | (356,383) | $ | 16.06 |
| Forfeited | (91,159) | $ | 24.56 |
| Expired | (483,499) | $ | 37.70 |
| Stock options outstanding at December 31, 2025 | 2,478,871 | $ | 20.47 |
| Stock options exercisable at December 31, 2025 | 1,836,376 | $ | 22.48 |

The total intrinsic value of options exercised was $1.5 million, $4.8 million and $0.1 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Options outstanding that have vested and are expected to vest at December 31, 2025 are as follows:

| | Number of Options Issued | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (Years) | Aggregate Intrinsic Value (In thousands) |
|---|---|---|---|---|
| Vested | 1,836,376 | $ 22.48 | 5.77 | $ 6,725 |
| Expected to Vest | 588,205 | 14.75 | 7.86 | 4,084 |
| Total | 2,424,581 | | | $ 10,809 |

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock at December 31, 2025 for stock options that were in-the-money.

Restricted Stock Units and Performance Restricted Stock Units

The following table summarizes RSUs and performance restricted stock units, or PSUs, activity during the year ended December 31, 2025:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| RSUs and PSUs outstanding at December 31, 2024 | 4,842,670 | $ 15.38 |
| RSUs granted | 1,853,239 | $ 18.38 |
| RSUs vested | (1,765,017) | $ 15.98 |
| RSUs forfeited | (913,873) | $ 14.35 |
| PSUs granted | 270,405 | $ 18.99 |
| PSUs vested | (300,318) | $ 15.05 |
| PSUs forfeited | (56,167) | $ 25.41 |
| RSUs and PSUs outstanding at December 31, 2025 | 3,930,939 | $ 15.54 |

The total fair value of RSUs vested during 2025 was $31.8 million. As of December 31, 2025, the total intrinsic value of outstanding RSUs was approximately $68.9 million.

The Company granted PSUs, included in RSUs, under the stock incentive plans. The PSUs granted to employees consist of financial and operational metrics to be met over a performance period of two years. The number of shares, based on expected performance achievement, underlying outstanding PSUs was 226,183 and 335,583 as of December 31, 2025 and December 31, 2024, respectively. The weighted-average remaining recognition period was 2.09 years and 1.07 years for the years ended December 31, 2025 and 2024, respectively.

2014 Employee Stock Purchase Plan

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

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

During the offering period in 2025 that ended on June 30, 2025, 84,234 shares were purchased for aggregate proceeds of $1.4 million from the issuance of shares, which occurred on June 30, 2025.

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

The Company issued 150,981 shares and 159,019 shares of common stock during the years ended December 31, 2025 and December 31, 2024, respectively, pursuant to the ESPP. The Company received proceeds of $2.4 million and $1.4 million from the purchases of shares during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had 541,706 shares available for issuance under the ESPP.

Board of Directors Stock Awards Granted for Services

For the years ended December 31, 2025, 2024 and 2023, the Company paid a portion of its directors' compensation through the award of fully vested common shares. The stock awards are classified as equity, and compensation expense was recognized upon the issuance of the shares at the grant date price per share, which is the fair value. For the years ended December 31, 2025, 2024 and 2023, a total of 4,794, 16,582 and 21,965 shares, respectively, were issued to the Company's directors for a total fair value of $0.1 million, $0.1 million and $0.2 million, respectively, which was included in general and administrative expense on the consolidated statements of operations.

Valuation Assumptions

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Employee stock purchase plan** | | | |
| Expected term (in years) | 0.5 | 0.5 | 0.5 |
| Expected volatility | 64.40% – 89.52% | 69.60% – 91.99% | 75.91% – 93.38% |
| Risk-free interest rate | 3.59% – 4.29% | 5.24% – 5.37% | 5.26% – 5.47% |
| Expected dividend yield | — % | — % | — % |

Risk-free Interest Rate: The Company based the risk-free interest rate over the expected term of the award based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of grant.

Volatility: The Company used an average historical stock price volatility of its own stock.

