



Dear CareDx Shareholders,

We concluded 2023 in a position of strength and market leadership despite facing a new set of complexities associated with Medicare coverage changes only two months into the year. We quickly assessed the situation and executed a strategic reset of our company priorities to adapt to this change. Through our swift financial and operational actions, we mitigated the economic impact of these changes, stabilized our revenue base, and ended the year with a strong balance sheet. Our dedicated team worked tirelessly to ensure patient access to our cutting-edge transplant innovations, overcoming hurdles and striving to emerge even stronger, while also fighting to restore coverage. We also regained momentum in our testing services business, with patient test volumes increasing sequentially in the last two quarters of 2023.

During this critical time, we witnessed continued support from leading medical societies and patients, advocating for access to our transformative transplant molecular testing, including AlloSure® and AlloMap®. These endorsements underscore the important role our innovations play in enhancing transplant patient care.

In 2023, CareDx achieved several milestones, making continued progress in driving our innovations into clinical practice.

- Delivered approximately 165,700 patient testing results to transplant patients.
- Achieved two industry-first distinctions with AlloSure® Lung becoming the first donor-derived cell-free DNA (dd-cfDNA) approved for Medicare coverage for lung transplant patients, and HeartCare® representing the first transplant molecular testing solution with two technologies approved for Medicare coverage for heart transplant patients.
- Notably, the Medicare approval of HeartCare® in August 2023 reaffirmed our clinical approach of using two complementary technologies for better patient care. Our goal is to best serve the clinical needs for managing transplant patients by integrating the most valuable and informative data. This approach can continue to leverage our rich pipeline of innovation in the future.
- Advanced the adoption of CareDx's portfolio of innovative solutions by working closely with researchers to create and share the latest data demonstrating the clinical utility of molecular diagnostics in immunosuppression management and the potential of AI-integrated technology.

- Progressed our multi-center prospective studies. KOAR, our kidney allograft outcomes registry, completed the last patient clinical visits, and SHORE, our ongoing surveillance HeartCare® outcomes registry, reached an interim analysis milestone. Both are likely to see initial publications in 2024, highlighting evidence that may inform payer coverage policy.
- Made progress in advancing our pipeline of innovations, including UroMap®, AlloMap® Kidney, HistoMap™, and AlloHeme®.
- And, repurchased 2.9 million shares of common stock for \$27.5 million under our share buyback program in 2023.

Our impact extends beyond testing services.

An integral part of our success lies in the widespread adoption of our patient and digital solutions. Over 70% of transplant centers use one or more of our solutions designed to improve transplant operations, quality improvement, patient management, and health equity. Our CareDx® Pro platform delivers a single user interface that facilitates access to our portfolio of digital and testing services solutions, furthering our mission to enhance transplant patient care. We continue to bring innovation to new transplant laboratories worldwide through our kitted products utilizing next-generation sequencing (NGS) and qPCR technologies. Our market leadership in NGS HLA typing through our AlloSeq® Tx line and broad geographical footprint allows us to benefit from scale leverage as our products business continues to grow.

Looking ahead to 2024 and beyond.

We have confidence in our outlook, encouraged by our momentum as we enter 2024. Our team is focused on building on the testing services revenue baseline set in the second half of 2023 and expanding access to our innovative portfolio across all three businesses as we continue the path back to profitability. Our strategic focus remains on financial and operational performance, while also leveraging our revenue cycle management infrastructure and investing in multi-center, purpose-driven studies aimed at helping to secure additional reimbursement coverage.

Long term, we are still in the early stages of a growing \$6 billion market opportunity to help care for some of the highest-need patients in the U.S. healthcare system. Transplant patients in the U.S. are experiencing incrementally improved short-term outcomes, yet they still face the challenge of ensuring that their newly transplanted kidney, heart, or lung lasts as long as it should. Our aim is to change that, and in doing so, we are prepared to tap into a substantial

market opportunity and deliver shareholder value by addressing a critical need in the healthcare landscape.

CareDx is strategically positioned to capitalize on this growing transplant market opportunity, as emerging technologies, such as perfusion and xenotransplantation, are primed to increasingly help address the massive supply-demand imbalance for organ transplants. CareDx maintains a leadership role in this market, which is characterized by a differentiated financial phenotype with strong gross margins and a healthy cash position. As a result, we are poised for continued growth, profitability, and shareholder value enhancement.

Closing thoughts as we embark on the future.

We are humbled by the trust bestowed on us by patients and clinicians. Our dedication to the mission of delivering innovative solutions to improve patient care remains steadfast, driven by the significance of our work.

Consider Eddie G., whose life was drastically improved after receiving a new heart. Previously struggling to reach his mailbox, he now takes long walks and lives life more fully. However, he must remain vigilant about his heart health, and thanks to our non-invasive testing, early signs of rejection were detected so his physician could intervene before there was serious heart damage. Eddie expressed, "It's not an exaggeration to say that early detection from molecular testing most likely saved my life." The value of our services for patients like Eddie underscores the ongoing significance of our innovations, emphasizing their important role in enhancing both pre- and post-transplant patient journeys.

We ended 2023 underscoring our resilience as a company and team. We extend our sincere appreciation to our dedicated employees, shareholders, and the broader transplant community for their steadfast support of transplant innovation. Your ongoing trust and confidence in the value we are creating for transplant patients fuel our relentless pursuit of excellence as we strive to reach and serve more patients in need.

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Hanna", with a stylized, cursive script.

John W. Hanna

President and CEO

**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, 2023

OR

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

For the transition period from _____ to _____

Commission File Number 001-36536

CAREDX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

94-3316839
(I.R.S. Employer
Identification Number)

8000 Marina Boulevard
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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
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, 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2023, 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 \$437.0 million. 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 26, 2024 was 51,778,523.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2024 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, 2023.

TABLE OF CONTENTS

<u>Item No.</u>	<u>Page No.</u>
PART I	6
Item 1. Business	6
Item 1A. Risk Factors	25
Item 1B. Unresolved Staff Comments	64
Item 1C. Cybersecurity	64
Item 2. Properties	65
Item 3. Legal Proceedings	65
Item 4. Mine Safety Disclosures	65
PART II	66
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	66
Item 6. [Reserved]	67
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	68
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	85
Item 8. Financial Statements and Supplementary Data	86
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	131
Item 9A. Controls and Procedures	131
Item 9B. Other Information	133
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	133
PART III	134
Item 10. Directors, Executive Officers and Corporate Governance	134
Item 11. Executive Compensation	134
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	134
Item 13. Certain Relationships and Related Transactions, and Director Independence	134
Item 14. Principal Accountant Fees and Services	134
PART IV	135
Item 15. Exhibits, Financial Statement Schedules	135
Item 16. Form 10-K Summary	138
Signatures	139

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

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

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

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled “Risk Factors” 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, Inc., or “CareDx” or the “Company” or “we” or “us” and “our”, together with our subsidiaries, is a leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. We offer testing services, products, and patient and digital solutions along the pre- and post-transplant patient journey, and we are a leading provider of genomics-based information for transplant patients. Our headquarters is located in Brisbane, California. Our primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia and Stockholm, Sweden.

Our commercially available 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 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. We have signed multiple biopharma research partnerships for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. We also offer high-quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. We provide digital solutions to transplant centers following the acquisitions of Otrr Complete Transplant Management, or Otrr, and XynManagement, Inc., or XynManagement. We have since increased our offerings in patient and digital solutions with the acquisitions of TransChart LLC, or TransChart, MedActionPlan.com, LLC, or MedActionPlan, and The Transplant Pharmacy, LLC, or TTP, in 2021, HLA Data Systems, LLC, or HLA Data Systems, in January 2023 and MediGO, Inc., or MediGO in July 2023. During 2023, we performed more than 165,000 commercial tests from our Brisbane, California, laboratory. According to the U.S. Department of Health and Human Services’ Organ Procurement and Transplantation Network, there are approximately 256 and 149 centers performing kidney, heart and lung transplants, respectively, in the United States.

Testing Services

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

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our dd-cfDNA offering. In transplantation there is well-established literature from studies around the world demonstrating the value of dd-cfDNA in the management of solid organ transplantation. AlloSure Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA targeting polymorphisms in the DNA with an approach specifically designed for transplantation to differentiate dd-cfDNA.

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

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

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

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

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

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

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long-term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated. AlloSure Kidney enables more frequent, quantitative and safer assessment of allograft rejection and injury status. Monitoring of graft injury through AlloSure Kidney allows clinicians to optimize allograft biopsies, identify allograft injury and guide immunosuppression management more accurately.

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Most recently, its utility in the assessment of clinical and sub-clinical rejection was evaluated in over 1,000 patients and published in Kidney International.

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

KidneyCare

KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of iBox in one surveillance solution. We have yet to submit any applications to private payers for reimbursement coverage of AlloMap Kidney or iBox.

In September 2019, we announced the enrollment of the first patient in the OKRA study, which is an extension of the K-OAR study. OKRA is a prospective, multi-center, observational registry of patients receiving KidneyCare for surveillance. Combined with the K-OAR study, more than 3,000 patients have been enrolled.

Heart

AlloMap Heart is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate-to-severe acute cellular rejection. Since 2008, we have sought to expand the adoption and utilization of our AlloMap Heart solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap Heart, secure positive reimbursement decisions from large private and public payers, develop and enhance our relationships with key members of the transplant community, including opinion leaders at major transplant centers, and explore opportunities and technologies for the development of additional solutions for post-transplant surveillance.

We believe the use of AlloMap Heart, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant, can improve patient care by helping healthcare providers

avoid the use of unnecessary, invasive surveillance biopsies and may help to determine the appropriate dosage levels of immunosuppressants. In 2008, AlloMap Heart received 510(k) clearance from the U.S. Food and Drug Administration for marketing and sale as a test in heart transplant recipients who have stable graft function at the time of testing, to aid in the identification of those who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 1, 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MolDX to replace the former product-specific policies. The common policy LCD is titled “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. The Revised Billing Article requires certain companies, including CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has acknowledged that the Billing Article is a change as to its previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. We continued the Medicare reimbursement submissions for AlloMap Heart and AlloSure Heart following the issuance of the new Billing Articles by MolDX. In addition, we informed Noridian on May 18, 2023 that until Noridian adopts the Revised Billing Article, we would continue to submit AlloMap Heart tests for reimbursement only when used in conjunction with AlloSure Heart as required by the billing article in effect at Noridian. We also informed Noridian on May 18, 2023 of overall plans to comply with the Billing Articles to the best of our ability. On August 28, 2023, we further informed Noridian that beginning on August 17, 2023, when it publicized the adoption of the Revised Billing Article, we would submit AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

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

We have also successfully completed several landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap Heart for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap Heart based on our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am. J. Transplantation 2006) study, which was published in the AJT. A subsequent clinical utility trial, Invasive Monitoring Attenuation through Gene Expression (Pham MX et al., N. Eng. J. Med., 2010), published in The New England Journal of Medicine, demonstrated that clinical outcomes in recipients managed with AlloMap Heart surveillance were equivalent (non-inferior) to outcomes in recipients managed with biopsies. The results of our clinical trials have also been presented at major medical society congresses. AlloMap Heart is now recommended as part of the International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

HeartCare includes the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap Heart – a measure of immune activation, and (ii) AlloSure Heart – a measure of graft injury.

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, acute cellular rejection and antibody mediated rejection. In September 2018, we initiated the SHORE study, a prospective, multicenter, observational, registry of patients receiving HeartCare for surveillance. Patients enrolled in SHORE will be followed for 5 years with collection of clinical data and assessment of 5-year outcomes.

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

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

Lung

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

Cellular Therapy

In April 2020, we initiated a research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. AlloCell is being commercialized through research agreements with biopharma companies developing cell therapies. In 2021, we executed multiple additional agreements with biopharma therapeutics companies to use AlloCell in research and clinical studies.

In July 2021, we launched the Assessing Chimerism and Relapse of Bone marrow/HCT transplant using AlloHeme Testing study, or the ACROBAT study. The ACROBAT study is a prospective, multicenter, observational cohort study to evaluate the use of AlloHeme, a microchimerism NGS tool to predict post-transplant relapse in patients with allogeneic hematopoietic cell transplants, or HCT. This study is currently enrolling patients.

Products

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

Our product portfolio includes AlloSeq Tx, QTYPE, Olerup SSP, AlloSeq HCT, and AlloSeq cfDNA. QTYPE enables Human Leukocyte Antigen, or HLA, typing at a low to intermediate resolution for samples that require a fast turnaround time and uses real-time polymerase chain reaction, or PCR, methodology. Olerup SSP is used to type HLA alleles based on the sequence specific primer, or SSP, technology.

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

We received CE mark authorization for AlloSeq cfDNA in January 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

In September 2019, we launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than other solutions on the market and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx 17 received CE mark authorization in May 2020.

In June 2020, we launched AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market. AlloSeq HCT received CE mark authorization in May 2022.

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

In 2023, we continued to develop and progress our NGS product lines and software through exclusive and non-exclusive collaborations.

Patient and Digital Solutions

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

In May 2019, we acquired 100% of the outstanding common stock of Ottr. Ottr was formed in 1993 and is a leading provider of transplant patient management software, or the Ottr software, which provides comprehensive solutions for transplant patient management. The Ottr software enables integration with electronic medical records, or EMR, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

In August 2019, we acquired 100% of the outstanding common stock of XynManagement. XynManagement provides two unique solutions, XynQAPI software, or XynQAPI, and XynCare. XynQAPI simplifies transplant quality tracking and

Scientific Registry of Transplant Recipients reporting. Our XynCare offering includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

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

In January 2021, we acquired TransChart. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Access, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs and closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

In June 2021, we acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

In June 2021, we entered into a strategic agreement, which was amended in April 2022, with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure with large transplant databases 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 November 2021, we acquired MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

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

In January 2023, we acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. HLA Data Systems is a leader in the laboratory information management industry for human leukocyte antigen laboratories.

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

Our History

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.

Our software solutions are currently used in over 170 transplant centers in the U.S.

As of December 31, 2023, 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, Sweden and Australia.

We are organized and operate as a single reportable segment. Refer to Note 15 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Limitations of Existing Approaches for Surveillance of Transplant Recipients

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. In 2020, the estimated average charges in the U.S. for a heart transplant were \$1.66 million and for a kidney transplant were \$0.44 million for the period 30 days before the transplant and 180 days after the transplant. The lifetime cost for transplant recipients varies significantly depending on each individual patient's circumstances. Unsuccessful treatment of rejection can result in an additional transplant. In the case of a kidney transplant, the median annual Medicare cost of care for a recipient whose kidney fails and is on dialysis is 500% more than the median annual cost of care for a recipient with a functioning transplant.

The historical standard for heart transplant surveillance has been the microscopic examination of heart tissue obtained through an invasive endomyocardial biopsy. In the biopsy procedure, a catheter is inserted into the right internal jugular vein in the recipient's neck and threaded into the right ventricle of the heart. Four pieces of tissue are cut from the wall of the heart and sent to the laboratory for examination by a pathologist who uses a microscope to look for evidence of cellular rejection. Limitations of biopsies include: (i) the pathologist evaluations, which are subjective and dependent upon visual assessment and qualitative interpretation, (ii) tissue sampling errors, and (iii) the potential for procedure-related complications such as damage to the valve structures in the heart. The typical schedule of biopsy surveillance may involve eight to ten biopsies within the first six months after transplant and up to fifteen biopsies within the first year post-transplant.

Because repeated biopsies can cause cumulative risk and trauma to the heart, the frequency of biopsy surveillance after one year is low, despite the fact that recipients would benefit from continued monitoring for rejection and management of their immunosuppressive drugs for the rest of their lives. With less biopsy data collected after the first year post-transplant, clinicians have less information upon which to tailor immunosuppression treatment for their recipients.

The use of renal biopsies for surveillance of kidney transplants is similarly limited due to the costs and risks associated with the invasive procedure. Therefore, the main clinical test of transplanted kidney surveillance is serum creatinine levels. An increase in serum creatinine levels is an indicator of diminished kidney function, and although this test is widely used, changes in serum creatinine are nonspecific as to cause and not sensitive, as serum creatinine may only be detected after significant and irreversible renal function loss has occurred.

The prevention and treatment of rejection in heart and kidney transplant recipients is managed primarily through the use of immunosuppressive drugs. Surveillance biopsies are infrequent after the first year because of procedural risks, discomfort, inconvenience, expense and the low rate of finding silent rejection. As a result, clinicians have limited and infrequent information about an individual recipient's risk of rejection over the months and years following transplant. In the average recipient, the immune system gradually adapts to the organ graft, and the need for immunosuppression declines over time. However, there is meaningful variation in the level of rejection activity and need for immunosuppression among transplant recipients. Limited insight into the immune status of the individual recipient often causes clinicians to adopt a "one-size-fits-all" approach to immunosuppression to help protect against the severe consequences of rejection. Although typical doses of immunosuppressants result in a low rate of rejection in the transplant population as a whole, many individuals may receive more intense immunosuppressants than they actually need.

The Need for a Better Surveillance Solution

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 reduce the use of invasive biopsies. We believe that core elements of effective surveillance solutions include:

- highly accurate and quantitative results differentiating rejection from non-rejection status;
- non-invasive procedures that do not create risks to the recipient;
- ease of implementation;
- earlier detection of rejection; and
- the ability to provide results with timing and at a frequency that allows for informed and effective treatment decisions.

Clinical Studies for our Testing Services

Kidney

In March 2017, the Journal of the American Society of Nephrology published the article *Cell-Free DNA and Active Rejection in Kidney Allografts*. The article reported that increased levels of dd-cfDNA detected using AlloSure Kidney are associated with active rejection of the kidney allograft. The data for this article came from the Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, study sponsored by CareDx. Evidence from this study suggests that AlloSure Kidney, a non-invasive blood test, may enable more frequent, quantitative, and safer assessment of allograft rejection and injury. As part of a surveillance strategy, AlloSure Kidney can help identify patients with new or ongoing organ injury. In the DART study, to investigate the use of AlloSure Kidney as a surveillance tool, the investigators prospectively collected blood specimens from renal transplant patients at scheduled intervals and at the time of clinically indicated biopsies. Key findings of the study were as follows:

- AlloSure Kidney provides clear stratification of patients for probability of rejection;
- Active rejection patients showed median AlloSure Kidney levels at 1.6%;
- Antibody-mediated rejection, or ABMR, patients showed median AlloSure Kidney levels at 2.9%;
- Non-rejection patients showed median AlloSure Kidney levels of 0.21%; and
- AlloSure Kidney was superior to serum creatinine in identifying which patients had active rejection.

This was the first report to establish clinical performance characteristics for dd-cfDNA in renal transplant patients with an analytically validated assay of dd-cfDNA in a large, multicenter observational study of dd-cfDNA. This progress was made possible by collaboration with 14 major renal transplant centers and their patients who volunteered to participate in the study.

A publication in the Journal of Applied Laboratory Medicine in March 2017 described the biological variation and clinical reference intervals of dd-cfDNA in stable healthy renal transplant recipients. These results indicated levels and amount of change in dd-cfDNA that would not be likely associated with stable kidney transplant recipients.

In January 2018, we initiated the "K-OAR" study to develop additional data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients. Publications based on the analyses of the accumulated DART database results were used as a guide to design K-OAR. K-OAR is a multicenter, non-blinded, prospective observational cohort study which has enrolled more than 1,900 renal transplant recipients who received AlloSure Kidney as part of long-term surveillance. The clinical outcomes of these patients were entered into a registry database as the patients were surveilled for three years.

The study cohort was designed to include a minimum of 300 patients from centers that use renal surveillance biopsies to show the value of AlloSure Kidney in subclinical rejection. The remaining patients were to be from centers that had not performed protocol surveillance biopsies prior to K-OAR, but for cause biopsies, which is the more common practice. A prospective propensity matched control cohort from up to 2,000 patients will be retrospectively analyzed from the subset of centers to show the value of AlloSure Kidney compared to its non-use.