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

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

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense relating to employee and non-employee stock-based awards for the years ended December 31, 2025, 2024 and 2023, included on the consolidated statements of operations as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Cost of testing services | $ 1,263 | $ 1,560 | $ 1,854 |
| Cost of product | 464 | 870 | 1,165 |
| Cost of patient and digital solutions | 624 | 1,276 | 1,377 |
| Research and development | 5,043 | 6,501 | 6,556 |
| Sales and marketing | 8,090 | 11,035 | 12,470 |
| General and administrative | 19,380 | 45,164 | 25,664 |
| Total | $ 34,864 | $ 66,406 | $ 49,086 |

As of December 31, 2025, unrecognized stock-based compensation expense related to stock options, RSUs, and PSUs was approximately $5.5 million, $34.8 million, and $2.3 million, respectively. The remaining unrecognized compensation cost related to the unvested stock options, RSUs, and PSUs is expected to be recognized over a weighted-average period of 2.13 years, 2.12 years, and 2.09 years, respectively.

## 12. INCOME TAXES

The components of the provision for (benefit from) income taxes are summarized as follows (in thousands):

| | As of December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Pre-tax earnings** | | | |
| Domestic | $ (19,128) | $ 55,151 | $ (188,421) |
| Foreign | (1,955) | (2,292) | (1,722) |
| | $ (21,083) | $ 52,859 | $ (190,143) |
| | | | |
| **Current tax expense (benefit)** | | | |
| US federal | $ — | $ 2 | $ (117) |
| US state & local | 420 | 198 | 186 |
| Foreign | — | 9 | — |
| Total current tax expense (benefit) | 420 | 209 | 69 |
| | | | |
| **Deferred tax expense (benefit)** | | | |
| US federal | $ (77) | $ (10) | $ 184 |
| US state & local | (11) | (26) | (112) |
| Foreign | (61) | 137 | — |
| Total deferred tax expense (benefit) | (149) | 101 | 72 |
| | | | |
| **Provision for (benefit from) income taxes** | $ 271 | $ 310 | $ 141 |

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures, as described in Note 2, *Summary of Significant Accounting Policies*, the Company's actual provision for tax differed from the amounts computed by applying the U.S. federal income tax rate of 21% to pretax income as a result of the following (in thousands, except for percentages):

| | As of December 31, | |
|---|---|---|
| | 2025 | |
| **Effective tax rate reconciliation** | | |
| **US federal statutory income tax rate** | $ (4,427) | 21.0 % |
| **Domestic federal** | | |
| Tax credits | | |
| Research credits | (77) | 0.4 % |
| Nontaxable and nondeductible items | | |
| Non-deductible executive compensation | 2,217 | (10.5)% |
| Changes in valuation allowances | (254) | 1.2 % |
| Excess tax benefits on share-based payments | (2,115) | 10.0 % |
| Other | 323 | (1.5)% |
| **Domestic state and local income taxes, net of federal effect** | (407) | 1.9 % |
| **Foreign tax effects** | 350 | (1.7)% |
| **Worldwide changes in unrecognized tax benefits** | 4,662 | (22.1)% |
| **Total income tax expense (benefit)** | $ 271 | (1.3)% |

The reconciliation of taxes at the federal statutory rate to our provision for (benefit from) income taxes for the years ended December 31, 2024 and 2023 in accordance with the guidance prior to the adoption of ASU 2023-09 was as follows (in millions):

| | Year ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Federal tax statutory rate | 21.0 % | 21.0 % |
| Stock-based compensation | (6.3)% | (3.8)% |
| Change in valuation allowance | (18.9)% | (18.1)% |
| Foreign rate differential | — % | 0.2 % |
| Non-deductible executive compensation | 9.9 % | (0.4)% |
| Research credits | (5.1)% | 0.4 % |
| Changes in net operating loss carryforwards, including expirations | — % | 0.8 % |
| Other | — % | (0.2)% |
| Effective income tax rate | 0.6 % | (0.1)% |

The Company determines the amount of state tax liability based on current year operations. In accordance with the guidance under ASU 2023-09, California, Pennsylvania, and New York contributed to a majority of the effect of the state income taxes.