The primary safety endpoint of this study is the amount of kidney tissue scarring and atrophy at one-year post-transplant, quantified by biopsy-based histopathology grade(s). The primary efficacy endpoint is the change in estimated glomerular filtration rate, or eGFR, with the number of renal allograft biopsies performed during the first year being a secondary outcome. Other endpoints include patient survival, graft survival, change and serum creatinine, evaluated at years 1, 2 and 3 post-transplantation.

In September 2019, we announced the commencement of the "OKRA" study, which is an extension of K-OAR. OKRA is a prospective, multi-center, observational registry of patients receiving KidneyCare for surveillance. KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the prognostic artificial intelligence technology of iBox for a multimodality surveillance solution. We have yet to submit any applications to private payers for reimbursement coverage of KidneyCare.

In December 2021, Kidney International published the article Clinical outcomes from the Assessing AlloSure Dd-cfDNA Monitoring Insights of Renal Allografts With Longitudinal Surveillance (ADMIRAL). The article reports that increased levels of dd-cfDNA detected using AlloSure Kidney are associated with active rejection of the kidney allograft. ADMIRAL supports the work of DART further clinically validating the utility in a cohort of 1,092 patients. The high-level summary of the manuscript shows:

- Use in both subclinical and clinical rejection: Elevated AlloSure ($\geq 0.5\%$) strongly correlated with clinical and subclinical allograft rejection ($p < 0.001$);
- Predictor of de novo donor-specific antibody (dnDSA): AlloSure associated with a 271% increased risk of development of dnDSA ($p = 0.001$);
- AlloSure as a leading indicator: AlloSure was elevated 91 days (median) ahead of donor-specific antibody identification;
- AlloSure is superior to serum creatinine (AUC of 80% v 49%, respectively);
- Identifies eGFR decline: Persistently elevated AlloSure (> 1 result above 0.5%) predicted a $> 25\%$ decline in eGFR over 3 years (HR 1.97, $p = 0.041$), while persistently low levels identify allograft quiescence; and
- AlloSure differentiates rejections that are going to cause long-term damage vs short-term rejection, which has treatment implications: oral outpatient treatment vs inpatient, expensive and potentially harmful therapies.

Heart

The clinical validation and utility of AlloMap Heart is supported by a number of major clinical trials involving more than 2,000 heart transplant recipients and published in leading peer-reviewed medical journals. Our trials are designed to evaluate the clinical utility of our solutions and are an integral part of our business strategy, clinical development and marketing programs. In heart transplantation, two major observational trials, CARGO and CARGO II, enabled the initial development, validation and further validation of AlloMap Heart to detect and monitor acute cellular rejection in heart transplant recipients. In addition to preserving blood samples and clinical data from these two trials, we have sponsored a multi-year, 34-center registry named OAR, which focused on long-term outcomes of patients. These repositories contain over 37,000 samples obtained from individual recipients who were typically followed for 10 serial visits and over one year or more, and who in many cases have associated biopsy-based rejection grades and other clinical outcome endpoints. We believe this extensive biorepository and database will be useful for new product development derived from analyses, correlative studies and validation efforts.

Additional clinical utility trials, including IMAGE and the *Early Invasive Monitoring Attenuation through Gene Expression*, or EIMAGE, have demonstrated that clinical outcomes in recipients managed with AlloMap Heart surveillance were equivalent to outcomes in recipients managed with biopsies. We have also published two reports of retrospective analyses from IMAGE and CARGO II trials that demonstrate that the variability in AlloMap Heart scores over time in an individual patient may be useful in predicting the risk for the patient of a future event of rejection and graft dysfunction.

In September 2018, we initiated SHORE. SHORE is a prospective, multi-center, observational registry of patients receiving HeartCare for surveillance. HeartCare combines the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure[®] Heart in one surveillance solution.

Lung

The ALAMO multicenter observational study is enrolling towards a 500-patient target following initiation in December 2021. The study focuses on surveillance in lung transplant recipients within the first year post-transplant. Beyond demonstrating the clinical validity of AlloSure in detecting Acute Lung Allograft Dysfunction, a composite outcome of acute rejection and clinically meaningful infections, the study explores its clinical utility by capturing clinician decision-making processes to further demonstrate the practical clinical application of AlloSure. In addition, the study will collect samples to enable development of AlloMap Lung.

Products

Our suite of AlloSeq products are commercial “NGS”-based kitted solutions. These products include: AlloSeq[™] Tx, a high-resolution “HLA” typing solution; AlloSeq[™] cfDNA, a surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients; and AlloSeq[™] HCT, a solution for chimerism testing for stem cell transplant recipients.

Our other HLA typing products include: Olerup SSP, based on the “SSP” technology; and QTYPE, which uses real-time “PCR” methodology to perform HLA typing.

QTYPE was commercially launched at the end of September 2016. QTYPE enables HLA typing at a low to intermediate resolution for samples that require a fast turnaround time and uses real-time PCR methodology. QTYPE primarily focuses on low to intermediate resolution typing where high-resolution typing is not a requirement but even more rapid typing results are required, such as for deceased donor typing. Typing with QTYPE requires approximately one hour compared to the up to 2-3 hours that it takes to do traditional 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 150 different typing products. We offer one of the most up-to-date and comprehensive libraries of HLA typing kits based on SSP technology.

TruSight HLA was discontinued in December 2021 and we have progressively converted existing customers to AlloSeq. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These 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. Our AlloSeq products are designed to run on Illumina’s NGS instrumentation.

Research and Development

Our research and development activities focus on developing cutting-edge organ transplant surveillance solutions, further expanding on our pre-transplant matching solutions and seeking to continuously explore and develop new clinically relevant approaches to our products. Clinical operations dedicated to the design and implementation of high quality studies and registries for data collection to develop evidence to address unmet clinical needs of transplant recipients are included in research and development.

One area of focus for research and development activities has been to integrate acquired technology from the acquisitions of Ottr, XynManagement, TransChart, MedActionPlan, HLA Data Systems and MediGO, and pursuant to our license and collaboration agreements with OrganX and with a private entity. Integration of such technology with our current service offerings aligns a rich data set with augmented intelligence tools to better assess risk and help physicians better manage their daily patient care.

Research and development expenses of \$81.9 million, \$90.4 million and \$76.5 million were incurred during the years ended December 31, 2023, 2022 and 2021, respectively.

Our ongoing efforts include:

- increasing understanding of biological processes of transplant rejection through analysis of immune system gene expression and dd-cfDNA in ongoing clinical trials such as K-OAR and OKRA, and commercial laboratory testing to further improve clinical utility of AlloSure Kidney and KidneyCare;
- validation and clinical utility studies of AlloSure for other organs such as pancreas and liver;
- increasing understanding of biological processes of transplant rejection through analysis of genes/metagenes in archived and ongoing clinical trials, OAR registry, SHORE registry and commercial laboratory testing to further improve clinical utility of AlloMap Heart, AlloSure Heart and HeartCare;
- technology platform and procedure optimization as well as further advances of laboratory information management to increase efficiency and lower costs in our testing and laboratory operations;
- validation and clinical utility studies of dd-cfDNA reagents and software distributed outside the United States;
- developing solutions for monitoring the success of hematopoietic stem cell transplantation;
- developing solutions to identify allograft rejection in transplant biopsy tissue;
- further development of QTYPE to expand its addressable market by including additional genetic content;
- further development of NGS product lines such as AlloSeq Tx, AlloSeq cfDNA and AlloSeq HCT;
- merging and analyzing internal and public clinical data sets to better understand factors that impact short- and long-term outcomes;
- designing a multi-stakeholder transplant innovation ecosystem to accelerate improved patient management;
- integrating real world data to confirm and extend results from other clinical data sets;
- developing and deploying smart analytics and machine learning artificial intelligence that provide clinical utility with respect to patient health; and
- developing solutions for assessment of infection in transplant recipients.

Testing Services Advancement and Development

Our research and development efforts are not limited to specific technology platforms, biomarkers or methodologies. Instead, we aim to leverage current and future innovations in biomarker identification and measurement, study design and data integration in developing future solutions.

dd-cfDNA for Kidney Transplants

Our published DART and Assessing AlloSure Dd-cfDNA Monitoring Insights of Renal Allografts With Longitudinal Surveillance (ADMIRAL) clinical studies have established the clinical validity of AlloSure Kidney for kidney transplant patients. DART was the first report to establish clinical performance characteristics for dd-cfDNA in renal transplant patients and was based on a prospective, multicenter observational study. Elevations in AlloSure Kidney were found to be strongly correlated with active rejection, especially with ABMR.

The K-OAR study is the next step in developing data to support the clinical utility of AlloSure Kidney. K-OAR commenced in January 2018 and is a post-transplant clinical outcomes study in approximately 1,900 patients managed with AlloSure Kidney surveillance compared to a contemporary control group managed without AlloSure Kidney.

OKRA is a multicenter, prospective, observational registry, designed to measure outcomes of kidney transplant recipients managed with KidneyCare. KidneyCare complements AlloSure Kidney by including multimodality testing with the addition of AlloMap Kidney Gene Expression Profiling and prognostic graft assessment using iBox. OKRA targets more than 50 transplant centers and will enroll over 1,500 newly transplanted patients.

The ADMIRAL article reports that increased levels of dd-cfDNA detected using AlloSure Kidney are associated with allograft rejection. The long-term utility shown in a cohort of 1,092 patients supports the work of all of the publications prior to this. Data from the 1,092 kidney transplant recipients monitored for dd-cfDNA over a three-year period was analyzed to assess the association of dd-cfDNA with histologic evidence of allograft rejection. Elevation of dd-cfDNA was significantly correlated with clinical and subclinical allograft rejection. dd-cfDNA values of 0.5% or more were associated with a nearly three-fold increase in risk of development of de novo donor-specific antibodies and were determined to be elevated a median of 91 days ahead of donor specific antibody identification. Persistently elevated dd-cfDNA (more than one result above 0.5%) predicted over a 25% decline in the estimated glomerular filtration rate over three years (hazard ratio 1.97). Therefore, routine monitoring of dd-cfDNA allowed early identification of clinically important graft injury. Biomarker monitoring complemented histology and traditional laboratory surveillance strategies as a prognostic marker and risk-stratification tool post-transplant.

AlloMap Kidney Gene Expression Tool

The AlloMap Kidney test is a gene expression profile that quantifies immune quiescence in kidney transplant patients. AlloMap Kidney has exhibited robust performance characteristics with an accuracy correlation coefficient of 0.997 and a precision coefficient of variation of 0.049 across testing. Clinical validation using samples from prospective, multi-center studies demonstrated a sensitivity of 70% and specificity of 66% for allograft rejection, while the negative predictive value to AlloSure Kidney was 95% to discriminate rejection from quiescence at 10% prevalence of rejection. Two publications describe the performance of AlloMap Kidney: *Clinical Validation of an Immune Quiescence Gene Expression Signature in Kidney Transplantation* in Kidney360 in 2021 and *Validation of a gene expression signature to measure immune quiescence in kidney transplant recipients in the CLIA setting* in Biomarkers in Medicine in 2022.

dd-cfDNA for Heart Transplants

AlloSure Heart dd-cfDNA provides additional value for heart patient monitoring in addition to AlloMap Heart. The use of both together constitutes HeartCare.

Studies have reported that a higher percentage of dd-cfDNA in the bloodstream of patients is found with moderate or severe heart rejection compared to patients without rejection. A dd-cfDNA solution such as AlloSure for the heart helps clinicians identify recipients with a higher probability of rejection and determine which patients warrant a subsequent biopsy, because the likelihood of detecting rejection in the biopsy specimen would be enhanced.

Accordingly, we offer HeartCare. HeartCare combines the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from the two complementary measures: (i) AlloMap Heart – a measure of immune activation; and (ii) AlloSure Heart – which measures graft injury. HeartCare provides complementary information about distinct biological processes, such as immune quiescence, active injury, ACR and AMR in heart transplant recipients.

We have established our proprietary strategy for quantification of donor specific dd-cfDNA and published a validation study of AlloSure Heart in 2019. We offer AlloSure Heart as a laboratory-developed test for management of heart transplant recipients. HeartCare is offered for clinical use and HeartCare is included as the primary studied test in our SHORE registry of dd-cfDNA in association with gene-expression profiling (AlloMap Heart) in heart transplant recipients.

The ISHLT guidelines published in 2023 note the growing adoption of dd-cfDNA testing among heart transplant recipients. These guidelines advocate for lifelong surveillance of the transplanted heart for rejection and acknowledge the utility and evidence underlying the use of dd-cfDNA in surveillance for rejection in a framework of clinical surveillance. The guidelines also speak to the use of multimodality testing using gene expression profiling and dd-cfDNA in the surveilling the transplanted heart for rejection.

HistoMap

In May 2020, we established a partnership with Veracyte, Inc., pursuant to which we have certain exclusive worldwide field rights to develop and commercialize products, such as HistoMap using the nCounter technology from NanoString.

In 2021, we entered into a collaboration with Arkana Laboratories, a leading kidney pathology laboratory, to develop HistoMap Kidney, a gene expression profiling, or GEP, solution to identify allograft rejection types in transplant biopsy tissue. The partnership will combine our clinical and test development expertise with the deep biorepositories of Arkana. The first article from this partnership was published in the journal Laboratory Investigation in 2023, *Development and Validation of a Multi-Class Model Defining Molecular Archetypes of Kidney Transplant Rejection: A Large Cohort Study of the Banff Human Organ Transplant Gene Expression Panel*.

Product Advancement and Development

Our ongoing research and development for our lab products business is focused on kitted products for pre-transplant and post-transplant patient testing. In the last decade, the ubiquity of sequencing has unveiled significant additional sequence diversity in the HLA region on chromosome 6 of the human genome. While the clinical impact of some of the sequence diversity is unclear, many newly identified HLA alleles need to be integrated into ongoing updates of the QTYPE and AlloSeq Tx kits. We also introduced AlloSeq Tx at the 2019 ASHI Annual Meeting and continue to improve the product.

We are developing further improved versions of NGS HLA testing that will provide full gene coverage while streamlining the laboratory workflow. AlloSeq Tx is the first of its kind next-generation sequencing HLA typing solution, utilizing hybrid capture technology. This technology enables the most comprehensive sequencing available, covering more of the HLA genes than current solutions and adding coverage of non-HLA genes that may impact transplant patient matching and patient management.

We expanded our market-leading portfolio of NGS transplantation offerings with the global launch of AlloSeq cfDNA and AlloSeq HCT. These post-transplant surveillance products enable access to our dd-cfDNA technology to laboratories and patients outside the United States. Updated versions of these tests were introduced in 2023.

Finally, our research and development staff are collaborating to advance the synergies of products across the pre- and post-transplant continuum.

Patient and Digital Solutions Business Development

We develop, deploy and promote a rational set of software tools and data-driven services that provide clinical utility with respect to medication adherence and overall patient health. Our vision is to add smart analytics and machine learning to artificial intelligence in transplantation. Going forward, we will strive to bring our multi-modality testing solutions and machine learning algorithms to the transplant clinic under our AiTraC umbrella. AiTraC will utilize the large amounts of clinical data that are collected through our registry studies to provide caregivers with point of care decision-making support tools that allow them to stratify the patient population.

We acquired Otrr and XynManagement in 2019. In 2021, we acquired TransChart, MedActionPlan and TTP. In 2023, we acquired HLA Data Systems and MediGO. These acquisitions have strengthened our growing portfolio of transplant software solutions across the transplant patients' journey. We are committed to continue evolving these software programs, including medication adherence management, and further integrating them into transplant center electronic health record systems with the CareDx Pro Platform for a unified digital user experience. Our testing service offerings will also be integrated via the CareDx Pro Platform to offer clinicians a great experience. We are actively working on additional partnerships and patient-focused service offerings.

Reimbursement

We have been successful in achieving reimbursement for our testing services. Reimbursement for AlloSure Kidney comes primarily from Medicare. Reimbursement for AlloMap Heart comes primarily from Medicare and private third-party payers such as insurance companies and managed care organizations.

Medicare

We are reimbursed by Medicare for AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung tests performed on patients covered by Medicare. Tests performed on patients covered by Medicare represented 27%, 34% and 40% of all tests in 2023, 2022 and 2021, respectively. Approximately 53%, 64% and 68% of all testing services revenue was derived from Medicare for the years ended December 31, 2023, 2022 and 2021, respectively.

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017. The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841. AlloSure Kidney has received positive coverage decisions from several commercial payers, and is reimbursed by other private payers on a case-by-case basis.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

AlloSure Heart has been a covered service for Medicare beneficiaries since December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. AlloSure Heart has received a positive coverage decision from Geisinger Health and is covered for use throughout Kaiser.

Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries. The Medicare reimbursement rate for AlloSure Lung is \$2,753.

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

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 national payers. However, other private payers and Medicaid payers have not yet adopted positive coverage policies for AlloSure Kidney.

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 several BCBS plans and UnitedHealthcare. Many other payers have positive coverage policies for AlloMap Heart.

AlloSure Heart and AlloSure Kidney are covered by several commercial payers. 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.

International

Our lab products have a broad international presence. We sell directly to customers in many regions and also sell through third-party distributors and sub-distributors throughout Europe and the rest of the world.

Testing and Laboratory Operations

AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart 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, AlloSure Lung, AlloMap Heart, AlloSure Heart and other tests in the development pipeline for the next few years.

When a clinician orders AlloMap Heart, a blood sample is drawn and processed and sent via overnight courier to our laboratory. The test results are typically reported to the ordering clinician within two business days of receipt of the sample. Test samples that fail to meet quality control criteria are immediately re-tested and the ordering clinician is notified of the need to re-test if turnaround time will be affected.

When AlloSure Kidney, AlloSure Heart or AlloSure Lung is ordered by a clinician, a blood sample is drawn and sent overnight to our laboratory. Results are typically reported to the ordering clinician by fax or electronically via EMR or WebPortal within two business days of receipt of the sample. Test samples that fail to meet quality control criteria are immediately re-tested and the ordering clinician is notified of the need to re-test if turnaround time will be affected.

We rely solely on certain suppliers to provide some of the laboratory instruments and key reagents that we use to perform AlloSure Kidney, AlloSure Lung, AlloMap Heart, and AlloSure Heart 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.

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 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 and QTYPE. The facility has a certified Quality Management System, or QMS, to the ISO 13485: 2016 standard. 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 a valid EC certificate for compliance to Directive 98/79/EC Annex IV, excluding Sections 4 and 6, Full Quality Assurance System In Vitro Diagnostic Medical Devices. Annual surveillance audits are also conducted by the site's notified body to ensure ongoing compliance.

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, is used to support the production, packaging and labeling of our proprietary AlloSeq brand kits. The facility maintains a valid EC certificate for compliance to Directive 98/79/EC Annex IV, excluding Sections 4 and 6, Full Quality Assurance System In Vitro Diagnostic Medical Devices, and is certified to standards ISO 13485: 2016 and the Canadian Medical Devices Conformity Assessment System, or CMDCAS, for Medical Devices, undergoing the same certification and surveillance audit requirements. In 2023, we added contract manufacturing in the U.S. and Europe to our global manufacturing capabilities to support our growth.

Sales and Marketing

Testing Services Sales and Marketing Team

We have a direct field team in the United States that interacts with all aspects of the testing services channel, including sales, marketing, medical science liaison, managed care, and patient care management representatives.

Our marketing strategy focuses on the clinical benefits of AlloSure Kidney, AlloSure Lung, AlloSure Heart and AlloMap Heart, and the scientific validation that supports our tests. Our strategy includes education to clinicians and the care team at transplant centers, assistance with scheduling ordered tests for patients, and working with centers to adopt formal protocols.

Product Sales and Marketing Team

The product business has sales offices in Stockholm, Sweden; West Chester, Pennsylvania, United States; and Fremantle, Australia, which manage direct sales to customers and sales through third-party distributors.

Patient and Digital Solutions Sales and Marketing Team

Our sales teams are located in the United States. They manage customer sales for Ottr software, XynQAPI, Tx Access and MedActionPlan software. Our strategy includes educating clinicians and care teams at transplant centers through software demos. Our marketing team supporting the product marketing for Ottr, XynQAPI, AlloCare and other digital offerings is based in Brisbane, California. Our pharmacy sales support team is located in Flowood, Mississippi.

Competition

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

Testing Services

Our competition principally includes clinical reference labs and hospital labs 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, and Oncocyte Inc., or Oncocyte, 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, AlloSure Lung, AlloMap Heart, AlloSure Heart 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 labs 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

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. 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 in 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.

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, 2023, we had 10 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have one issued U.S. patent covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart, which will expire in March 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease, which will expire between April 2024 and September 2029.

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, Otrr 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 10 existing U.S. patents related to transplant rejection and autoimmunity, four are the product of an exclusive licensing agreement.

In May 2018, we entered into the License 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 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 patents covering methods and technology for measurement of gene expression in urine to diagnose kidney transplant rejection.

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

In March 2023, we entered into a license and collaboration agreement with a private entity pursuant to which we were granted an irrevocable, non-transferable right to commercialize 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, 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 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 survey and 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 March 2022 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2024.

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 continued 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, AlloMap Heart, AlloSure Kidney, AlloSure Lung and AlloSure Heart.

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 lab expertise and test procedures and correct analyses are followed.

In October 2023, the FDA proposed a new policy under which the FDA intends to provide greater oversight of LDTs, through a phase-out of its general enforcement discretion approach to LDTs. In connection with this, the FDA proposed a rule that would amend its regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug and Cosmetic Act. There is no assurance whether, or when, this proposed policy and/or rule will be adopted or as to the content of any policies or rules eventually adopted. Any future rulemaking, guidance, or other oversight of LDTs and clinical laboratories that develop and perform them, if and when finalized, may affect the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. A similar situation may occur if Congress decides to enable newly proposed regulations, such as the updated Verifying Accurate Leading-edge IVCT Development Act of 2021. There is no assurance whether, or when, this proposed policy and/or rule will be adopted or as to the content of any policies or rule that may eventually be adopted.

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

Health Insurance Portability and Accountability Act

Under the federal Health Insurance Portability and Accountability Act of 1996, or 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 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 protected health information, or PHI, occurs.

In addition to federal privacy regulations, there are a number of state laws governing 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 and 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 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 members of the U.S. Congress regarding their plans to repeal and replace the Affordable Care Act, and the Biden administration has announced plans to expand federal healthcare programs, such as Medicare and Medicaid. 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.

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, services, 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 also are 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 privacy laws, such as the California Consumer Privacy Act, or the CCPA, which took effect in January 2020, and was amended by the California Privacy Rights Act effective January 2023, secure new privacy rights for consumers and impose new obligations on us. Other states have similarly adopted privacy laws which took effect in 2023, including Virginia, Colorado, Utah and Connecticut. Additionally, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee and Texas also adopted privacy laws, which take effect from July 1, 2024 through 2026.

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. The number and scope of these requirements continues to grow, and there can be no assurance that we will be able to maintain any approvals that may be required to market our pre-transplant line of products outside the United States. Further, there may be significant expense and effort required to comply with these approvals for new products as they become ready for the commercial marketplace or for our existing products that we wish to sell abroad.

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 on 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 requirements of the In Vitro Diagnostic Regulation (2017/746) (IVDR). The IVDR requirements are 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 are also actively working with our Notified Body to bring the quality management system at the sites to be compliant with IVDR requirements by May 2025.

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, that went into effect in May 2018. It also addresses the transfer of personal data outside the EU and EEA. The GDPR aims primarily to give control to individuals over their personal data and to simplify the regulatory environment for international business by unifying the regulation within the EU. 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 and the data subjects' citizenship or residence—that is processing the personal information of data subjects inside the EEA. Following the United Kingdom's exit from the EU, the United Kingdom adopted the Data Protection Act 2018, which is the United Kingdom's implementation of the GDPR, or the UK GDPR. The UK GDPR imposes similar requirements for personal data about United Kingdom data subjects.

Controllers and processors of personal data must 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 data. Data controllers and processors must design information systems with privacy in mind. No personal data may be processed unless it is done under one of six lawful bases specified by the regulation (consent, contract, public interest, vital interest, legitimate interest or legal requirement). When the processing is based on consent, the data subject has the right to revoke it at any time.

Data controllers and processors must clearly disclose any data collection, declare the lawful basis and purpose for data processing, and state how long data is being retained and if it is being shared with any third parties or outside of the EEA, or, in the case of the UK GDPR, outside of the UK. Data subjects have the right to request a portable copy of the data collected by a data controller or processor in a common format, and, under certain circumstances, the right to have their data erased. Businesses must report data breaches to national supervisory authorities within 72 hours after becoming aware of the breach if they have an adverse effect on user privacy. In some cases, violators of the GDPR or UK GDPR may be fined up to €20 million or up to 4% of the annual worldwide turnover of the preceding financial year in case of an enterprise, 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, 2023, we had 643 employees, of which 635 were full-time employees. We had 157 employees in manufacturing operations and support, 164 in research and development, 194 in sales and marketing and 128 in general and administrative positions. As of December 31, 2023, 567 employees were located in the United States and 76 were located outside of the United States.

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, in 2022, we launched the LinkedIn

Learning platform, a learning library and repository for self-guided personal and professional learning opportunities for our employees. In addition, we dedicated time on a quarterly basis for all employees to explore learning and development topics. We call this Care4U Time.

In addition, we believe it is important to have regular engagement with our employees to understand their needs. Apart from regular weekly 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 United States 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 works councils and other 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.

We have a zero-tolerance policy for discrimination. In 2021, we established 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 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 Securities Exchange Act of 1934, as amended, 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 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, AlloSure Lung, AlloMap Heart, AlloSure Heart, or our other solutions due to historical practices or due to more favorable reimbursement policies associated with other means of monitoring transplants.
- 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.
- 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, AlloSure Lung, AlloMap Heart, AlloSure Heart, 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.
- We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. In addition, an application, data security or network incident may allow unauthorized access to our systems or data or our customers' data, disable access to our service, harm our reputation, create additional liability and adversely impact our financial results.
- 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, AlloSure Lung, AlloMap Heart and AlloSure Heart.
- 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, 2023, our net loss was \$190.3 million. As of December 31, 2023, we had an accumulated deficit of \$678.3 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of KidneyCare, HeartCare, AlloSeq, AiTraC and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;

- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the 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 our status as a public company; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

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

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

For the year ended December 31, 2023, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 53% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, the reimbursement rate for AlloMap Heart is currently \$3,240 for Medicare beneficiaries.

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

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

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

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

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

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

On a five-year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractors, or MAC, services. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U.S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for AlloMap Heart, AlloSure Kidney, AlloSure Heart or AlloSure Lung at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for AlloSure Kidney, AlloMap Heart, AlloSure Heart or AlloSure Lung could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

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

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

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

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

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

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

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

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

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

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

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

Reimbursement for AlloSure Kidney, AlloMap Heart and AlloSure Heart comes primarily from Medicare and private third-party payers such as insurance companies and managed care organizations. The reimbursement process can take six months or more to complete depending on the payer and a new LCD through Medicare takes approximately 18 months. See the discussion regarding the Billing Articles under the risk factor above titled *“We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance”*.

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

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

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

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

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

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

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

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18, 2020 in the U.S. District Court for the District of Delaware, or the Court, alleging we made false and misleading claims about the performance capabilities of AlloSure. The trial concluded on March 14, 2022, with the jury finding that Natera violated the Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding us \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury. Both parties have appealed and briefing is ongoing. Our appeal may be unsuccessful or, if it is successful and the damages are upheld, we may be unable to collect any monetary damages. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising.

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

In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13, 2020 in the Court alleging, among other things, that AlloSure infringes Natera’s U.S. Patent 10,526,658. This case was consolidated with our patent infringement suit on February 4, 2020. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera’s U.S. Patent 10,597,724. The suit seeks a judgment that we have infringed Natera’s patents, an order preliminarily and permanently enjoining us from any further infringement of such patents and unspecified damages. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera’s U.S. Patents 10,655,180 and 11,111,544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera’s U.S. Patent 10,526,658. On September 6, 2022, we withdrew our motion to dismiss. On December 11, 2023, the Court dismissed Natera’s U.S. Patent 10,597,724. Natera has appealed that decision. On January 26, 2024, following a five-day trial, a jury concluded that we did not infringe Natera’s U.S. Patent 10,655,180 but did infringe Natera’s U.S. Patent 11,111,544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera’s U.S. Patent 11,111,544 expires in September 2026. We anticipate continued litigation as to whether our current AlloSure process infringes the patent. Natera may also move for injunctive relief. We intend to seek judicial review of the verdict and contest any potential claims of ongoing infringement and any motion for injunctive relief. We intend to defend these matters vigorously, and believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

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

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

allegations in the amended complaint. On May 24, 2023, the court granted our motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against us, Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; and Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors. Under a briefing schedule ordered by the court on June 12, 2023, defendants filed a motion to dismiss and motion to strike the second amended complaint on July 26, 2023, plaintiffs' opposition was filed on August 30, 2023 and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 2023. The parties filed a joint status statement with the court on February 15, 2024. We intend to defend ourselves vigorously, and believe that we have good and substantial defenses to the claims alleged in the suit, but there is no guarantee that we will prevail.

Additionally, on September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Edelman Derivative Action, against us as nominal defendant and Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors; and the other members of our Board of Directors. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of our Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to us, violated Sections 14(a) and 20(a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

In addition, on February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California, or the Stevenson Derivative Action, against us as nominal defendant and Reginald Seeto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors; and other current and former members of our Board of Directors. The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the individual defendants breached their fiduciary duties as our directors and/or officers and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

On March 9, 2023, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action and stayed both actions pursuant to the terms of the stay order in the Edelman Derivative Action. The consolidated derivative action remains stayed. The parties in the Stevenson Derivative Action filed a joint status statement with the court on September 6, 2023, and the parties in the consolidated derivative action filed a joint status statement and administrative motion with the court on February 13, 2024.

Additionally, on February 8, 2024, Christian Jacobsen filed a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against us as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of our Board of Directors (the "Jacobsen Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of our Company, violated Section 14(a) of the Exchange Act, are liable for contribution under Sections 10(b) and 21(D) of the Exchange Act, engaged in unjust enrichment, waste of corporate assets, aiding and abetting, insider trading, and misappropriation of information, and/or are liable for indemnification. The suit seeks declaratory relief, disgorgement, and to recover alleged damages sustained by us as a result of the alleged violations, along with plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. The Jacobsen Derivative Action was designated related to the consolidated derivative action.

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

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

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.

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;
- lack of clinical validation data to support the effectiveness of the test;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- failure to obtain or maintain necessary clearances or approvals to market the test; or
- lack of commercial acceptance by patients, clinicians or third-party payers.

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.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of additional diagnostic solutions by us may be delayed and, as a result, our business will suffer and our stock price may decline.

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. In addition, 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.

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, AlloSure Lung, AlloMap Heart, AlloSure Heart 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, AlloSure Lung, AlloMap Heart, AlloSure Heart, 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, AlloSure Lung, AlloMap Heart, AlloSure Heart, our other products and patient and digital solutions and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our tests, products and patient and digital solutions could decline, which would harm our business and financial results.

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

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

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

If clinicians, hospital administrators and laboratories do not adopt and 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 have been, and we expect that our operating results will continue to be, subject to quarterly fluctuations. Our net income (loss) and other operating results will be affected by numerous factors, including:

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

- total operating expenses; and
- changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts.

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

If the use of AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart or any of our other solutions is not supported by studies published in peer-reviewed scientific and medical publications, and then periodically supplemented with additional support in peer-reviewed journals, the rate of adoption of our current and future solutions by clinicians and treatment centers and the rate of reimbursement of our current and future solutions by payers may be negatively affected.

Transplant, like all specialties, is based on evidence-based medicine. As a result, laying a strong foundation of evidence and improved clinical utility is essential in the adoption of the tools offered by us. The results of our studies involving AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart have been presented at major medical society congresses and published in peer-reviewed publications in leading medical journals. This continued presence in peer-reviewed publications is necessary to promote clinician adoption and favorable reimbursement decisions. We believe that peer-reviewed journal articles that provide evidence of the utility of our solutions or the technology underlying AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our other products and patient and digital solutions are very important to the commercial success of our solutions. 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, AlloSure Lung, AlloMap Heart, AlloSure Heart and our future solutions, and demonstrate the clinical benefits of these solutions. Clinicians may not adopt, and third-party payers may not cover or adequately reimburse for, our current and future products and patient and digital solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our diagnostic current and future products and patient and digital solutions provide accurate, reliable and cost-effective information that is useful in monitoring transplant recipients and making informed and timely treatment decisions.

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.

While we have had success in generating peer-reviewed publications regarding AlloSure Kidney, AlloSure Lung, AlloMap Heart, and AlloSure Heart, additional peer-reviewed publications regarding AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our future products and patient and digital solutions may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies that would be the subject of the article. If our current and future products and patient and digital solutions or the technology underlying AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or our future products and patient and digital solutions do not receive sufficient favorable exposure in peer-reviewed publications, the rate of clinician adoption and positive reimbursement coverage decisions could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for diagnostic solutions such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study.

To ensure the success of AlloSure Kidney and future tests based on donor-derived cell-free DNA, or dd-cfDNA, we will need to continue our efforts to complete and publicize research and trials, especially the Kidney Allograft Outcomes AlloSure Registry, or K-OAR, registry study, that provides evidence of the utility of dd-cfDNA and validate AlloSure Kidney as a solution.

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

Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute rejection in kidney and heart transplant recipients by utilizing biopsies. Many clinicians use AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloSure Kidney, AlloSure Lung, AlloMap Heart or AlloSure Heart as biopsy alternatives,

per se, if treatment center administrators view our test as an alternative to a biopsy but believe they would derive more revenue from the performance of biopsies, such administrators may be motivated to reduce or avoid the use of our test. While biopsies 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, donor specific antibodies, complete blood count, lipid profile and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs. Our competitors also include companies that are focused on the development and commercialization of molecular diagnostic tests. In the field of post-transplant surveillance, Natera, Eurofins, and Oncocyte, have commercially available molecular diagnostics tests.

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

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

In addition to businesses focused on pre-transplantation such as Thermo Fisher's One Lambda and Immucor, Inc.'s LIFECODES, companies that have not historically focused on transplantation but that possesses existing knowledge of dd-cfDNA technology have indicated they are considering this market.

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

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

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

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 additional 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 such as AlloSure Kidney 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.

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, AlloSure Lung, AlloMap Heart and AlloSure Heart depends, in large part, on our ability to perform AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart tests on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new

equipment or processes or hire new personnel could result in higher costs of processing or an inability to meet market demand in a timely manner.

There can be no assurance that we will be able to perform AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, 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 2022 to 2023, our revenue declined from \$321.8 million to \$280.3 million, which represents an annual decrease of (13)%. In the future, our revenue may not grow at all and it may continue to decline. We believe that our future revenue will depend on, among other factors:

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

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

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

We perform all of our testing services for the U.S. 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.

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 U.S. 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, AlloSure Lung, AlloMap Heart, AlloSure Heart, 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, AlloSure Lung, AlloMap Heart, AlloSure Heart 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.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition or results of operations, including the sustainability of our business over time. In addition, the SEC has announced proposed rules that, among other matters, will establish a framework for reporting of climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

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, AlloSure Lung, AlloMap Heart, AlloSure Heart or the other 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, 2023, we had cash, cash equivalents and marketable securities of \$235.4 million and an accumulated deficit of \$678.3 million. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

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

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our new solutions;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional FDA or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all, and might include the issuance of equity securities, debt, cash from collaboration agreements or a combination of these. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock and would result in dilution to our stockholders. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

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

Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we were to lose one or more of these key employees, including due to disease, disability or death, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. We do not currently maintain “key person” insurance on any of our employees.

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

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

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

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

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

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

There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill and other intangible assets, any of which could harm our business

and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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

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, AlloSure Lung, AlloMap Heart, AlloSure Heart 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. 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 U.S. 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 U.S., including:

- uncertain or changing regulatory registration and approval processes;
- failure by us to obtain regulatory approvals or adequate reimbursement for the use of our current and future solutions in various countries;
- competition from companies located in the countries in which we offer our products that may put us at a competitive disadvantage;
- financial risks, such as longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- logistics and regulations associated with shipping recipient samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to process solutions locally;
- difficulties in managing and staffing international operations and assuring compliance with foreign corrupt practices laws;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities;
- multiple, conflicting and changing laws and regulations such as healthcare regulatory requirements and other governmental approvals, permits and licenses;

- the imposition of trade barriers such as tariffs, quotas, trade wars, preferential bidding or import or export licensing requirements;
- political and economic instability, including interruptions in international relations, wars, terrorism and political unrest, general security concerns, outbreak of disease, boycotts, curtailment of trade and other business restrictions, including the ongoing conflict between Ukraine and Russia, the global impact of restrictions and sanctions imposed on Russia and the Israel-Hamas war;
- 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, 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. Any of these changes could adversely affect our business. Additionally, operating internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenue or profitability.

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. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

We are also unable to predict how changing global economic conditions or potential global health concerns will affect our partners, suppliers and distributors. Any negative impact of such matters on our partners, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

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.

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

Many of the countries in which we operate, including the U.S. and several of the members of the European Union, or EU, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; increased inflation globally and in the U.S. in particular; 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 business could be adversely impacted by inflation.

Inflation rates, particularly in the United States, have increased recently to levels not seen in years. We may experience inflationary pressures, primarily in personnel costs and with certain laboratory supplies. We anticipate inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be further diminished, our expenses could

increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows.

Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

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

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, automobile, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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.

We may use third party collaborators to help us develop, validate or commercialize any new diagnostic solutions, and our ability to commercialize such solutions could be impaired or delayed if these collaborations are unsuccessful.

We may in the future selectively pursue strategic collaborations for the development, validation and commercialization of any new diagnostic solutions we may develop. In any future third party collaboration, we may be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. 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.

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.

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

We have previously announced restructuring plans intended to optimize costs and simplify our organizational and corporate structure, and we most recently implemented such plans in January, May and December 2023. Any additional restructuring efforts may, divert management's attention, increase expenses on a short-term basis and lead to potential issues with employees, customers or suppliers. If we do not complete these activities in a timely manner; do not realize anticipated cost savings, synergies and efficiencies or business disruption occurs during or following such activities; or incur unanticipated charges, our business, financial condition, operating results and cash flows may be materially impaired.

Risks Related to Acquisitions, Partnerships and Investments

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

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

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

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

We may not be able to achieve the anticipated strategic benefits from our acquisition of Ottr Complete Transplant Management, or Ottr, or XynManagement, Inc., or XynManagement, TransChart, MedActionPlan, or the Transplant Pharmacy, or TTP, HLA Data Systems, MediGO, 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, HLA Data Systems, and MediGO's 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 agreed to minimum purchase commitments of finished products and raw materials from Illumina and 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.