Deferred income tax assets and liabilities consist of the following (in thousands):

| | As of December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Deferred tax assets:** | | |
| Net operating loss carryforwards | $ 34,632 | $ 29,839 |
| Tax credit carryforwards | 14,429 | 14,045 |
| Accruals | 8,322 | 5,027 |
| Lease Liability | 5,543 | 6,843 |
| Section 174 Capitalized Costs | 24,381 | 33,651 |
| Stock-based compensation | 15,793 | 16,163 |
| Other | 1,130 | 1,061 |
| Total deferred tax assets | 104,230 | 106,629 |
| Valuation allowance | (92,636) | (92,217) |
| Deferred tax assets, net of valuation allowance | 11,594 | 14,412 |
| **Deferred tax liabilities:** | | |
| Purchased intangibles | (3,269) | (4,828) |
| Right-of-Use Asset | (4,693) | (5,858) |
| Property and equipment | (3,363) | (3,524) |
| Other | (450) | (366) |
| Total deferred tax liabilities | (11,775) | (14,576) |
| **Net deferred tax asset (liability)** | $ (181) | $ (164) |

The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (1) cumulative results of operations in recent years, (2) sources of recent losses, (3) estimates of future taxable income and (4) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets.

Accordingly, the U.S. and Sweden net deferred tax assets have been offset by a full valuation allowance. The valuation allowance increased by $0.4 million and decreased by $10.6 million during the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, the Company had domestic federal net operating loss carryforwards of $130.8 million, domestic state net operating loss carryforwards of $6.2 million, and foreign net operating loss carryforwards of $29.3 million that can reduce future taxable income. The domestic federal and state net operating loss carryforwards will begin to expire in 2026 and 2027, respectively. The foreign and $111 million of federal net operating loss carryforwards can be carried forward indefinitely.

As of December 31, 2025, the Company had credit carryforwards of approximately $12.4 million and $13.9 million available to reduce future taxable income, if any, for domestic federal and California state income tax purposes, respectively. The domestic federal credit carryforwards will begin to expire in 2026. California credits have no expiration date.

A reconciliation of the Company's unrecognized tax benefits is as follows (in thousands):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Unrecognized tax benefits** | | | |
| Balance, beginning of year | $ 8,641 | $ 6,184 | $ 5,436 |
| Increases related to prior year tax positions | 4,587 | 1,134 | — |
| Decreases related to prior year tax positions | (525) | — | (91) |
| Increases related to current year tax positions | 776 | 1,323 | 839 |
| Balance, end of year | $ 13,479 | $ 8,641 | $ 6,184 |

| | Year ended December 31, 2025 |
|---|---|
| **Income taxes paid, net of refunds received** | |
| U.S. state & local | 284 |
| Total | 284 |

None of the $13.5 million of net unrecognized tax benefit as of December 31, 2025, if recognized, would impact the Company's effective tax rate. During the year ended December 31, 2025, given the Company's valuation allowance, the uncertain tax benefits would not have impacted the effective tax rate.

The Company files U.S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to net operating loss and credit carryovers, the domestic federal and state income tax returns are subject to tax authority examination from inception. In the foreign jurisdictions where the Company files income tax returns, the statutes of limitations with respect to these jurisdictions vary from jurisdiction to jurisdiction and range from 4 to 6 years.

As of December 31, 2025, the Company had gross unrecognized tax benefits of $13.5 million which included penalties and interest of $0.2 million, of which approximately $0.2 million is recorded as a noncurrent liability. At this time, the Company is unable to make a reasonably reliable estimate of the timing of payments in individual years in connection with these tax liabilities; therefore, such amounts are not included in the above contractual obligation table.

## 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, 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):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Testing services revenue** | | | |
| United States | $ 273,379 | $ 248,247 | $ 209,158 |
| Rest of World | 1,116 | 1,134 | 527 |
| | $ 274,495 | $ 249,381 | $ 209,685 |
| **Product revenue** | | | |
| United States | $ 29,908 | $ 26,024 | $ 19,753 |
| Rest of World | 18,469 | 14,759 | 13,764 |
| | $ 48,377 | $ 40,783 | $ 33,517 |
| **Patient and digital solutions revenue** | | | |
| United States | $ 56,652 | $ 43,461 | $ 36,719 |
| Rest of World | 281 | 160 | 403 |
| | $ 56,933 | $ 43,621 | $ 37,122 |
| | | | |
| **Total revenue** | | | |
| Total United States | $ 359,939 | $ 317,732 | $ 265,630 |
| Total Rest of World | $ 19,866 | $ 16,053 | $ 14,694 |
| | $ 379,805 | $ 333,785 | $ 280,324 |

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

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| Long-lived assets: | | |
| United States | $ 32,635 | $ 33,286 |
| Rest of World | 336 | 266 |
| Total | $ 32,971 | $ 33,552 |

The CODM assesses the Company's performance by using net (loss) income. 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, products and digital solutions offerings.

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Revenue:** | | | |
| Testing services revenue | $ 274,495 | $ 249,381 | $ 209,685 |
| Product revenue | 48,377 | 40,783 | 33,517 |
| Patient and digital solutions revenue | 56,933 | 43,621 | 37,122 |
| **Total revenue** | 379,805 | 333,785 | 280,324 |
| **Less:** | | | |
| Cost of testing services[1] | 59,394 | 52,734 | 54,472 |
| Cost of product[1] | 20,738 | 20,904 | 15,672 |
| Cost of patient and digital solutions[1] | 37,007 | 28,502 | 23,631 |
| Personnel cost | 131,276 | 116,251 | 103,354 |
| Professional and legal fees | 41,973 | 42,655 | 63,695 |
| Research materials and clinical trials expense | 10,197 | 14,653 | 18,277 |
| Depreciation and amortization expense | 12,033 | 12,455 | 12,413 |
| Stock-based compensation expense | 34,864 | 66,406 | 49,086 |
| Litigation settlement expense | 5,710 | (96,300) | 96,300 |
| Transformational initiative costs[2] | 2,824 | — | — |
| Other segment items[3] | 54,317 | 34,741 | 45,575 |
| Interest income, net | (9,174) | (11,765) | (11,867) |
| **Segment and consolidated net (loss) income** | $ (21,354) | $ 52,549 | $ (190,284) |

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

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

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

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2025, 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 December 31, 2025, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control – Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2025, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included in this Item 8 of this Annual Report on Form 10-K.

**Remediation of Previously Disclosed Material Weakness in Internal Control over Financial Reporting**

As previously reported, as of December 31, 2024, a material weakness existed in our internal control over financial reporting. 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. This material weakness related to our failure to 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.

During the fiscal year ended December 31, 2025, we implemented an intensive program to remediate this material weaknesses which included expanding resources, enhancing our control activities for key systems and business processes, and providing comprehensive training. Specifically, we:

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

During the year ended December 31, 2025, we completed execution of our remediation plan. The execution of our remediation plan also included validation and testing of the design and operating effectiveness of certain new and enhanced internal controls in the period-end financial reporting process over a sustained period of financial reporting cycles**.** As a result of these efforts, we determined that the material weakness had been remediated as of December 31, 2025.

**Changes in Internal Control over Financial Reporting**

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 quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## ITEM 9B. OTHER INFORMATION

### Trading Arrangements

During the three months ended December 31, 2025, except as set forth below, none of our directors or officers (as defined in Section 16 of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(c) of Regulation S-K.

On December 12, 2025, John W. Hanna, our 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 242,434 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 March 26, 2027, subject to early termination for certain specified events set forth in the plan.

On December 11, 2025, Hannah Valantine, our board member, adopted a trading plan intended to satisfy the conditions under Rule 10b5-1(c) of the Exchange Act. Dr. Valantine's plan is for the sale of up to 40,882 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 December 31, 2026, subject to early termination for certain specified events set forth in the plan.

## ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025 in connection with the Annual Meeting of Stockholders to be held in 2026, or the 2026 Proxy Statement. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 10.

Our Board of Directors has adopted Corporate Governance Guidelines. These guidelines address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. In addition, our Board of Directors has adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer, and other executive and senior financial officers. The full text of our Corporate Governance Guidelines and our Code of Business Conduct and Ethics is posted on our website at www.caredx.com in the Corporate Governance section of our Investors webpage. We intend to post any amendments to our Code of Business Conduct and Ethics, and any waivers of our Code of Business Conduct and Ethics for directors and executive officers, on the same website.