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

Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. In addition, we are subject to and expect to continue to be subject to one or more audits under the CMS Recovery Audit Contractor, or RAC, program, the CMS Targeted Probe and Educate, or TPE, program, the Unified Program Integrity Contractors, or UPIC, program and other federal and state audits. Following two rounds of TPE audit in 2022 in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us in the first quarter of 2023 it was making a referral to CMS given disagreement as to the interpretation of the applicable LCDs. We appealed claims which had a basis for appeal. Ultimately, 100% of claims which were appealed were resolved in our favor. We have also met with CMS to discuss the difference in interpretation and intend to continue this dialogue regarding our position that the Noridian interpretation is inconsistent with the LCD, MolDX’s and Noridian’s prior associated responses to public comments, and medical necessity. In addition, in the second quarter of 2023, we received a record request from UPIC. UPIC has the authority to implement Medicare payment suspensions during the pendency of an audit and the ability to refer billing matters to other regulatory agencies. In the third quarter of 2023, the UPIC provided us with notice that we had received Medicare payments in error, resulting in an overpayment of \$38,975.02. The UPIC further stated that going forward it wished to support our efforts to remedy the billing issues and it would continue to monitor our Medicare claim submission patterns. We have appealed the denied claims consistent with our statutory rights. We expect further intensification of the regulatory environment surrounding the healthcare industry, as third-party firms engaged by CMS and others conduct extensive pre- and post-payment audits of claims data as well as medical and other records in order to identify improper payments to healthcare providers under the Medicare and Medicaid programs. We could be forced to expend considerable resources responding to these audits or other inquiries. These billing complexities, and the resulting uncertainty in obtaining payment for AlloSure Kidney, AlloMap Heart, AlloSure Heart and future solutions, as well as the results of Noridian’s referral to CMS and any audits or inquiries evaluating our services create a risk of further regulatory or enforcement action from these or other regulatory agencies, or that our claims are denied or that any historical reimbursement of such claims is subject to forfeiture and could negatively affect our revenue, cash flows and profitability.

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

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 U.S., 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%. The Protecting Access to Medicare Act of 2014 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 members of the U.S. Congress regarding plans to repeal and replace the Affordable Care Act, and the Biden administration has announced plans to expand 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 or repeal, replacement or expansion of the Affordable Care Act on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could decrease the amount of reimbursement available from governmental and other third-party payers. On April 1, 2013, cuts to the federal budget resulting from sequestration were implemented, requiring a 2% cut in Medicare payment for all services, including AlloSure Kidney and AlloMap Heart, and is expected to remain in effect through at least 2025. 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 and our future diagnostic solutions, increase costs, divert management’s attention and adversely affect our ability to generate revenue and achieve profitability.

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

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

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

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 March 2022 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2024.

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

The FDA has traditionally chosen not to exercise its authority to regulate laboratory developed tests, or LDTs, because it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as "in vitro diagnostic multivariate index assays," or IVDMIAs. We applied for, and obtained in August 2008, 510(k) clearance for AlloMap Heart for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

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

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

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

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

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

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

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

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

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. We previously received a civil investigative demand, or CID, from the United States Department of Justice, or DOJ, requesting that we produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the SEC in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. On September 25, 2023, we reported that by letter dated September 19, 2023, we were notified by the staff of the

SEC that the SEC has concluded its investigation as to our company and does not intend to recommend an enforcement action by the SEC against us. We also previously received an information request from a state regulatory agency. The state regulatory agency later requested that we submit an application for state licensure for certain specimen processing activities. We are in the process of applying for that license. We previously received a request for information from a separate state regulatory agency and we may receive additional requests for information from the DOJ or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the prior SEC subpoena, or the state regulatory agency information request raise or raised any issues regarding the safety or clinical utility of any of our products or services and are cooperating fully with the investigations and the request for information. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of the DOJ investigation 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.

Our patent position for AlloMap Heart is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and quiescent leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of December 31, 2023, we had 10 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have one issued U.S. patent covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart, which will expire in March 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease, which will expire between April 2024 and September 2029.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. For example, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid. The Court's finding does not have any impact on our ability to continue providing AlloSure. This ruling may limit our ability to prevent Natera and other competitors and third parties from developing and marketing products similar to ours and we may not be able to prevent Natera and others from developing or selling products that are covered by our products or technologies without payment to us. In addition, our exclusive license agreement with Stanford that previously covered certain patents related to diagnostic and predictive technologies terminated in October

2023. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

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

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

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

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

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. For example, see the risk factor above titled "*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*" for a discussion of our recently completed and ongoing litigation with Natera.

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

In the event we determine that a party is infringing our intellectual property rights, we may try to negotiate a license arrangement with such party or we may determine to initiate a lawsuit against such party. The process of negotiating a license with a third party can be lengthy, and may take months or even years in some circumstances. In addition, it is possible that third parties who we believe are infringing our intellectual property rights are unwilling to license our intellectual property from us on terms we can accept, or at all. For example, see the risk factor above titled "*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” for a discussion of our recently completed and ongoing litigation with Natera.

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

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

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

Filing, prosecuting, defending and enforcing patents on all of our technologies and solutions throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the U.S. 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 U.S. 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 U.S. may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

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

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

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

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

Our business is dependent on licenses from third parties.

We license technology from third parties necessary to develop and commercialize our products. On May 4, 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in transplantation diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients.

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

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

In March 2023, we entered into a license and collaboration agreement with a private entity pursuant to which we were granted an irrevocable, non-transferable right to commercialize their proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation for a period of four years with exclusive rights in the United States.

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

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

Risks Related to Cybersecurity and Data Privacy

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

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

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

We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, we may face increased cybersecurity risks due to our reliance on internet technology, which may create additional opportunities for cybercriminals to exploit vulnerabilities. While we maintain monitoring practices and protections for our information technology to reduce these risks and test our systems on an ongoing basis for any potential threats, there can be no assurance that these efforts will prevent a cyber-attack or other security breach.

Third parties have attempted, and may in the future attempt, to fraudulently induce employees, contractors or consumers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and/or physical facilities in order to gain access to our data or our critical information, which could result in significant legal and financial exposure. We have experienced cybersecurity incidents and expect that we will continue to be subject to cybersecurity attacks in the future. In addition, a contractor or other third party with whom we do business, as well as parties with which we do not do business, may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information. While we still continue to evaluate and implement additional protective measures to reduce the risk and detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third party training regarding phishing, malware, and other cyber risks, monitoring of networks and systems and maintenance of back up of protective systems), which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shut downs due to attack by hackers or breaches, phishing scams, ransomware, systems failures, computer viruses, employee errors or other malfeasance. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

Any such breach or interruption could compromise our networks or those of our third-party service providers, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill our payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future products and solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. We have insurance coverage

in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents. Furthermore, in the future such insurance may not be available on commercially reasonable terms, or at all.

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

Risks Related to Our Common Stock

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

Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. In 2023, our closing stock price ranged from \$4.90 to \$17.61 per share. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including:

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

Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, national stock exchanges, and in particular the market for life science companies, have experienced significant price and volume fluctuations that have often

been unrelated or disproportionate to the operating performance of those companies. Moreover, we may be subject to additional securities class action litigation as a result of volatility in the price of our common stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

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 prior decision to withdraw our revenue guidance for fiscal 2023;
- our decision to issue future financial guidance and the terms of such guidance; and
- general economic conditions and slow or negative growth of our markets.

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

Our executive officers, directors and holders of 5% or more of our outstanding common stock (based on the most recent public filings), and entities affiliated with them, beneficially own in the aggregate approximately 66.2% of our common stock as of February 26, 2024. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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.

During the year ended December 31, 2023, we purchased an aggregate of 2,942,997 shares of our common stock under the Repurchase Program for an aggregate purchase price of \$27.5 million. As of December 31, 2023, \$21.9 million remained available for future repurchases under the Repurchase Program.

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

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

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

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

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

We have identified material weaknesses in our internal control over financial reporting as of December 31, 2022, which were not remediated at December 31, 2023. If we are unable to remediate these material weaknesses and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner.

Effective internal control over financial reporting is necessary for us to provide reasonable assurance regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States. In connection with the preparation of our consolidated financial statements as of December 31, 2022 and for the year then ended, we identified material weaknesses in our internal control over financial reporting, which were not remediated at December 31, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management concluded that we had the following material weaknesses as of December 31, 2023:

- **General Information Technology Controls.** We did not design and maintain effective general information technology controls, or GITCs, for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology, or IT, program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) computer and network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement account balances and disclosures.
- **Purchase Order Approval Workflow.** We did not design and maintain effective process-level control activities related to procurement to ensure appropriate approval of purchase orders, which could affect the amount and classification of costs capitalized or expensed.
- **Committee of Sponsoring Organizations of the Treadway Commission (COSO) Framework.** We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an adequate process in place to complete its assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner.

These material weaknesses have not been remediated as of the date of this Annual Report on Form 10-K. Our management has been engaged in developing and implementing remediation plans to address the material weaknesses described above. However, the material weaknesses will not be fully remediated until management can demonstrate the full effectiveness of controls over a sufficient period of time, and we can give no assurance on the success of such measures or the outcome of our assessment of these measures at this time.

If the steps we take to remediate the material weaknesses are ineffective, these material weaknesses could result in material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filings of our required periodic reports. This might lead to investors losing confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities, which could require additional financial and management resources.

Furthermore, if we identify any new material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate our existing material weaknesses or avoid potential future material weaknesses.

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 of 1933, as amended, 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 of 1933, as amended. This provision does not apply to claims brought pursuant to the Securities Exchange Act of 1934, as amended, 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 U.S., which may adversely affect our operating results.

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

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

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

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

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

We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act, or Section 404, and other requirements will increase our costs and require additional management resources. Pursuant to Section 404, we are required to, among other things, file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We are continuing to implement and update new finance and accounting systems as we grow our business and organization and to satisfy internal control and reporting requirements.

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

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

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

If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting or otherwise fail to maintain or implement effective controls and procedures for financial reporting, we could be unable to accurately and timely report our financial position, results of operations, and cash flows or key operating metrics, which could result in late filings of our annual and quarterly reports under the Securities Exchange Act of 1934, as amended,

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.

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

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

ITEM 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.
- **Education and Awareness:** We provide 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 periodic 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 Committee of the Board, or the Audit Committee, 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 Committee, oversees our risk management program, including the management of cybersecurity threats. The Board and the Audit 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 Committee also receive prompt and timely information regarding any cybersecurity risk that meets pre-established reporting thresholds. Annually, the Board and the Audit Committee discuss our approach to overseeing cybersecurity threats with our Chief Information Security Officer/Chief Information Officer, or CISO/CIO, and other senior management members.

The CISO/CIO, in coordination with senior management including the Office of the Chief Executive Officer, or the CEO, 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 CISO/CIO 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 Committee when appropriate.

The CISO/CIO has served in various roles in information technology and information security for over 20 years, including serving as the Chief Information Security Officer of another public company for over 6 years. The CISO/CIO holds undergraduate and graduate degrees in computer science and has attained the professional certification of Certified Chief Information Security Officer. Our CEO, 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 Affects 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 “*We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. In addition, an application, data security or network incident may allow unauthorized access to our systems or data or our customers’ data, disable access to our service, harm our reputation, create additional liability and adversely impact our financial results*” 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, 2023:

<u>Location</u>	<u>Function</u>	<u>Square Footage</u>
United States		
Brisbane, California	Corporate headquarters	26,506
Brisbane, California	Research & development and clinical laboratories	68,318
West Chester, Pennsylvania	Sales office and distribution	6,336
Omaha, Nebraska	Digital solutions office	24,984
Columbus, Ohio	Digital solutions office	3,806
Flowood, Mississippi	Transplant pharmacy	4,800
Gaithersburg, Maryland	General office use	2,118
Europe		
Stockholm, Sweden	Research & development and product manufacturing	24,940
Australia		
Fremantle	Research & development and product manufacturing	11,593

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 9, *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 26, 2024, there were approximately 63 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.

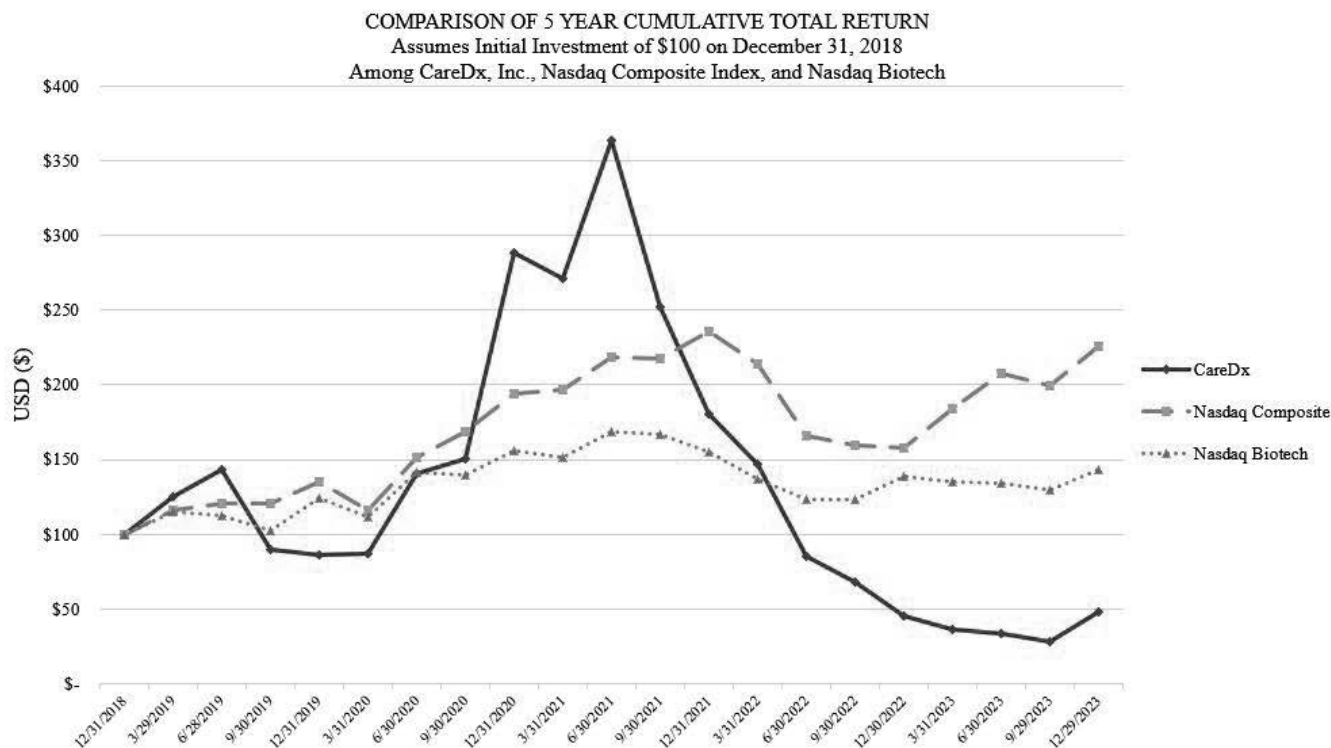
Dividend Policy

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. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Any payment of cash dividends will also 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 Securities Act of 1934, as amended, or 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, 2018 through December 29, 2023 against the Nasdaq Market Composite Index and Nasdaq Biotech Index, assuming a \$100 investment made on December 31, 2018. 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 2023.

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

During the quarter ended December 31, 2023, we effected stock repurchases pursuant to our stock repurchase program. In addition, 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, 2023 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 (4)	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
October 1, 2023 - October 31, 2023	103,711	(1)	\$ 5.86	92,000	\$ 47.2 (4)
November 1, 2023 - November 30, 2023	1,950,633	(2)	9.29	1,931,190	29.2 (4)
December 1, 2023 - December 31, 2023	780,625	(3)	9.77	755,569	21.9 (4)
Total	<u>2,834,969</u>			<u>2,778,759</u>	

(1) Comprised of: (a) 11,711 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$6.51, which represents the average fair market value of our common stock on the date of withholding, and (b) 92,000 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$5.78.

(2) Comprised of: (a) 19,443 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$7.18, which represents the average fair market value of our common stock on the date of withholding, and (b) 1,931,190 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$9.31.

(3) Comprised of: (a) 25,056 shares of our common stock withheld from employees for the payment of taxes, for which the average price paid per share with respect to withheld shares was \$11.43, which represents the average fair market value of our common stock on the date of withholding, and (b) 755,569 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of \$9.71.

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

ITEM 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 Securities and Exchange Commission. Historical results are not necessarily indicative of future results.

Overview and Recent Highlights

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

Testing Services

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

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our dd-cfDNA offering. In transplantation there is well-established literature from studies around the world demonstrating the value of dd-cfDNA in the management of solid organ transplantation. AlloSure Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA targeting polymorphisms in the DNA with an approach specifically designed for transplantation to differentiate dd-cfDNA.

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

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

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

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

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

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

Multiple studies have demonstrated that significant allograft injury can occur in the absence of changes in serum creatinine. Thus, clinicians have limited ability to detect injury early and intervene to prevent long-term damage using this marker. While histologic analysis of the allograft biopsy specimen remains the standard method used to assess injury and differentiate rejection from other injury in kidney transplants, as an invasive test with complications, repetitive biopsies are not well tolerated. AlloSure Kidney enables more frequent, quantitative and safer assessment of allograft rejection and injury status. Monitoring of graft injury through AlloSure Kidney allows clinicians to optimize allograft biopsies, identify allograft injury and guide immunosuppression management more accurately.

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Most recently, its utility in the assessment of clinical and sub-clinical rejection, was evaluated in over 1,000 patients and published in Kidney International.

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

KidneyCare

KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of iBox in one surveillance solution. We have not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or iBox.

In September 2019, we announced the enrollment of the first patient in the OKRA study, which is an extension of the K-OAR study. OKRA is a prospective, multi-center, observational registry of patients receiving KidneyCare for surveillance. Combined with the K-OAR study, more than 3,000 patients have been enrolled into the study.

Heart

AlloMap Heart is a gene expression test that helps clinicians monitor and identify heart transplant recipients with stable graft function who have a low probability of moderate-to-severe acute cellular rejection. Since 2008, we have sought to expand the adoption and utilization of our AlloMap Heart solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap Heart, secure positive reimbursement decisions from large private and public payers, develop and enhance our relationships with key members of the transplant community, including opinion leaders at major transplant centers, and explore opportunities and technologies for the development of additional solutions for post-transplant surveillance.

We believe the use of AlloMap Heart, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a heart transplant, can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and may help to determine the appropriate dosage levels of immunosuppressants. In 2008, AlloMap Heart received 510(k) clearance from the U.S. Food and Drug Administration for marketing and sale as a test in heart transplant recipient who have stable graft function at the time of testing, to aid in the identification of those who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 1, 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MolDX Medicare coverage decision for AlloSure Heart. Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MolDX to replace the former product-specific policies. The common policy LCD is titled “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. The Revised Billing Article requires certain companies, including

CareDx, to implement new processes to address the requirements related to Medicare claim submissions. MolDX has acknowledged that the Billing Article is a change as to its previous billing article, which provided coverage only where AlloSure Heart was used in conjunction with AlloMap Heart. We continued the Medicare reimbursement submissions for AlloMap Heart following the issuance of the new Billing Articles by MolDX. In addition, we informed Noridian on May 18, 2023 that until Noridian adopts the Revised Billing Article, we would continue to submit AlloMap Heart tests for reimbursement only when used in conjunction with AlloSure Heart as required by the billing article in effect at Noridian. We also informed Noridian on May 18, 2023 of our overall plans to comply with billing articles to the best of our ability. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers. On August 28, 2023, we further informed Noridian that beginning on August 17, 2023, when it publicized the adoption of the Revised Billing Article, we would submit AlloSure Heart and AlloMap Heart testing claims in compliance with the Revised Billing Article, including submitting AlloSure Heart claims when not used in conjunction with AlloMap Heart, and submitting HeartCare (AlloSure Heart and AlloMap Heart used together in a single patient encounter) claims for surveillance testing in lieu of a biopsy from 55 days to 370 days post-transplant. AlloMap Heart has received positive coverage decisions for reimbursement from many of the largest U.S. private payers.