Our Board of Directors has adopted an insider trading policy. Our insider trading policy prohibits our directors, officers (including our executive officers), employees and agents, as well as their immediate family members, from engaging in short sales of our securities and from engaging in transactions in publicly-traded options and other derivative securities with respect to our securities. This prohibition extends to any hedging or similar transactions designed to decrease the risks associated with holding our securities. Our insider trading policy also prohibits us from transacting in our securities unless in compliance with U.S. Securities Laws and prohibits certain individuals, including our directors and executive officers, from pledging our securities as collateral for loans. Our insider trading policy is filed as an exhibit to this Annual Report on Form 10-K.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement. The 2026 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 11.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement. The 2026 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025. To the extent that we do not file our 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 12.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information contained in our 2026 Proxy Statement. The 2026 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 13.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement. The 2026 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2025. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 14.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements:

Our Consolidated Financial Statements are listed in the "Index to Consolidated Financial Statements" of CareDx, Inc. Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto included in this Annual Report on Form 10-K.

(a)(3) Exhibits

The following exhibits are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

| Exhibit Number | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant. | 10-Q | 001-36536 | 3.1 | 8/28/2014 |
| 3.2 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, filed June 17, 2021. | 8-K | 001-36536 | 3.1 | 6/21/2021 |
| 3.3 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation, dated June 16, 2023. | 8-K | 001-36536 | 3.1 | 6/20/2023 |
| 3.4 | Amended and Restated Bylaws of the Registrant, effective as of December 12, 2025. | 8-K | 001-36536 | 3.1 | 12/15/2025 |
| 4.1 | Form of Registrant's common stock certificate. | 10-K | 001-36536 | 4.1 | 3/31/2015 |
| 4.2# | 2014 Equity Incentive Plan, as amended. | 10-Q | 001-36536 | 4.2 | 7/29/2021 |
| 4.3# | Form of Option Agreement under the 2014 Equity Incentive Plan for New Options. | SC TO-I | 005-88252 | 99(d)(3) | 10/12/2017 |
| 4.4# | 2014 Employee Stock Purchase Plan and forms of agreements thereunder. | S-8 | 333-197493 | 4.5 | 7/18/2014 |
| 4.5# | 2016 Inducement Equity Incentive Plan. | 10-Q | 333-211538 | 4.5 | 7/29/2021 |
| 4.6# | 2019 Inducement Equity Incentive Plan. | 10-Q | 001-36536 | 4.7 | 7/29/2021 |
| 4.7 | Description of Securities of the Registrant | 10-K | 001-36536 | 4.7 | 2/28/2025 |
| 4.8# | Amendment No. 1 to the CareDx, Inc. 2024 Equity Incentive Plan. | 8-K | 001-36536 | 10.1 | 6/12/2025 |
| 10.1#* | Form of Change of Control and Severance Agreement between the Registrant and each of its executive officers. | | | | |
| 10.2# | Form of Indemnification Agreement between the Registrant and each of its directors and executive officers. | S-1 | 333-196494 | 10.1 | 6/3/2014 |
| 10.3# | Executive Incentive Compensation Plan. | 10-K | 001-36536 | 10.19 | 3/31/2015 |
| 10.4 | Lease, dated April 27, 2006, as amended on November 10, 2010, by and between the Registrant and BMR-Bayshore Boulevard LLC, for office and laboratory space located at 3260 Bayshore Boulevard, Brisbane, California 94005. | S-1 | 333-196494 | 10.12 | 6/3/2014 |
| 10.5+ | Second Amendment to Lease, dated January 2, 2020, by and between the Registrant and BMR-Bayshore Boulevard LP (formerly known as BMR-Bayshore Boulevard LLC), for office and laboratory space located at 3260 Bayshore Boulevard, Brisbane, California 94005. | 10-Q | 001-36536 | 10.1 | 4/30/2020 |
| 10.6+ | Third Amendment to Lease, dated June 27, 2022, by and between the Registrant and BMR-Bayshore Boulevard LP. | 10-Q | 001-36536 | 10.2 | 11/3/2022 |