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

We have also successfully completed several landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap Heart for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap Heart based on our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am. J. Transplantation 2006) study, which was published in the AJT. A subsequent clinical utility trial, Invasive Monitoring Attenuation through Gene Expression (Pham MX et al., N. Eng. J. Med., 2010), published in The New England Journal of Medicine, demonstrated that clinical outcomes in recipients managed with AlloMap Heart surveillance were equivalent (non-inferior) to outcomes in recipients managed with biopsies. The results of our clinical trials have also been presented at major medical society congresses. AlloMap Heart is now recommended as part of the International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

HeartCare includes the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure Heart in one surveillance solution. An approach to surveillance using HeartCare provides information from two complementary measures: (i) AlloMap Heart – a measure of immune activation, and (ii) AlloSure Heart – a measure of graft injury.

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, acute cellular rejection and antibody mediated rejection. In September 2018, we initiated the SHORE study, a prospective, multi-center, observational, registry of patients receiving HeartCare for surveillance. Patients enrolled in SHORE will be followed for 5 years with collection of clinical data and assessment of 5-year outcomes.

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

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

Lung

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

Cellular Therapy

In April 2020, we initiated a research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy. AlloCell is being commercialized through research

agreements with biopharma companies developing cell therapies. In 2021, we executed multiple additional agreements with biopharma therapeutics companies to use AlloCell in research and clinical studies.

In July 2021, we launched the Assessing Chimerism and Relapse of Bone marrow/ HCT transplant using AlloHeme Testing study, or the ACROBAT study. The ACROBAT study is a prospective, multicenter, observational cohort study to evaluate the use of AlloHeme, a microchimerism NGS tool to predict post-transplant relapse in patients with allogeneic hematopoietic cell transplants, or HCT. This study is currently enrolling patients.

Products

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

Our product portfolio includes AlloSeq Tx, QTYPE, Olerup SSP, AlloSeq HCT, and AlloSeq cfDNA. QTYPE enables Human Leukocyte Antigen, or HLA, typing at a low to intermediate resolution for samples that require a fast turnaround time and uses real-time polymerase chain reaction, or PCR, methodology. Olerup SSP is used to type HLA alleles based on the sequence specific primer, or SSP, technology.

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

We received CE mark authorization for AlloSeq cfDNA in January 2020. Our ability to increase the clinical uptake for AlloSeq cfDNA will be a result of multiple factors, including local clinical education, customer lab technical proficiency and levels of country-specific reimbursement.

In September 2019, we launched AlloSeq Tx, the first of its kind NGS high-resolution HLA typing solution utilizing hybrid capture technology. This technology enables the most comprehensive sequencing, covering more of the HLA genes than other solutions on the market and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx 17 received CE mark authorization in May 2020.

In June 2020, we launched AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market. AlloSeq HCT received CE mark authorization in May 2022.

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

In 2023, we continued to improve and progress our NGS product lines and software through exclusive and non-exclusive collaborations.

Patient and Digital Solutions

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

In May 2019, we acquired 100% of the outstanding common stock of Ottr. Ottr was formed in 1993 and is a leading provider of transplant patient management software, or the Ottr software, which provides comprehensive solutions for transplant patient management. The Ottr software enables integration with electronic medical records, or EMR, systems, including Cerner and Epic, providing patient surveillance management tools and outcomes data to transplant centers.

In August 2019, we acquired 100% of the outstanding common stock of XynManagement. XynManagement provides two unique solutions, XynQAPI software, or XynQAPI, and XynCare. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients reporting. XynCare includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

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

In January 2021, we acquired TransChart. TransChart provides EMR software to hospitals throughout the United States to care for patients who have or may need an organ transplant. As part of our acquisition of TransChart in January 2021, we acquired Tx Access, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs and closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

In June 2021, we acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

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

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

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

In January 2023, we acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. HLA Data Systems is a leader in the laboratory information management industry for human leukocyte antigen laboratories.

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

Financial Operations Overview

Revenue

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

Testing Services Revenue

Our testing services revenue is derived from AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung tests, which represented 75%, 82% and 87% of our total revenues for the years ended December 31, 2023, 2022 and 2021, respectively. Our testing services revenue depends on a number of factors, including (i) the number of tests performed; (ii) establishment of coverage policies by third-party insurers and government payers; (iii) our ability to collect from payers with whom we do not have positive coverage determination, which often requires that we pursue a case-by-case appeals process; (iv) our ability to recognize revenues on tests billed prior to the establishment of reimbursement policies, contracts or payment histories; and (v) how quickly we can successfully commercialize new product offerings.

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 12%, 9% and 9% of total revenue for the years ended December 31, 2023, 2022 and 2021, respectively. We recognize product revenue from the sale of products to end-users, distributors and strategic partners when all revenue recognition criteria are satisfied. We generally have a contract or a purchase order from a customer with the specified required terms of order, including the number of products ordered. Transaction prices are determinable and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement. There are no further performance obligations related to a contract and revenue is recognized at the point of delivery consistent with the terms of the contract or purchase order.

Patient and Digital Solutions Revenue

Our patient and digital solutions revenue is mainly derived from sales of our Ottr software, XynQAPI, MedActionPlan, mTilda (HLA Data Systems), MediGO, TransChart and Tx Access licenses, services and SaaS agreements across the digital portfolio, as well as our pharmacy sales at TTP. Patient and digital solutions revenue represented 13%, 9% and 3% of total revenue for the years ended December 31, 2023, 2022 and 2021, respectively.

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 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 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 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 and second revenue recognition criteria 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 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.

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

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

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

by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately \$7.8 million in the second quarter of 2023.

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

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 and products are delivered and risk of loss passed to the customer upon either shipping or delivery, as per the terms of the agreement.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue is mainly derived from a combination of SaaS and perpetual software license agreements entered into with various transplant centers, which are our customers for this class of revenue. The main performance obligations in connection with our SaaS and perpetual software license agreement are the following: (i) implementation services and delivery of the perpetual software license are considered a single performance obligation, (ii) post contract support. We allocate the transaction price to each performance obligation based on relative stand-alone selling prices of each distinct performance obligation. Digital revenue in connection with perpetual software license agreements is recognized over time based on our satisfaction of each distinct performance obligation in each agreement.

Perpetual software license agreements typically require advance payments from customers upon the achievement of certain milestones. We record deferred revenue in relation to these agreements when cash payments are received, or invoices are issued in advance of our performance, and generally recognize revenue over the contractual term, as performance obligations are fulfilled.

In addition, we derive patient and digital solutions revenue from software subscriptions and medication sales. We generally bill software subscription fees in advance. Revenue from software subscriptions is deferred and recognized ratably over the subscription term. The medication sales revenue is recognized based on the negotiated contract price with the governmental, commercial and non-commercial payers with any applicable patient co-pay. We recognize revenue from medication sales when prescriptions are 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. 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.

We use the straight-line attribution method for recognizing compensation expense. 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.

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 re-measured over their service performance period, which is generally the same as the vesting period.

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 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 re-measure this liability each reporting period and record changes in the fair value as a component of operating expenses. In circumstances where the contingent consideration is classified as equity, we recognize it at fair value at the acquisition date. Contingent consideration classified as equity is not subsequently re-measured.

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 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.

Our annual impairment test date is December 1st. A qualitative assessment is initially made to determine whether it is necessary to perform a quantitative assessment. A qualitative assessment includes, among others, consideration of: (i) past, current and projected future earnings; (ii) recent trends and market conditions; and (iii) valuation metrics involving similar companies that are publicly-traded and acquisitions of similar companies, if available. If this qualitative assessment indicates that it is more likely than not that an impairment exists, or if we decide to bypass this option, we proceed to perform the quantitative assessment. The quantitative assessment consists of a comparison between the estimated fair value of our reporting unit and its respective carrying amount including goodwill. Where the carrying value of the reporting unit exceeds its estimated fair value, we will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit.

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, 2023, 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, 2023, 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, which are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. Accordingly, amortization of the acquired in-process technology assets and favorable license agreement will not occur until the products reach commercialization.

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, 2023, 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 may not be recoverable. We then compare the carrying amounts of the assets with the future net undiscounted cash flows expected to be generated by such asset. If an impairment exists, we measure the impairment based on the excess carrying value of the asset over the asset's fair value determined using discounted estimates of future cash flows. We have not identified any material impairment losses to date.

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.

Factors Affecting Our Performance

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

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

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

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, we received a final MoIDX Medicare coverage decision for AlloSure Heart. In November 2020, Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MoIDX to replace the former product-specific policies. The foundational LCD is titled "MoIDX: Molecular Testing for Solid Organ Allograft Rejection" and the associated LCD numbers are L38568 (MoIDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the same MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753. Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance, is covered, subject to certain limitations, for Medicare beneficiaries through the same MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993.

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

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

period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$8.9 million, or the Impacted March Tests.

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

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

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

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

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

Reimbursement for AlloMap Heart

AlloMap Heart test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap Heart, as the ISHLT included AlloMap in its guidelines and payers adopted coverage policies and no longer consider AlloMap Heart to be experimental and investigational. The rate at which our tests are covered and reimbursed has, and is expected to continue to vary by payer. Revenue growth depends on our ability to maintain Medicare and third-party payer reimbursement, and to expand utilization by healthcare providers. See the discussion above under “*The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report*”.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, laboratories that receive the majority of their

Medicare revenues from payments made under the CLFS would report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 indicating that data for reporting for the new PAMA process would begin in 2017 and the new market-based rates took effect on January 1, 2018. Effective January 1, 2018, Medicare reimburses us \$3,240 for AlloMap Heart testing of Medicare beneficiaries, an increase from the 2017 reimbursement rate of \$2,841. The CARES Act froze then-current (2020) CMS CLFS rates through 2021. Further, the CARES Act delayed the reporting cycle under PAMA to January 1 and March 31, 2022. The next data collection period is January 1 through June 30, 2024.

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

Reimbursement for AlloSure Kidney

On September 26, 2017, we received notice that the MolDX Program developed by Palmetto GBA had set AlloSure Kidney reimbursement at \$2,841. Effective October 9, 2017, AlloSure Kidney was made available for commercial testing with Medicare coverage and reimbursement. See the discussion above under “*The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report*”. We believe the use of AlloSure Kidney, in conjunction with other clinical indicators, can help healthcare providers and their patients better manage long-term care following a kidney transplant. In particular, we believe AlloSure Kidney can improve patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

Reimbursement for AlloSure Heart

In October 2020, we received a final Palmetto MolDX Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, our Medicare Administrative Contractor, issued a parallel coverage policy granting coverage when used in conjunction with AlloMap Heart, which became effective in December 2020. The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. See the discussion above under “*The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report*”.

Reimbursement for AlloSure Lung

Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the MolDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753. See the discussion above under “*The Number of AlloMap Heart, AlloSure Lung, AlloSure Kidney and AlloSure Heart Tests We Receive and Report*”.

Continued Growth of Product Sales

We develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and solid organs.

Our historical product portfolio includes QTYPE and Olerup SSP. QTYPE enables speed and precision in HLA typing at a low to intermediate resolution for samples that require a fast turnaround time and uses real-time PCR methodology. QTYPE received CE mark certification on April 10, 2018. Olerup SSP is used to type HLA alleles based on the SSP technology.

On May 4, 2018, we entered into a license and collaboration agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina’s NGS product line for use in transplantation diagnostic testing. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina’s TruSight HLA product line. TruSight HLA was discontinued in December 2021 and we have progressively converted existing customers to AlloSeq Tx. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients.

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

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

In June 2020, we launched AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients. This technology has the potential to provide better sensitivity and data analysis compared to current solutions on the market. AlloSeq HCT received CE mark authorization in May 2022.

Continued Growth of Patient and Digital Sales

The growth of our patient and digital revenues is tied to the continued successful implementation of our Ottr, MedActionPlan and XynQAPI software businesses, as well as continued support and maintenance of existing MedActionPlan, Ottr and XynManagement customers. The Ottr software, TransChart, Tx Access and XynQAPI are currently implemented in multiple locations in the U.S. The Ottr software implementation and XynQAPI implementation and support teams are based in Omaha, Nebraska. In addition, patient solutions offered by TTP in Flowood, Mississippi include hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. With the addition of HLA Data Systems, we are now able to support HLA laboratories in managing their day-to-day workflow. With the addition of MediGO, we are now serving the organ procurement market for organ logistical needs.

Development of Additional Services and Products

Our development pipeline includes other solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. We expect to invest in research and development in order to develop additional services and products. Our success in developing new services and products will be important in our efforts to grow our business by expanding our potential market opportunity and diversifying our sources of revenue.

Timing of Research and Development Expenses

Our spending on research and development may vary substantially from quarter to quarter. We conduct clinical studies to validate our new products, as well as on-going clinical and outcome studies to further the published evidence to support our commercialized tests. Spending on research and development for both experiments and studies may vary significantly by quarter depending on the timing of these various expenses.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

(In thousands)

	<u>Year Ended December 31,</u>		
	<u>2023</u>	<u>2022</u>	<u>Change</u>
Revenue:			
Testing services revenue	\$ 209,685	\$ 263,748	\$ (54,063)
Product revenue	33,517	29,251	4,266
Patient and digital solutions	37,122	28,794	8,328
Total revenue	280,324	321,793	(41,469)
Operating expenses:			
Cost of testing services	57,642	72,286	(14,644)
Cost of product	18,379	17,639	740
Cost of patient and digital solutions	25,978	22,287	3,691
Research and development	81,866	90,388	(8,522)
Sales and marketing	83,334	96,027	(12,693)
General and administrative	117,868	100,397	17,471
Restructuring cost	2,320	—	2,320
Litigation expense	96,300	—	96,300
Total operating expenses	483,687	399,024	84,663
Loss from operations	(203,363)	(77,231)	(126,132)
Other income (expense):			
Interest income, net	11,867	3,762	8,105
Change in estimated fair value of common stock warrant liability	10	107	(97)
Other income (expense), net	1,343	(2,872)	4,215
Total other income	13,220	997	12,223
Loss before income taxes	(190,143)	(76,234)	(113,909)
Income tax (expense) benefit	(141)	(379)	238
Net loss	<u>\$ (190,284)</u>	<u>\$ (76,613)</u>	<u>\$ (113,671)</u>

Testing services revenue

Testing services revenue decreased by \$54.1 million, or (20)%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The decrease is primarily driven by Medicare revenue across AlloSure and AlloMap testing services associated with the implementation of the requirements related to Medicare claim submissions outlined in the Billing Articles. This decrease was partially offset by an increase in AlloSure Lung revenue for Medicare beneficiaries and an increase in the average selling price on non-Medicare testing services, primarily due to improved collection efforts during the year ended December 31, 2023.

Product revenue

Product revenue increased by \$4.3 million, or 15%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to growth from NGS typing products.

Patient and digital solutions revenue

Patient and digital solutions revenue increased by \$8.3 million, or 29%, during the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to organic growth related to our digital offerings and pharmacy revenue of \$2.7 million, with the remaining increase driven by the acquisitions of HLA Data Systems and MediGO.

Cost of testing services

Cost of testing services decreased by \$14.6 million, or (20)%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The decrease is attributed to lower testing services volume across AlloMap and AlloSure tests,

primarily due to the implementation of the revised billing practices to address the requirements related to Medicare claim submissions outlined in the Billing Articles, as well as lower royalty expense and cost saving measures.

Cost of product

Cost of product increased by \$0.7 million, or 4%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to an increase in cost of goods from sale of products, partially offset by cost saving measures.

Cost of patient and digital solutions

Cost of patient and digital solutions increased by \$3.7 million, or 17%, for the year ended December 31, 2023, compared to the year ended December 31, 2022. The increase in the cost of patient and digital solutions is in line with the increase in revenue for patient and digital solutions and is primarily due to an increase in cost of goods from sales in the pharmacy business and our digital offerings.

Research and development

Research and development expenses decreased by \$8.5 million, or (9)%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to a decrease in headcount and personnel-related costs of \$3.6 million, a decrease in consulting and professional fees of \$3.8 million and a decrease in stock-based compensation expense of \$0.8 million.

Sales and marketing

Sales and marketing expenses decreased by \$12.7 million, or (13)%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to a decrease in headcount and personnel-related costs of \$7.0 million, a decrease in stock-based compensation expense of \$1.9 million, a decrease in travel costs of \$1.1 million and a decrease in tradeshow and events of \$2.3 million.

General and administrative

General and administrative expenses increased by \$17.5 million, or 17%, for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to an increase in legal expenses of \$6.3 million, an increase in stock-based compensation expense of \$4.9 million, an increase in software expense of \$2.8 million and an increase in personnel-related costs of \$2.6 million.

Restructuring costs

Restructuring costs of \$2.3 million were incurred for the year ended December 31, 2023, which relate to employee severance pay and related costs.

Litigation expense

Litigation expense relates to the patent infringement claims filed by Natera against us and alleging that our product, AlloSure, infringes Natera's U.S. Patent 11,111,544. The jury awarded Natera an amount of \$96.3 million and we recorded the amount as litigation expense for the year ended December 31, 2023.

Interest income, net

Interest income, net, increased by \$8.1 million for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to interest income earned on U.S. agency securities and corporate debt securities as a result of rising interest rates.

Other income (expense), net

Other income (expense), net, increased by \$4.2 million for the year ended December 31, 2023, compared to the year ended December 31, 2022, primarily due to a \$1.5 million gain from sale of our investment in Miromatrix, a \$1.0 million gain from settlement of an obligation and a \$1.1 million gain from the recovery of an impaired loan that was already written-off and was included in the purchase price of an asset acquisition of a private entity.

Income tax (expense) benefit

For the year ended December 31, 2023, we recorded an income tax expense of \$0.1 million on a loss before income taxes of \$190.1 million. The difference in the effective tax rate for the year ended December 31, 2023 from the federal statutory tax rate is mainly due to the state income tax expense per the new research and development regulations, whereas in prior years we only recognized the deferred tax assets from foreign losses with the full valuation allowance.

For the year ended December 31, 2022, we recorded an income tax expense of \$0.4 million on a loss before income taxes of \$76.2 million. The difference in the effective tax rate for the year ended December 31, 2022 from the federal statutory tax rate is mainly due to the state income tax expense per the new research and development regulations, whereas in prior years we only recognized the deferred tax assets from foreign losses with the full valuation allowance.

Comparison of the Years Ended December 31, 2022 and 2021

For a discussion regarding our financial condition and results of operations for the year ended December 31, 2022 as compared to the year ended December 31, 2021, please refer to the discussion under the heading “Results of Operations—Comparison of the Years Ended December 31, 2022 and 2021” in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 27, 2023.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of \$678.3 million at December 31, 2023. As of December 31, 2023, we had cash, cash equivalents and marketable securities of \$235.4 million, and no debt outstanding.

With our continuing growth, we may require additional financing in the future to fund working capital and our development of future products. Additional financing might include issuance of equity securities, including through underwritten public offerings or “at-the-market” offerings, debt offerings or financings or a combination of these financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. We believe our existing cash balance and expected cash from existing operations, including cash from current license agreements and future license and collaboration agreements, or a combination of these, will be sufficient to meet our anticipated cash requirements for the next 12 months.

Shelf Registration Statement

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

Stock Repurchase Program

On December 3, 2022, our Board of Directors approved our Stock Repurchase Program, or the Repurchase Program, whereby we may purchase up to \$50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of our Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans and block trades and in privately negotiated transactions. During the year ended December 31, 2023, we purchased an aggregate of 2,942,997 shares of our common stock under the Repurchase Program for an aggregate purchase price of \$27.5 million. As of December 31, 2023, \$21.9 million remained available for future repurchases under the Repurchase Program.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2023, 2022 and 2021:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	\$ (18,388)	\$ (25,239)	\$ (19,294)
Investing activities	40,446	(228,502)	47,712
Financing activities	(29,606)	(4,535)	185,642
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(112)	23	(303)
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (7,660)</u>	<u>\$ (258,253)</u>	<u>\$ 213,757</u>

Cash Flows from Operating Activities

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

Net cash used in operating activities for the year ended December 31, 2023 was \$18.4 million. Our net loss of \$190.3 million was our primary use of cash in operating activities. Our net loss also included the following noncash items: \$49.1 million in stock-based compensation expense, \$14.4 million of depreciation and amortization expense, amortization of right-of-use assets of \$5.4 million, asset impairments and write-downs of \$1.0 million, amortization of premium on short-term marketable securities, net of \$4.9 million, gain on settlement of obligation and recovery of written-off investment of \$2.1 million and revaluation of contingent consideration to estimated fair value of \$2.7 million. Cash used in operating activities was also due to an increase in accounts receivable of \$16.0 million. Cash used in operating activities was partially offset by an increase in net operating assets of \$90.6 million.

Net cash used in operating activities for the year ended December 31, 2022 was \$25.2 million. Our net loss of \$76.6 million was our primary use of cash in operating activities. Our net loss also included the following noncash items: \$46.6 million in

stock-based compensation expense, \$11.6 million of depreciation and amortization expense, amortization of right-of-use assets of \$4.4 million, asset impairments and write-downs of \$0.8 million, unrealized loss on long-term marketable equity securities of \$1.2 million and amortization of premium on short-term marketable securities, net of \$0.4 million. Cash used in operating activities was also due to an increase in accounts receivable of \$6.7 million. Cash used in operating activities was partially offset by an increase in net operating assets of \$7.6 million.

Cash Flows from Investing Activities

For the year ended December 31, 2023, net cash provided by investing activities was \$40.4 million and primarily related to proceeds from maturities of marketable securities of \$256.0 million and sale of corporate equity securities of \$2.5 million. These proceeds were partially offset by the purchase of short-term marketable securities of \$201.2 million, additions of capital expenditures of \$8.3 million, payments for acquired intangibles of \$0.9 million, purchase of corporate equity securities of \$1.0 million and acquisition of business, net of cash acquired of \$6.7 million.

For the year ended December 31, 2022, net cash used in investing activities was \$228.5 million and primarily related to the purchase of short-term marketable securities of \$315.1 million, additions of capital expenditures, net of \$21.2 million, payments for acquired intangibles of \$3.1 million, and acquisition of business, net of cash acquired of \$0.6 million. These payments were partially offset by the proceeds of \$111.6 million for the maturities of short-term marketable securities.

Cash Flows from Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 was \$29.6 million and primarily related to repurchase and retirement of common stock of \$27.5 million, taxes paid related to net share settlements of restricted stock units of \$3.1 million and payments of contingent consideration of \$0.6 million. These payments were partially offset by the proceeds from exercises of stock options of \$0.1 million and proceeds from issuances of shares of common stock under our employee stock purchase plan of \$1.5 million.

Net cash used in financing activities for the year ended December 31, 2022 was \$4.5 million and primarily related to taxes paid related to net share settlements of restricted stock units of \$5.9 million, payments of contingent consideration of \$2.6 million, and repurchase and retirement of common stock of \$0.6 million. These payments were partially offset by the proceeds from exercises of stock options of \$2.4 million and proceeds from issuances of shares of common stock under our employee stock purchase plan of \$2.2 million.

For a discussion regarding our cash flows for the year ended December 31, 2021, 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, 2022, filed with the SEC on February 27, 2023.

Contractual Obligations

For a discussion regarding our significant contractual obligations as of December 31, 2023 and the effect those obligations are expected to have on our liquidity and cash flows in future periods, please refer to Note 9 of the 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 or government regulations, unanticipated events in foreign countries could have a material adverse effect on our operations.

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 and cash equivalents and marketable securities of \$235.4 million at December 31, 2023, which consisted of bank deposits and money market funds, and we had cash, cash equivalents and marketable securities of \$293.1 million at December 31, 2022, which consisted of bank deposits and money market funds. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of \$2.4 million on our consolidated balance sheets.

Foreign Currency Exchange Risk

We have operations in Sweden and Australia and sell to other countries throughout the world. As a result, we are subject to significant foreign currency risks, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing services revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in U.S. dollars and the Euro. Our patient and digital solutions revenue is primarily denominated in U.S. dollars. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Swedish Krona, the Euro, and the Australian dollar, which are also subject to fluctuations due to changes in foreign currency exchange rates. An unfavorable 10% change in foreign currency exchange rates for our assets and liabilities denominated in foreign currencies at December 31, 2023, would have negatively impacted our financial results for the year ended December 31, 2023 by \$0.6 million and our product revenue by \$1.4 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. 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**

	<u>Page No.</u>
Reports of Independent Registered Public Accounting Firm (PCAOB ID No. 34)	87
Consolidated Balance Sheets	92
Consolidated Statements of Operations	93
Consolidated Statements of Comprehensive Loss	94
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity	95
Consolidated Statements of Cash Flows	96
Notes to Consolidated Financial Statements	97

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders 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, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 28, 2024, expressed an adverse opinion on the Company's internal control over financial reporting because of material weaknesses.

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 Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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 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 history of reimbursements.

The transaction price estimate includes analysis of an average reimbursement per test and a percentage of tests reimbursed. This estimate requires significant judgement. 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 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, included the following, among others:

- 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 2023.
 - 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.

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

Critical Audit Matter Description

Revenue recognized for tests billed to Medicare is based on the agreed current reimbursement rate per test adjusted for historical collection trends where applicable. During 2023, new billing articles (the Billing Articles) issued by Palmetto MolDX, or MolDX, impacted Medicare coverage for certain of the Company's tests, including AlloSure Kidney, AlloSure Heart and AlloMap Heart, and required the Company to implement new processes to address the requirements related to the Medicare claim submissions for reimbursement.

We identified management's determination of whether the reimbursement claim submission for an AlloSure Kidney, AlloSure Heart, or AlloMap Heart test for which Medicare is the payer complied with the requirements of the Billing Articles, as a critical audit matter because of the challenging judgments required to determine if a reimbursement claim submission complied with the requirements of the Billing Articles. This required a high degree of auditor judgment and increased extent of effort when performing audit procedures to determine if the reimbursement claim submission for the test met the new requirements of the Billing Articles.

How the Critical Audit Matter Was Addressed in the Audit

- We read the Billing Articles regarding the requirements for Medicare reimbursement for each type of testing service.
- We made inquiries of members of the Company's accounting department, billing department, and legal department regarding the impact of the Billing Articles and the effects on revenue recognition.
- We tested the Company's revised billing practices in response to the Billing Articles and evaluation of whether collection of consideration was probable when Medicare was identified as the payer, by making selections and agreeing required test information to source documents and tracing to cash receipts received from Medicare through December 31, 2023.

Impact on Audit of Financial Statements Because of Material Weaknesses in Internal Control Over Reporting - Refer to Management's Annual Report on Internal Control Over Financial Reporting

Critical Audit Matter Description

As discussed in Management's Annual Report on Internal Control Over Financial Reporting, the Company identified material weaknesses across multiple components of the Internal Control – Integrated Framework (2013) issued by COSO.

Because these material weaknesses impact the Company's controls over information technology (IT) systems and business processes, affect substantially all financial statement account balances and disclosures, and required us to increase the extent of our audit effort, including the need to modify the nature and extent of audit evidence obtained, we have identified the impact to our audit procedures as a result of the material weaknesses as a critical audit matter.

How the Critical Audit Matter Was Addressed in the Audit

As a result of the material weaknesses, in performing our audit procedures we lowered the threshold for investigating differences between recorded amounts and independent expectations developed by us that we would have otherwise used, and increased the number of selections we would have otherwise made if the Company's controls were designed and operating

effectively. In addition, we performed additional procedures to test the completeness and accuracy of the information included in all system reports or information generated by the Company's IT systems which were utilized for audit evidence.

/s/ Deloitte & Touche LLP

San Jose, California

February 28, 2024

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders 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, 2023, 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, because of the effect of the material weaknesses identified below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2023, 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, 2023, of the Company and our report dated February 28, 2024, 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 Annual 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.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management’s assessment:

General Information Technology Controls (GITCs)

The Company did not design and maintain effective general information technology controls (“GITCs”) for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, the Company did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology (“IT”) program and data changes affecting financial IT

applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) computer and network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement accounts and disclosures.

Purchase Order Approval Workflow

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

COSO Framework

The Company did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of the Company's internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of the Company's internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, the Company's management concluded that the Company did not have an adequate process in place to complete its assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2023, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte & Touche LLP

San Jose, California
February 28, 2024

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

	As of December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,197	\$ 89,921
Marketable securities	153,221	203,168
Accounts receivable	51,061	66,312
Inventory	19,471	19,232
Prepaid and other current assets	7,763	9,216
Total current assets	313,713	387,849
Property and equipment, net	35,246	35,529
Operating leases right-of-use assets	29,891	34,689
Intangible assets, net	45,701	43,051
Goodwill	40,336	37,523
Restricted cash	586	522
Other assets	1,353	3,828
Total assets	<u>\$ 466,826</u>	<u>\$ 542,991</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 12,872	\$ 9,942
Accrued compensation	19,703	16,902
Accrued and other liabilities	45,497	49,131
Total current liabilities	78,072	75,975
Deferred tax liability	136	—
Common stock warrant liability	—	32
Deferred payments for intangible assets	2,461	2,418
Operating lease liability, less current portion	28,278	33,406
Other liabilities	96,551	249
Total liabilities	205,498	112,080
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: \$0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock: \$0.001 par value; 100,000,000 shares authorized at December 31, 2023 and 2022; 51,503,377 shares issued and outstanding at December 31, 2023; 53,583,301 shares issued and 53,533,250 shares outstanding at December 31, 2022	49	52
Additional paid-in capital	946,511	898,806
Accumulated other comprehensive loss	(6,963)	(7,503)
Accumulated deficit	(678,269)	(460,444)
Total stockholders' equity	261,328	430,911
Total liabilities and stockholders' equity	<u>\$ 466,826</u>	<u>\$ 542,991</u>

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,		
	2023	2022	2021
Revenue:			
Testing services revenue	\$ 209,685	\$ 263,748	\$ 259,285
Product revenue	33,517	29,251	26,832
Patient and digital solutions	37,122	28,794	10,280
Total revenue	280,324	321,793	296,397
Operating expenses:			
Cost of testing services	57,642	72,286	71,251
Cost of product	18,379	17,639	18,930
Cost of patient and digital solutions	25,978	22,287	7,208
Research and development	81,866	90,388	76,525
Sales and marketing	83,334	96,027	77,245
General and administrative	117,868	100,397	74,964
Restructuring costs	2,320	—	—
Litigation expense (Note 17)	96,300	—	—
Total operating expenses	483,687	399,024	326,123
Loss from operations	(203,363)	(77,231)	(29,726)
Other income (expense):			
Interest income, net	11,867	3,762	160
Change in estimated fair value of common stock warrant liability	10	107	106
Other income (expense), net	1,343	(2,872)	(2,628)
Total other income (expense)	13,220	997	(2,362)
Loss before income taxes	(190,143)	(76,234)	(32,088)
Income tax (expense) benefit	(141)	(379)	1,426
Net loss	<u>\$ (190,284)</u>	<u>\$ (76,613)</u>	<u>\$ (30,662)</u>
Net loss per share (Note 3):			
Basic	<u>\$ (3.54)</u>	<u>\$ (1.44)</u>	<u>\$ (0.59)</u>
Diluted	<u>\$ (3.54)</u>	<u>\$ (1.44)</u>	<u>\$ (0.59)</u>
Weighted-average shares used to compute net loss per share:			
Basic	<u>53,764,705</u>	<u>53,321,625</u>	<u>52,241,076</u>
Diluted	<u>53,764,705</u>	<u>53,321,625</u>	<u>52,241,076</u>

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

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

	Year ended December 31,		
	2023	2022	2021
Net loss	\$ (190,284)	\$ (76,613)	\$ (30,662)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	540	(2,833)	(2,574)
Net comprehensive loss	<u>\$ (189,744)</u>	<u>\$ (79,446)</u>	<u>\$ (33,236)</u>

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

CareDx, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital		Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	49,441,166	\$ 49	632,253	\$	(2,096)	\$ (352,527)	\$ 277,679
Issuance of common shares through public equity offering, net of commissions and offering costs of \$12,495	2,211,538		2	188,853	—	—	188,855
Contingent consideration classified as equity	—		—	(222)	—	—	(222)
Issuance of common stock under employee stock purchase plan	45,464		2,139		—	—	2,139
RSU settlements, net of shares withheld	464,693		(18,441)		—	—	(18,441)
Issuance of common stock for services	3,984		296		—	—	296
Issuance of common stock for cash upon exercise of stock options	753,383		1	12,775	—	—	12,776
Issuance of common stock for cash upon exercise of warrants	3,132		205		—	—	205
Employee stock-based compensation expense	—		35,825		—	—	35,825
Foreign currency translation adjustment	—		—	(2,574)	—	—	(2,574)
Net loss	—		—	—	—	(30,662)	(30,662)
Balance at December 31, 2021	52,923,360		853,683		(4,670)	(383,189)	465,876
Issuance of common stock under employee stock purchase plan	93,422		2,230		—	—	2,230
Repurchase and retirement of common stock	(50,051)		—		—	(642)	(642)
RSU settlements, net of shares withheld	411,176		(6,067)		—	—	(6,067)
Issuance of common stock for services	12,764		319		—	—	319
Issuance of common stock for cash upon exercise of stock options	142,579		2,435		—	—	2,435
Employee stock-based compensation expense	—		46,206		—	—	46,206
Foreign currency translation adjustment	—		—	(2,833)	—	—	(2,833)
Net loss	—		—	—	—	(76,613)	(76,613)
Balance at December 31, 2022	53,533,250		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 for cash 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

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,		
	2023	2022	2021
Operating activities:			
Net loss	\$ (190,284)	\$ (76,613)	\$ (30,662)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Stock-based compensation	49,086	46,553	36,081
Asset impairments and write-downs	1,000	840	2,437
Depreciation and amortization	14,386	11,595	8,797
Amortization of right-of-use assets	5,438	4,412	3,088
Unrealized loss on long-term marketable equity securities	—	1,181	1,743
Realized gain on sale of long-term marketable equity securities, net	(284)	—	—
Loss on disposal of asset	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)	(107)	(106)
Revaluation of contingent consideration to estimated fair value	2,677	727	(609)
Accretion of discount and amortization of premium on short-term marketable securities, net	(4,927)	390	1,129
Other non-cash items	—	—	(222)
Changes in operating assets and liabilities:			
Accounts receivable	16,016	(6,660)	(24,416)
Inventory	54	(2,859)	(6,927)
Prepaid and other assets	1,767	(1,049)	(5,144)
Accounts payable	2,904	(2,054)	1,789
Accrued compensation	2,655	(9,251)	7,516
Accrued and other liabilities	89,608	11,327	10,690
Accrued royalties	(1,557)	—	—
Operating lease liabilities, net	(5,418)	(3,456)	(2,603)
Refund liability - CMS advance payment	—	—	(20,496)
Change in deferred taxes	566	(215)	(1,379)
Net cash used in operating activities	(18,388)	(25,239)	(19,294)
Investing activities:			
Maturities of short-term marketable securities	256,038	111,587	88,905
Purchases of short-term marketable securities	(201,165)	(315,145)	—
Purchases of long-term marketable securities	—	—	(5,500)
Purchase of corporate equity securities	(965)	—	—
Sale of corporate equity securities	2,460	—	—
Additions of capital expenditures	(8,344)	(21,234)	(13,559)
Acquisition of intangible assets	(896)	(3,100)	(6,700)
Acquisition of business, net of cash acquired	(6,682)	(610)	(15,434)
Net cash provided by (used in) investing activities	40,446	(228,502)	47,712
Financing activities:			
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	—	—	188,855
Payment of contingent consideration	(625)	(2,625)	—
Principal payments on finance lease obligations	—	—	(66)
Repurchase and retirement of common stock	(27,541)	(642)	—
Proceeds from exercise of warrants	4	—	4
Proceeds from exercise of stock options	120	2,435	12,775
Proceeds from issuance of common stock under employee stock purchase plan	1,495	2,230	2,139
Taxes paid related to net share settlement of restricted stock units	(3,059)	(5,933)	(18,065)
Net cash (used in) provided by financing activities	(29,606)	(4,535)	185,642
Effect of exchange rate changes on cash and cash equivalents	(112)	23	(303)
Net (decrease) increase in cash, cash equivalents and restricted cash	(7,660)	(258,253)	213,757
Cash, cash equivalents, and restricted cash at beginning of period	90,443	348,696	134,939
Cash, cash equivalents, and restricted cash at end of period	\$ 82,783	\$ 90,443	\$ 348,696
Supplemental disclosures of cash information			
Cash paid for interest	\$ —	\$ 8	\$ 1
Cash paid for income taxes	\$ 738	\$ 392	\$ 14
Supplemental disclosures of cash flow information			
Shares issued in lieu of payment	\$ 216	\$ 319	\$ 296
Operating lease right-of-use assets	\$ 607	\$ 22,267	\$ 6,079
Purchases of capital expenditures in accounts payable and accrued liabilities	\$ 647	\$ 1,423	\$ 3,953
Employee stock purchase plan shares included in accrued compensation	\$ 556	\$ 686	\$ 1,521
Contingent consideration	\$ 3,499	\$ —	\$ 5,341

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 leading precision medicine company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients and caregivers. The Company’s headquarters are in Brisbane, California. The primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia; and Stockholm, Sweden.

The Company’s commercially available testing services consist of AlloSure® Kidney, a donor-derived cell-free DNA (“dd-cfDNA”) solution for kidney transplant patients, AlloMap® Heart, a gene expression solution for heart transplant patients, AlloSure® Heart, a dd-cfDNA solution for heart transplant patients, and AlloSure® Lung, a dd-cfDNA solution for lung transplant patients. The Company has initiated several clinical studies to generate data on its existing and planned future testing services. In April 2020, the Company announced its first biopharma research partnership for AlloCell, a surveillance solution that monitors the level of engraftment and persistence of allogeneic cells for patients who have received cell therapy transplants. The Company also offers high-quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. The Company also provides digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management (“Ottr”) and XynManagement, Inc. (“XynManagement”), as well as the acquisitions of TransChart LLC (“TransChart”), MedActionPlan.com, LLC (“MedActionPlan”) and The Transplant Pharmacy, LLC (“TTP”) in 2021, HLA Data Systems, LLC (“HLA Data Systems”) in January 2023 and MediGO, Inc. (“MediGO”) in July 2023.

Testing Services

AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a Local Coverage Determination (“LCD”), first issued by Palmetto MoIDX (“MoIDX”), which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and then adopted by Noridian Healthcare Solutions, the Company’s Medicare Administrative Contractor (“Noridian”). The Medicare reimbursement rate for AlloSure Kidney is currently \$2,841.

AlloMap Heart has been a covered service for Medicare beneficiaries since January 2006. The Medicare reimbursement rate for AlloMap Heart is currently \$3,240. In October 2020, the Company received a final MoIDX Medicare coverage decision for AlloSure Heart. In November 2020, Noridian issued a parallel coverage policy granting coverage for AlloSure Heart when used in conjunction with AlloMap Heart, which became effective in December 2020. In 2021, Palmetto and Noridian issued coverage policies written by MoIDX to replace the former product-specific policies. The foundational LCD is titled “MoIDX: Molecular Testing for Solid Organ Allograft Rejection” and the associated LCD numbers are L38568 (MoIDX) and L38629 (Noridian). The Medicare reimbursement rate for AlloSure Heart is currently \$2,753. Effective May 9, 2023, AlloSure Lung is covered for Medicare beneficiaries through the same MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for AlloSure Lung is \$2,753. Effective April 1, 2023, HeartCare, a multimodality testing service that includes both AlloMap Heart and AlloSure Heart provided in a single patient encounter for heart transplant surveillance, is covered, subject to certain limitations, for Medicare beneficiaries through the same MoIDX LCD (Noridian L38629). The Medicare reimbursement rate for HeartCare is \$5,993.