| Exhibit Number | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 10.7+ | Lease, dated June 14, 2022, by and between the Registrant and HCP Life Science REIT, Inc. | 10-Q | 001-36536 | 10.4 | 8/14/2022 |
| 10.8+ | Lease, dated February 28, 2022, by and between the Registrant and One Miracle Place, LLC. | 10-Q | 001-36536 | 10.1 | 11/3/2022 |
| 10.9† | License and Commercialization Agreement, dated May 4, 2018, by and between the Registrant and Illumina, Inc. | 10-Q/A | 001-36536 | 10.3 | 10/9/2018 |
| 10.10 | Sales Agreement, dated April 14, 2022, by and between the Registrant and Jefferies LLC. | 8-K | 001-36536 | 1.1 | 4/15/2022 |
| 10.11+# | Retention Bonus Letter, dated December 1, 2023, by and between the Registrant and Abhishek Jain. | 10-K | 001-36536 | 10.19 | 2/28/2024 |
| 10.12# | Offer Letter, dated March 24, 2024, between the Registrant and John Hanna. | 8-K | 001-36536 | 10.1 | 4/16/2024 |
| 10.13# | Change of Control and Severance Agreement, dated March 25, 2024, between the Registrant and John Hanna. | 8-K | 001-36536 | 10.2 | 4/16/2024 |
| 10.14# | Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated March 24, 2024, between the Registrant and John Hanna. | 8-K | 001-36536 | 10.3 | 4/16/2024 |
| 10.15# | CareDx, Inc. 2024 Equity Incentive Plan. | 8-K | 001-36536 | 10.1 | 6/18/2024 |
| 10.16# | Offer Letter, dated July 27, 2024, between the Registrant and Keith Kennedy. | 8-K | 001-36536 | 10.1 | 9/12/2024 |
| 10.17# | Change of Control and Severance Agreement, dated July 27, 2024, between the Registrant and Keith Kennedy. | 8-K | 001-36536 | 10.2 | 9/12/2024 |
| 10.18# | Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated July 27, 2024, between the Registrant and Keith Kennedy. | 8-K | 001-36536 | 10.3 | 9/12/2024 |
| 10.19# | Inducement Restricted Stock Unit Agreement, effective as of September 12, 2024, by and between the Registrant and Keith Kennedy. | 10-Q | 001-36536 | 10.4 | 11/4/2023 |
| 10.20# | Inducement Stock Option Agreement, effective as of September 12, 2024, by and between the Registrant and Keith Kennedy. | 10-Q | 001-36536 | 10.5 | 11/4/2024 |
| 10.21# | Offer Letter, dated August 30, 2024, by and between the Registrant and Jessica Meng. | 10-Q | 001-36536 | 10.6 | 11/4/2024 |
| 10.22# | Change of Control and Severance Agreement, dated August 30, 2024, by and between the Registrant and Jessica Meng. | 10-Q | 001-36536 | 10.7 | 11/4/2024 |
| 10.23# | Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated August 30, 2024, by and between the Registrant and Jessica Meng. | 10-Q | 001-36536 | 10.8 | 11/4/2024 |
| 10.24# | Inducement Restricted Stock Unit Agreement, effective as of September 12, 2024, by and between the Registrant and Jessica Meng. | 10-Q | 001-36536 | 10.9 | 11/4/2024 |
| 10.25# | Inducement Stock Option Agreement, effective as of September 12, 2024, by and between the Registrant and Jessica Meng. | 10-Q | 001-36536 | 10.10 | 11/4/2024 |
| 10.26# | Care Dx, Inc. 2025 Inducement Equity Incentive Plan and the forms of award agreements thereunder. | S-8 | 333-291254 | 99.3 | 11/4/2025 |
| 10.27 | Outside Director Compensation Policy, as amended and restated June 13, 2025 | 10-Q | 001-36536 | 10.2 | 8/6/2025 |
| 10.28# | Change of Control and Severance Agreement, dated March 27, 2025, between CareDx, Inc. and Abhishek Jain. | 8-K | 001-36536 | 10.1 | 3/28/2025 |