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

In May 2021 and March 2023, the Company purchased a minority investment of common stock in the biotechnology company Miromatrix Medical, Inc. (“Miromatrix”) for an aggregate amount of \$5.1 million, and the investment is marked to market. Miromatrix works to eliminate the need for an organ transplant waiting list through the development of implantable engineered biological organs. In December 2023, Miromatrix was acquired by United Therapeutics Corporation.

Clinical Studies

In January 2018, the Company initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study (“K-OAR”) to develop additional data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients. K-OAR is a multicenter, non-blinded, prospective observational cohort study which has enrolled more than 1,900 renal transplant patients who will receive AlloSure Kidney long-term surveillance.

In September 2018, the Company initiated the Surveillance HeartCare™ Outcomes Registry (“SHORE”). SHORE is a prospective, multi-center, observational registry of patients receiving HeartCare for surveillance. HeartCare combines the gene expression profiling technology of AlloMap Heart with the dd-cfDNA analysis of AlloSure® Heart in one surveillance solution.

In September 2019, the Company announced the commencement of the Outcomes of KidneyCare on Renal Allografts (“OKRA”) study, which is an extension of K-OAR. OKRA is a prospective, multi-center, observational, registry of patients receiving KidneyCare for surveillance. KidneyCare combines the dd-cfDNA analysis of AlloSure Kidney with the gene expression profiling technology of AlloMap Kidney and the predictive artificial intelligence technology of iBox for a multimodality surveillance solution. The Company has not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare.

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

Products

The Company’s suite of AlloSeq products are commercial next generation sequencing (“NGS”)-based kitted solutions. These products include: AlloSeq™ Tx, a high-resolution Human Leukocyte Antigen (“HLA”) typing solution, AlloSeq™ cfDNA, a surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq™ HCT, a solution for chimerism testing for stem cell transplant recipients.

The Company’s other HLA typing products include: Olerup SSP®, based on the sequence specific primer (“SSP”) technology; and QTYPE®, which uses real-time polymerase chain reaction (“PCR”) methodology, to perform HLA typing.

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

Patient and Digital Solutions

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

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

In January 2021, the Company acquired TransChart. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As part of the Company’s acquisition of TransChart in January 2021, the Company acquired TxAccess, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs and closely follow and assist patients through the transplant waitlist process and, ultimately, through transplantation.

In June 2021, the Company acquired the Transplant Hero patient application. The application helps patients manage their medications through alarms and interactive logging of medication events.

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

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

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

In January 2023, the Company acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. HLA Data Systems is a leader in the laboratory information management industry for human leukocyte antigen laboratories.

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

Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of \$678.3 million at December 31, 2023. As of December 31, 2023, the Company had cash and cash equivalents and marketable securities of \$235.4 million and no debt outstanding.

Shelf Registration Statement

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

Stock Repurchase Program

On December 3, 2022, the Company's Board of Directors approved a stock repurchase program (the "Repurchase Program"), whereby the Company may purchase up to \$50 million of shares of its common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of the Company's Board of Directors through open market purchase, one or more Rule 10b5-1 trading plans and block trades and in privately negotiated transactions. During the year ended December 31, 2023, the Company purchased an aggregate of 2,942,997 shares of its common stock under the Repurchase Program for an aggregate purchase price of \$27.5 million. As of December 31, 2023, \$21.9 million remained available for future repurchase under the Repurchase Program.

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 ("U.S. GAAP") and include the accounts of the Company and its subsidiaries. Intercompany transactions have been eliminated.

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 of assets and liabilities and disclosure of contingent assets and liabilities and the reported amounts of revenues and expenses in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to transaction price estimates used for testing services revenue; standalone fair value of patient and digital solutions revenue performance obligations; accrued expenses for clinical studies; inventory valuation; the fair value of assets and liabilities acquired in a business combination or an asset acquisition (including identifiable intangible assets acquired); the fair value of contingent consideration recorded in connection with a business combination or an asset acquisition; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents, marketable securities and accounts receivable. 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 derived from revenue earned from AlloSure Kidney, AlloSure Heart and AlloMap Heart 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, from sales of patient and digital solutions software. The Company has not experienced any significant credit losses and does not require collateral on receivables. For the years ended December 31, 2023, 2022 and 2021, approximately 40%, 53% and 59%, respectively, of total revenue was billed to Medicare. No other payers represented more than 10% of total revenue for the years ended December 31, 2023, 2022 and 2021.

As of December 31, 2023 and 2022, approximately 36% and 27%, respectively, of accounts receivable was due from Medicare. No other payer represented more than 10% of accounts receivable at either December 31, 2023 or 2022.

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, 2023, the Company's short-term marketable securities consisted of corporate debt securities with maturities of greater than three months but less than twelve months at the time of purchase, which were classified as current assets on the consolidated balance sheet.

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

The Company considers investments in securities with remaining maturities of over one year as long-term investments. As of December 31, 2023, the Company's long-term marketable securities consisted of corporate equity securities. These long-term marketable securities are classified as other assets on the consolidated balance sheet.

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

Inventory

Inventory is finished goods, work in progress, and raw materials and consists of reagent plates, laboratory supplies, reagents and finished goods kits. Inventories are used in connection with tests performed, kits produced and prescription drugs, and may also be used for research and product development efforts. Laboratory supplies subsequently designated for research and product development use are expensed. Obsolete or damaged inventories are written off. Certain inventories are stated at the lower of purchased cost, determined on an average cost basis, or net realizable value. 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.

Property and Equipment, net

Property and equipment are stated at 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 ("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. In circumstances where the contingent consideration is classified as equity, the Company recognizes it at fair value at the acquisition date. Contingent consideration classified as equity is not subsequently remeasured.

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 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's annual impairment test date is December 1st. A qualitative assessment is initially made to determine whether it is necessary to perform a quantitative assessment. A qualitative assessment includes, among others, consideration of: (i) past, current and projected future earnings; (ii) recent trends and market conditions; and (iii) valuation metrics involving similar companies that are publicly-traded and acquisitions of similar companies, if available. If this qualitative assessment indicates that it is more likely than not that an impairment exists, or if the Company decides to bypass this option, it proceeds to the quantitative assessment. The quantitative assessment consists of a comparison between the estimated fair value of the Company's reporting unit and its respective carrying amount including goodwill. Where the carrying value of the reporting unit exceeds its estimated fair value, the Company will record an impairment charge based on that difference. The impairment charge will be limited to the amount of goodwill allocated to that reporting unit.

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 ensure the reasonableness of the reporting unit's fair value.

In connection with the Company's annual goodwill assessment on December 1, 2023, the Company performed a qualitative assessment taking into consideration past, current and projected future earnings, recent trends and market conditions; and the Company's 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 that time. As of December 31, 2023, no impairment of goodwill has been identified.

Intangible assets not subject to amortization

The Company evaluates the carrying value of intangible assets not subject to amortization, related to acquired in-process technology assets and a favorable license agreement, which are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. Accordingly, amortization of the acquired in-process technology assets and the favorable license agreement will not occur until the products reach commercialization.

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 occurring 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.

As of December 31, 2023, no impairment of acquired in-process technology assets and the favorable license agreement has been identified.

Intangible assets and long-lived assets subject to amortization

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 may not be recoverable. The Company then compares the carrying amounts of the assets with the future net undiscounted cash flows expected to be generated by such asset. If an impairment exists, the Company measures the impairment based on the excess carrying value of the asset over the asset's fair value determined using discounted estimates of future cash flows. The Company has not identified any material impairment losses to date.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received from selling an asset or the price paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which the Company would transact, and it takes into consideration the assumptions that market participants would use when pricing the asset or liability. The Company's assessment of the significance of a particular input to the fair value measurement of an asset or liability requires management to make judgments and to consider specific characteristics of that asset or liability.

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

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

As of December 31, 2023, the Company's leases had remaining terms of 0.42 years to 9.09 years, some of which include options to extend the lease term.

Revenue

The Company recognizes revenue from testing services, product sales, and patient and digital solutions revenue in the amount that reflects the consideration that it expects to be entitled in exchange for goods or services as it transfers control to its

customers. Revenue is recorded considering a five-step revenue recognition model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation.

Testing Services Revenue

AlloSure Kidney, AlloMap Heart, AlloSure Heart and AlloSure Lung patient tests are ordered by healthcare providers. The Company receives a test requisition form with payer information along with a collected patient blood sample. The Company considers the patient to be its customer and the test requisition form to be the contract. Testing services are performed in the Company's laboratory. Testing services represent one performance obligation in a contract and 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 and second revenue recognition criteria are satisfied when the Company receives a test requisition form with payer information from the healthcare provider. Generally, the Company bills third-party payers upon delivery of an AlloSure Kidney, AlloMap Heart, AlloSure Heart or AlloSure Lung test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer. The Company has used the portfolio approach under ASC Topic 606, *Revenue from Contracts with Customers*, to identify financial classes of payers. Revenue recognized for Medicare and other contracted payers is based on the agreed current reimbursement rate per test, adjusted for historical collection trends where applicable. The Company estimates revenue for non-contracted payers and self-payers using transaction prices determined for each financial class of payers using history of reimbursements. This includes analysis of an average reimbursement per test and a percentage of tests reimbursed. This estimate requires 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.

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

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

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

The Company continued the Medicare reimbursement submissions for AlloMap Heart or AlloSure Heart following the issuance of the Billing Articles. In addition, the Company informed Noridian on May 18, 2023 that until Noridian adopts the Revised Billing Article, the Company would continue to submit AlloSure Heart tests for reimbursement only when used in conjunction with AlloMap Heart according to requirements of the Billing Article currently effective at Noridian. The Company also informed Noridian on May 18, 2023 that (i) until June 30, 2023, the Company plans to submit claims for reimbursement for AlloMap Heart and AlloSure Heart tests for which the Company has not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing

Articles, and (ii) AlloSure Heart and AlloMap Heart orders placed on or after June 30, 2023 for other indications outside the surveillance and for-cause parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article.

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

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

Product Revenue

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

Patient and Digital Solutions Revenue

Patient and digital solutions revenue is mainly derived from a combination of software as a service (“SaaS”) and perpetual software license agreements entered into with various transplant centers, which are the Company’s customers for this class of revenue. The main performance obligations in connection with the Company’s SaaS and perpetual software license agreements are the following: (i) implementation services and delivery of the perpetual software license, which are considered a single performance obligation, and (ii) post contract support. The Company allocates the transaction price to each performance obligation based on relative stand-alone selling prices of each distinct performance obligation. Digital revenue in connection with perpetual software license agreements is recognized over time based on the Company’s satisfaction of each distinct performance obligation in each agreement.

Perpetual software license agreements typically require advance payments from customers upon the achievement of certain milestones. The Company records deferred revenue in relation to these agreements when cash payments are received or invoices are issued in advance of the Company’s performance, and generally recognizes revenue over the contractual term, as performance obligations are fulfilled.

In addition, the Company derives patient and digital solutions revenue from software subscriptions and medication sales. The Company generally bills software subscription fees in advance. Revenue from software subscriptions is deferred and recognized ratably over the subscription term. The medication sales revenue is recognized based on the negotiated contract price with the governmental, commercial and non-commercial payers with any applicable patient co-pay. The Company recognizes revenue from medication sales when prescriptions are delivered.

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 are 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 are 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 impaired, slow moving 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 prescription drugs 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 use of the Company's tests, as well as continued efforts related to improving the Company's existing products and patient and digital solutions service lines. 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 study costs comprised of work performed by contract research organizations under contract terms.

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. 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 uses the straight-line attribution method for recognizing compensation expense. 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.

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.

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, Australian dollar and the Euro. The revenue and expenses of such subsidiaries have been translated into U.S. dollars at average exchange rates prevailing during the period. 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 loss. Foreign currency translation gains and losses on revenue and expenses are recognized in the consolidated statements of operations.

Comprehensive Loss

Comprehensive loss consists of net loss and other 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 losses on the translation of foreign assets and liabilities.

Recent Accounting Pronouncements

There were no recently adopted accounting standards which would have a material effect on the Company's consolidated financial statements and accompanying disclosures, and no recently issued accounting standards that are expected to have a material impact on the Company's consolidated financial statements and accompanying disclosures.

Effective in Future Periods

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

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 340): Improvements to Income Tax Disclosures*, which requires annual disclosures in the rate reconciliation table to be presented using both percentages and reporting currency amounts, and this table must include disclosure of specific categories. Additional information will also be required for reconciling items that meet a quantitative threshold. The new guidance also requires enhanced disclosures of income taxes paid, including the amount of income taxes paid disaggregated by federal, state and foreign taxes and the amount of income taxes paid disaggregated by individual jurisdictions that exceed a quantitative threshold. The amendments should be applied on a prospective basis, but retrospective application is permitted. The amendments set forth in this ASU are effective for annual periods beginning after December 15, 2024 for public entities. This guidance will be effective for the Company's annual disclosures in fiscal year 2025. As the amendments only relate to disclosures, there will be no impact on the Company's financial position or results of operations.

3. NET LOSS PER SHARE

Basic and diluted net loss per share have been computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of common share equivalents as their effect would have been antidilutive.

For the years ended December 31, 2023, 2022 and 2021, all common share equivalents have been excluded from the calculation of diluted net loss per share, as their effect would be antidilutive.

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

	Year Ended December 31,		
	2023	2022	2021
Numerator:			
Net loss used to compute basic net loss per share	\$ (190,284)	\$ (76,613)	\$ (30,662)
Net loss used to compute diluted net loss per share	\$ (190,284)	\$ (76,613)	\$ (30,662)
Denominator:			
Weighted-average shares used to compute basic net loss per share	53,764,705	53,321,625	52,241,076
Weighted-average shares used to compute diluted net loss per share	53,764,705	53,321,625	52,241,076
Net loss per share:			
Basic	\$ (3.54)	\$ (1.44)	\$ (0.59)
Diluted	\$ (3.54)	\$ (1.44)	\$ (0.59)

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

	Year Ended December 31,		
	2023	2022	2021
Shares of common stock subject to outstanding options	3,055,208	2,921,925	1,863,633
Shares of common stock subject to outstanding common stock warrants	—	3,132	3,132
Restricted stock units	5,001,370	3,092,467	2,047,657
Total common stock equivalents	8,056,578	6,017,524	3,914,422

On January 25, 2021 and February 11, 2021, the Company completed an underwritten public offering, including the sale of shares pursuant to the exercise of the underwriters' over-allotment option, pursuant to which the Company sold 1,923,077 and 288,461 shares of common stock, respectively.

4. FAIR VALUE MEASUREMENTS

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

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

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

	December 31, 2023			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	\$ 60,525	\$ —	\$ —	\$ 60,525
Total	\$ 60,525	\$ —	\$ —	\$ 60,525
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 5,469	\$ 5,469
Long-term liabilities:				
Contingent consideration	—	—	2,461	2,461
Total	\$ —	\$ —	\$ 7,930	\$ 7,930
	December 31, 2022			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	\$ 66,594	\$ —	\$ —	\$ 66,594
Long-term marketable securities:				
Corporate equity securities	2,076	—	—	2,076
Total	\$ 68,670	\$ —	\$ —	\$ 68,670
Liabilities				
Short-term liabilities:				
Contingent consideration	\$ —	\$ —	\$ 1,025	\$ 1,025
Long-term liabilities:				
Contingent consideration	—	—	2,418	2,418
Common stock warrant liability	—	—	32	32
Total	\$ —	\$ —	\$ 3,475	\$ 3,475

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

	(Level 3)
Common Stock Warrant Liability and Contingent Consideration	
Balance at December 31, 2021	\$ 5,480
Change in estimated fair value of common stock warrant liability	(107)
Additions to contingent consideration	727
Payment related to contingent consideration	(2,625)
Balance at December 31, 2022	3,475
Exercise of warrants	(22)
Change in estimated fair value of common stock warrant liability	(10)
Change in estimated fair value of contingent consideration on business combination	2,677
Change in estimated fair value of contingent consideration on asset acquisition	166
Additions to contingent consideration	2,269
Payment related to contingent consideration	(625)
Balance at December 31, 2023	<u>\$ 7,930</u>

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

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

In December 2023, Miromatrix was acquired by United Therapeutics Corporation. The Company tendered and sold all of its shares of Miromatrix to United Therapeutics Corporation for \$2.5 million. The Company recognized a \$1.5 million gain from the disposal of its Miromatrix shares and recorded as other income (expense), net, on the consolidated statements of operations for the year ended December 31, 2023.

In determining fair value, the Company uses various valuation approaches within the fair value measurement framework. The valuation methodologies used for the Company's instruments measured at fair value and their classification in the valuation hierarchy are summarized below:

- *Money market funds*— Investments in money market funds are classified within Level 1. Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. At December 31, 2023 and 2022, money market funds were included as cash and cash equivalents in the consolidated balance sheets.
- *Long-term marketable equity and debt securities* – Investments in long-term marketable equity securities are classified within Level 1. The securities are recorded at fair value based on readily available quoted market prices in active markets. The securities are recorded at fair value based on observable inputs for quoted prices for identical or similar assets in markets that are not active. Long-term marketable securities are located within other assets on the consolidated balance sheets.
- *Contingent consideration* – Contingent consideration is classified within Level 3. Contingent consideration relates to asset acquisitions and business combinations. The Company recorded the estimate of the fair value of the contingent consideration based on its evaluation of the probability of the achievement of the contractual conditions that would result in the payment of the contingent consideration. Contingent consideration was estimated using the fair value of the milestones to be paid if the contingency is met based on management's estimate of the probability of success and projected revenues for revenue-based considerations at discounted rates ranging from 6% and 12% at December 31, 2023 and 12% at December 31, 2022. 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 to the fair value measurement of the contingent consideration liability. The carrying amount of the contingent consideration liability represents its fair value.

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

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, 2023	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 82,197	\$ 89,921	\$ 348,485
Restricted cash	586	522	211
Total cash, cash equivalents, and restricted cash at the end of the period	<u>\$ 82,783</u>	<u>\$ 90,443</u>	<u>\$ 348,696</u>

Marketable Securities

All short-term marketable securities were considered held-to-maturity at December 31, 2023. At December 31, 2023, some of the Company's short-term marketable securities were in an unrealized loss position. The Company determined that it had the positive intent and ability to hold until maturity all short-term marketable securities that have been in a continuous loss position, thus there was no recognition of any other-than-temporary impairment at December 31, 2023. All short-term marketable securities with unrealized losses as of the balance sheet date have been in a loss position for less than twelve months. Contractual maturities of the short-term marketable securities were within one year or less.

The long-term marketable equity securities were recorded in the consolidated balance sheets at fair market value with changes in the fair value recognized in earnings at December 31, 2023. The long-term marketable debt securities were considered available-for-sale. The contractual maturity of the long-term marketable debt securities are less than three years. During 2022, the Company wrote off \$0.5 million of long-term marketable debt securities.