| Exhibit Number | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Form | File No. | Exhibit | Filing Date |
| 10.29# | CareDx, Inc. Amended and Restated Outside Director Compensation Policy, as amended and restated effective June 13, 2025. | 10-Q | 001-36536 | 10.2 | 8/6/2025 |
| 10.30# | Offer Letter, dated May 20, 2025, between CareDx, Inc. and Nathan Smith. | 10-Q | 001-36536 | 10.3 | 8/6/2025 |
| 10.31# | Change of Control and Severance Agreement, dated May 20, 2025, between CareDx, Inc. and Nathan Smith. | 10-Q | 001-36536 | 10.4 | 8/6/2025 |
| 10.32# | Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated May 20, 2025, between CareDx, Inc. and Nathan Smith. | 10-Q | 001-36536 | 10.5 | 8/6/2025 |
| 10.33# | Release of Claims Agreement, dated August 6, 2025, between CareDx, Inc. and Abhishek Jain. | 10-Q | 001-36536 | 10.1 | 11/4/2025 |
| 10.34# | Consulting Agreement, dated August 6, 2025, between CareDx, Inc. and Abhishek Jain. | 10-Q | 001-36536 | 10.2 | 11/4/2025 |
| 10.35#* | Offer Letter, dated October 6, 2021, between CareDx, Inc. and Jeffrey Novack. | | | | |
| 10.36#* | Change of Control and Severance Agreement, dated March 26, 2025, between CareDx, Inc. and Jeffrey | | | | |
| 10.37#* | Confidential Information, Invention Assignment, Non-Competition, and Arbitration Agreement, dated October 6, 2021, between CareDx, Inc. and Jeffrey Novack. | | | | |
| 19.1* | Insider Trading Policy and Guidelines with Respect to Certain Transactions in Company Securities. | | | | |
| 21.1* | Subsidiaries of the Registrant. | | | | |
| 23.1* | Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm. | | | | |
| 24.1* | Power of Attorney (included on the signature page of this Annual Report on Form 10-K). | | | | |
| 31.1* | Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | |
| 31.2* | Principal Financial Officer's Certifications Pursuant to 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. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002). | | | | |
| 97 | CareDx, Inc. Clawback Policy | 10-K | 001-36536 | 97 | 2/28/2024 |
| 101.INS* | Inline XBRL Instance Document | | | | |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema | | | | |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase | | | | |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase | | | | |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase | | | | |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase | | | | |
| 104 | Cover Page Interactive Data File, formatted in Inline XBRL | | | | |

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† Confidential treatment has been granted with respect to certain portions of this Exhibit. Omitted portions have been filed separately with the SEC.

+ Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally copies of any of the omitted schedules and exhibits upon request by the SEC.

# Indicates management contract or compensatory plan or arrangement.

* Filed herewith.

** Furnished herewith.

**ITEM 16. FORM 10-K SUMMARY**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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: February 25, 2026

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

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

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John W. Hanna and Nathan Smith, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, on behalf of the registrant on the dates and the capacities indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ JOHN W. HANNA<br>John W. Hanna | President, Chief Executive Officer and Director<br>*(Principal Executive Officer)* | February 25, 2026 |
| /s/ NATHAN SMITH<br>Nathan Smith | Chief Financial Officer<br>*(Principal Accounting and Financial Officer)* | February 25, 2026 |
| /s/ GEORGE W. BICKERSTAFF, III<br>George W. Bickerstaff, III | Director | February 25, 2026 |
| /s/ FRED E. COHEN<br>Fred E. Cohen | Director | February 25, 2026 |
| /s/ CHRISTINE M. COURNOYER<br>Christine M. Cournoyer | Director | February 25, 2026 |
| /s/ MICHAEL D. GOLDBERG<br>Michael D. Goldberg | Director | February 25, 2026 |
| /s/ SURESH GUNASEKARAN<br>Suresh Gunasekaran | Director | February 25, 2026 |
| /s/ PETER MAAG, PH.D.<br>Peter Maag, Ph.D. | Director | February 25, 2026 |
| /s/ BRYAN RIGGSBEE<br>Bryan Riggsbee | Director | February 25, 2026 |
| /s/ ARTHUR TORRES<br>Arthur Torres | Director | February 25, 2026 |
| /s/ HANNAH VALANTINE<br>Hannah Valantine | Director | February 25, 2026 |