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

	December 31, 2023		
	Amortized Cost	Unrealized Holding Gains	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 80,468	\$ 2,038	\$ 82,506
Corporate debt securities	72,753	711	73,464
Total short-term marketable securities	153,221	2,749	155,970
Total	<u>\$ 153,221</u>	<u>\$ 2,749</u>	<u>\$ 155,970</u>

	December 31, 2022		
	Amortized Cost	Unrealized Holding Gains (Losses)	Fair Value
Short-term marketable securities:			
U.S. agency securities	\$ 79,347	\$ 452	\$ 79,799
Corporate debt securities	123,821	(220)	123,601
Total short-term marketable securities	203,168	232	203,400
Long-term marketable securities:			
Corporate equity securities	5,000	(2,924)	2,076
Total long-term marketable securities	5,000	(2,924)	2,076
Total	<u>\$ 208,168</u>	<u>\$ (2,692)</u>	<u>\$ 205,476</u>

Contractual maturities of the marketable securities at each balance sheet date are as follows (in thousands):

	December 31,	
	2023	2022
Within one year	\$ 153,221	\$ 203,168
After one year through five years	—	—
Total	<u>\$ 153,221</u>	<u>\$ 203,168</u>

6. BUSINESS COMBINATIONS AND ASSET ACQUISITION

Business Combinations

HLA Data Systems

In January 2023, the Company acquired HLA Data Systems, a Texas-based company that provides software and interoperability solutions for the histocompatibility and immunogenetics community. The Company acquired HLA Data Systems with a combination of cash consideration paid upfront and contingent consideration with a fair value of \$1.3 million.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of \$0.4 million associated with the acquisition were expensed as incurred, and classified as part of general and administrative expenses in the consolidated statement of operations.

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

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

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

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

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

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

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

MediGO

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

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

Goodwill of \$0.6 million arising from the acquisition primarily consists of synergies from integrating MediGO's technology with the current testing and digital solutions offered by the Company. The acquisition of MediGO will provide a comprehensive software platform that optimizes complex logistics from referral to recovery and during the critical movement of organs and teams and gives organ procurement organizations and transplant centers the ability to unify decentralized stakeholders, coordinate resources and make vital decisions with the goal of increasing organ utilization and improving equity and access to transplantation. None of the goodwill is expected to be deductible for income tax purposes. All of the goodwill has been assigned to the Company's existing operating segment.

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

	Estimated Fair Value	Estimated Useful Lives (Years)
Customer relationships	\$ 810	17
Developed technology	850	12
Trademarks	360	17
Total	<u>\$ 2,020</u>	

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

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

A discount rate of 25% was utilized in estimating the fair value of these three intangible assets.

The pro forma impact of the MediGO acquisition is not material, and the results of operations of the acquisition have been included in the Company's consolidated statements of operations from the respective acquisition date.

Combined Consideration Paid

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

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

The preliminary allocation of the purchase price to assets acquired and liabilities assumed was based on the fair value of such assets and liabilities as of the acquisition date.

Asset Acquisition

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

The purchased asset did not meet the definition of a business under ASC Topic 805, *Business Combinations*, and therefore the Company accounted for the transaction as an asset acquisition. In an asset acquisition, goodwill is not recognized, but rather, any excess consideration transferred over the fair value of the net assets acquired is allocated on a relative fair value basis to the identifiable assets acquired.

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

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill is recorded when the purchase price of an acquisition exceeds the fair value of the net tangible and identified intangible assets acquired.

Goodwill is tested annually for impairment at the reporting unit level during the fourth quarter or earlier upon the occurrence of certain events or substantive changes in circumstances. The Company identified an indicator of goodwill impairment during the quarter ended September 30, 2023 due to a sustained decrease in share price.

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

On December 1, 2023, 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, 2023, no impairment of goodwill has been identified.

The following table presents details of the Company's goodwill as of December 31, 2023 and 2022 (in thousands):

	2023	2022
Balance as of January 1,	\$ 37,523	\$ 36,983
Goodwill acquired	2,646	540
Remeasurement adjustment	167	—
Balance as of December 31,	<u>\$ 40,336</u>	<u>\$ 37,523</u>

Intangible Assets

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

	December 31, 2023				
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
Intangible assets with finite lives:					
Acquired and developed technology	\$ 37,367	\$ (18,340)	\$ (2,269)	\$ 16,758	7.2
Customer relationships	25,718	(9,094)	(1,959)	14,665	9.2
Commercialization rights	11,579	(4,496)	—	7,083	5.6
Trademarks and tradenames	5,220	(1,713)	(288)	3,219	9.3
Total intangible assets with finite lives	<u>79,884</u>	<u>(33,643)</u>	<u>(4,516)</u>	<u>41,725</u>	
Acquired in-process technology	1,250	—	—	1,250	
Favorable license agreement	2,726	—	—	2,726	
Total intangible assets with indefinite lives	<u>3,976</u>	<u>—</u>	<u>—</u>	<u>3,976</u>	
Total intangible assets	<u>\$ 83,860</u>	<u>\$ (33,643)</u>	<u>\$ (4,516)</u>	<u>\$ 45,701</u>	

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

	December 31, 2022				
	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	\$ 35,747	\$ (15,138)	\$ (2,369)	\$ 18,240	7.5
Customer relationships	21,898	(7,459)	(2,104)	12,335	9.0
Commercialization rights	11,579	(3,233)	—	8,346	6.6
Trademarks and tradenames	4,540	(1,345)	(315)	2,880	8.5
Total intangible assets with finite lives	<u>73,764</u>	<u>(27,175)</u>	<u>(4,788)</u>	<u>41,801</u>	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	<u>\$ 75,014</u>	<u>\$ (27,175)</u>	<u>\$ (4,788)</u>	<u>\$ 43,051</u>	

Acquisition of intangible assets

In January and July 2023, the Company acquired the intangible assets of HLA Data Systems and MediGO, respectively. The intangible assets are included in Acquired and developed technology, Customer relationships and Trademarks and tradenames as of December 31, 2023.

Amortization of Intangible Assets

Intangible assets are carried at cost less accumulated amortization. Amortization expenses are recorded to cost of testing services, cost of product, cost of patient and digital solutions, and sales and marketing expenses in the consolidated statements of operations.

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

	Year Ended December 31,		
	2023	2022	2021
Cost of testing services	\$ 1,316	\$ 1,316	\$ 1,316
Cost of product	1,655	1,716	1,905
Cost of patient and digital solutions	1,039	945	684
Sales and marketing	2,457	2,252	1,891
Total	<u>\$ 6,467</u>	<u>\$ 6,229</u>	<u>\$ 5,796</u>

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

Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Patient and Digital Solutions	Sales and Marketing	Total
2024	\$ 1,316	\$ 1,715	\$ 850	\$ 2,557	\$ 6,438
2025	1,316	1,715	681	2,557	6,269
2026	1,316	751	681	2,554	5,302
2027	1,316	751	681	2,541	5,289
2028	1,316	751	681	2,541	5,289
Thereafter	1,509	2,567	1,462	7,600	13,138
Total future amortization expense	<u>\$ 8,089</u>	<u>\$ 8,250</u>	<u>\$ 5,036</u>	<u>\$ 20,350</u>	<u>\$ 41,725</u>

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2023	2022
Finished goods	\$ 3,658	\$ 2,962
Work in progress	5,191	4,306
Raw materials	10,622	11,964
Total inventory	<u>\$ 19,471</u>	<u>\$ 19,232</u>

Property and Equipment, Net

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

	December 31,	
	2023	2022
Leasehold improvements	\$ 18,259	\$ 17,389
Machinery and equipment	18,051	16,294
Internally developed software	15,116	10,893
Construction in progress	8,306	7,639
Computer and office equipment	5,609	5,570
Furniture and fixtures	2,168	2,168
Property and equipment	<u>67,509</u>	<u>59,953</u>
Less: Accumulated depreciation and amortization	<u>(32,263)</u>	<u>(24,424)</u>
Property and equipment, net	<u>\$ 35,246</u>	<u>\$ 35,529</u>

Depreciation expense was \$7.9 million, \$5.2 million and \$2.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

There were no assets purchased under finance leases during 2023. Accumulated depreciation was \$0.6 million and \$0.6 million at December 31, 2023 and 2022, respectively. Related amortization expense, included in depreciation and amortization expense, was \$0.0 million, \$0.1 million and \$0.1 million for the three years ended December 31, 2023, 2022 and 2021, respectively.

Accrued and Other Liabilities

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

	December 31,	
	2023	2022
Clinical studies	\$ 15,744	\$ 14,816
Short-term lease liability	5,943	5,591
Professional fees	5,911	6,115
Contingent consideration	5,469	1,025
Deferred revenue	4,748	5,342
Laboratory processing fees and materials	2,890	2,189
Accrued royalty	348	4,633
Deferred payments for intangible assets	920	2,062
Accrued shipping expenses	335	489
License and other collaboration fees	250	1,000
Capital expenditures	151	1,316
Other accrued expenses	2,788	4,553
Total accrued and other liabilities	<u>\$ 45,497</u>	<u>\$ 49,131</u>

9. COMMITMENTS AND CONTINGENCIES

Leases

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

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

As of December 31, 2023, the carrying value of the ROU asset was \$29.9 million. The related current and non-current liabilities as of December 31, 2023 were \$5.9 million and \$28.3 million, respectively. The current and non-current lease liabilities are included in accrued and other current liabilities and operating lease liability, less current portion, respectively, in the consolidated balance sheets.

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

	2023	2022	2021
Operating lease cost	\$ 7,936	\$ 6,716	\$ 5,134
Finance lease cost	—	—	53
Total lease cost	<u>\$ 7,936</u>	<u>\$ 6,716</u>	<u>\$ 5,187</u>

Finance lease cost included interest from the lease liability and amortization of the ROU asset.

	December 31,	
	2023	2022
Other information:		
Weighted-average remaining lease term - Operating leases (in years)	5.43	6.26
Weighted-average discount rate - Operating leases (%)	7.1 %	7.1 %

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

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

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

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

	December 31,	
	2023	2022
ROU assets	\$ 12,073	\$ 14,321
Lease liabilities	\$ 13,221	\$ 15,302

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

	December 31,	
	2023	2022
ROU assets	\$ 5,347	\$ 5,814
Lease liabilities	\$ 5,627	\$ 6,005

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

	2023	2022	2021
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows used for operating leases	\$ 5,454	\$ 3,665	\$ 2,580
Operating cash flows used for finance leases	—	—	63
Total	<u>\$ 5,454</u>	<u>\$ 3,665</u>	<u>\$ 2,643</u>

Maturities of operating lease liabilities as of December 31, 2023, are as follows (in thousands):

Years ending December 31,	Operating Leases
2024	\$ 7,993
2025	7,875
2026	7,124
2027	7,274
2028	6,599
Thereafter	4,115
Total lease payments	<u>40,980</u>
Less imputed interest	<u>6,759</u>
Present value of future minimum lease payments	<u>34,221</u>
Less operating lease liability, current portion	<u>5,943</u>
Operating lease liability, long-term portion	<u>\$ 28,278</u>

Royalty Commitments

The Board of Trustees of the Leland Stanford Junior University (“Stanford”)

In June 2014, the Company entered into a license agreement with Stanford (the “Stanford License”), which granted the Company an exclusive license to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Under the terms of the Stanford License, the Company is required to pay an annual license maintenance fee, six milestone payments and royalties in the low single digits of net sales of products incorporating the licensed technology. In March 2023,

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

In May 2023, the Company submitted a petition of certiorari to the U.S. Supreme Court for consideration of the patent infringement suit and in October 2023, the U.S. Supreme Court declined to hear this patent infringement suit. As the Review is complete and the Company's petition for review was denied, the Stanford License automatically terminated, and in December 2023, the Company paid Stanford certain past royalties at a reduced rate that were previously suspended within 90 days of the termination. There was no outstanding obligation with Stanford as of December 31, 2023.

Illumina

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

Other Royalty Commitment

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

Cibiltech Commitments

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

In July 2023, the Company entered into a settlement agreement with Cibiltech (the “Settlement Agreement”), pursuant to which the Company agreed to pay a certain amount of its obligation owed to Cibiltech. A judicial court in Paris, France, granted the liquidation of Cibiltech, which filed for bankruptcy. In the Settlement Agreement, Cibiltech irrevocably waived and relinquished any and all claims, demands, grievances, proceeding, actions or other requests, whether judicial, administrative, arbitral or otherwise, against the Company. The outstanding obligation of the Company with Cibiltech was waived and relinquished, except for \$0.4 million, which was paid in July 2023, and represented the amount that the Company agreed to per the Settlement Agreement. There was no outstanding obligation as of December 31, 2023.

Tax Commitments

As of December 31, 2023, the Company had gross unrecognized tax benefits of \$6.2 million, which include penalties and interest of \$0.2 million. Approximately \$0.2 million has been 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.

Other Commitments

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

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

Litigation and Indemnification Obligations

In response to the Company’s false advertising suit filed against Natera Inc. (“Natera”) on April 10, 2019, Natera filed a counterclaim against the Company on February 18, 2020, in the U.S. District Court for the District of Delaware (the “Court”) alleging the Company made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of Court to amend its counterclaims to include additional allegations regarding purportedly false claims the Company made with respect to AlloSure,

and the Court granted Natera's request. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury finding that Natera violated the Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding the Company \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury, which the Company intends to appeal. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising. The case is now on appeal.

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

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

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

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

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

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

Olympios Matter

On April 15, 2022, a complaint was filed by Michael Olympios against the Company in the Superior Court of the State of California for the County of San Mateo (the "San Mateo County Court"). The complaint alleged that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olympios, and that the Company has defamed Dr. Olympios. Dr. Olympios also sought to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olympios. The Company filed a motion to compel arbitration and dismiss the case. On April 25, 2022, the San Mateo County Court granted the Company's *ex parte* application to stay the case and advance the hearing date to June 10, 2022 for the motion to compel arbitration and dismiss. At the June 10, 2022 hearing, the San Mateo County Court found that the decision should be made by the arbitrator, and stayed the case. On July 19, 2022, Dr. Olympios filed a motion to withdraw from arbitration before Judicial Arbitration and Mediation Services, Inc., which was denied on

August 18, 2022. Both the arbitration and the San Mateo County Court matter were settled in the fourth quarter of 2023 and have been resolved.

Securities Class Action

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

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

On May 24, 2023, the court granted the Company's motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against the Company, Reginald Seeto, Ankur Dhingra, and Peter Maag. Under a briefing schedule ordered by the court on June 12, 2023, defendants' motion to dismiss and motion to strike the second amended complaint was filed on July 26, 2023, plaintiffs' opposition was filed on August 30, 2023, and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 2023. The Company intends to defend itself vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suit, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for this suit. See Note 17, *Subsequent Events*, for further information.

Derivative Actions

On September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra, and other current and former members of the Company's Board of Directors (the "Edelman Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20(a) of the Exchange Act as controlling persons of the Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to the Company, violated Sections 14(a) and 20(a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by the Company as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

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

On February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Drs. Seeto and Maag and Mr. Dhingra and other current and former members of the Company's Board of Directors (the "Stevenson Derivative Action"). The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14(a) and 20(a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by the Company as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses.

On March 9, 2023, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action and stayed both actions pursuant to the terms of the stay order in the Edelman Derivative Action. The consolidated derivative action remains stayed. The parties in the Stevenson Derivative Action filed a joint status statement with the court on September 6, 2023. See Note 17, *Subsequent Events*, for further information.

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

Insurance Matter

In December 2022, the Company filed a lawsuit against its directors and officers liability insurance carriers in San Mateo County Superior Court. The Company seeks a declaration that costs and fees incurred by the Company in responding to governmental investigatory requests are covered under its policies. The Company also asserts breach of contract against its primary insurer Great American Insurance Company for denying the claim. The policies provide up to \$15 million in coverage limits. The Company intends to vigorously pursue its claims, and believes it has good and substantial support for its claims, but there is no guarantee that the Company will prevail in these claims. The parties are presently briefing the Company's entitlement to coverage under the policies.

10. STOCKHOLDERS' EQUITY

Stock Repurchase Program

On December 3, 2022, the Company's Board of Directors approved a Stock Repurchase Program (the "Repurchase Program"), whereby the Company may purchase up to \$50 million in shares of its common stock over a period of up to two years, commencing on December 8, 2022. The Repurchase Program may be carried out at the discretion of a committee of the Board of Directors through open market purchases, one or more Rule 10b5-1 trading plans, block trades and in privately negotiated transactions. For the years ended December 31, 2023 and 2022, the Company purchased an aggregate of 2,942,997 and 50,051 shares of its common stock, respectively, under the Repurchase Program for an aggregate purchase price of \$27.5 million and \$0.6 million, respectively. As of December 31, 2023, \$21.9 million remained available for future repurchases under the Repurchase Program.

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.

January 2021 Underwritten Public Offering of Common Stock

On January 25, 2021, the Company sold 1,923,077 shares of its common stock through an underwritten public offering at a public offering price of \$91.00 per share. The net proceeds to the Company from the offering were approximately \$164.0 million, after deducting underwriting discounts and commissions and offering expenses.

On February 11, 2021, the Company sold 288,461 shares of its common stock pursuant to the full exercise of the overallotment option granted to the underwriters in connection with the January 2021 offering. The net proceeds to the Company from the full exercise of the underwriters' overallotment option were approximately \$24.7 million.

The Company did not issue preferred stock during the years ended December 31, 2023, 2022 and 2021.

11. 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 (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 \$1.7 million, \$1.8 million and \$1.4 million for the years ended December 31, 2023, 2022 and 2021, respectively.

12. WARRANTS

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

During the year ended December 31, 2023, warrants to purchase approximately 3,000 shares of common stock were exercised for cash proceeds of \$4,000. During the year ended December 31, 2022, no warrants to purchase shares of common stock were exercised.

As of December 31, 2023, no warrants to purchase common stock were outstanding.

13. STOCK INCENTIVE PLANS

2014 Equity Incentive Plan

The Company grants stock based awards under 2014 Equity Incentive Plan (the “2014 Plan”) that allows for issuance of stock options, restricted stock units (“RSUs”) and other stock awards to the Company’s employees, directors, and consultants. Stock options granted under the 2014 Plan may be exercised when vested and generally expire ten years from the date of the grant or three months from the date of termination of employment. Vesting periods vary based on awards granted, however, certain stock-based awards may vest immediately or may accelerate based on performance-driven measures. Stock option awards generally vest over four years with first year annual cliff vesting. The RSUs generally vest annually over four years in equal increments. There were 670,455 shares of common stock reserved for future issuance under the 2014 Plan as of December 31, 2023.

2016 Inducement Plan

On April 21, 2016, the Company adopted the 2016 Inducement Equity Incentive Plan (the “2016 Plan”), pursuant to which the Company may grant 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. The terms in the 2016 Plan are substantially similar to the 2014 Plan. There were 62,752 shares of common stock reserved for future issuance under the 2016 Plan as of December 31, 2023.

The 2016 Plan allows RSUs to be granted in addition to stock options. The RSUs vest annually over four years in equal increments. The Company began granting RSUs pursuant to the 2016 Plan starting June 2016.

2019 Inducement Equity Incentive Plan

The Company grants stock based awards under 2019 Inducement Equity Incentive Plan (the “2019 Plan”) that allows for issuance of stock options, RSUs and other stock awards to new employees of the Company. Stock options granted under the 2019 Plan may be exercised when vested and generally expire ten years from the date of the grant or three months from the date of termination of employment. Vesting periods vary based on awards granted, however, certain stock-based awards may vest immediately or may accelerate based on performance-driven measures. Stock option awards generally vest over four years with first year annual cliff vesting. The RSUs generally vest annually over four years in equal increments. The terms in the 2019 Plan are substantially similar to the 2014 Plan. There were 135,904 shares of common stock reserved for future issuance under the 2019 Plan as of December 31, 2023.

Stock Options and RSUs

The following table summarizes option and RSUs activity under the Company’s 2014 Plan, 2016 Plan and 2019 Plan, and related information:

	Shares Available for Grant	Stock Options Outstanding	Weighted- Average Exercise Price	Number of RSU Shares	Weighted- Average Grant Date Fair Value
Balance—December 31, 2022	1,490,462	2,921,925	\$ 28.13	3,094,396	\$ 37.39
Additional options authorized	2,141,330	—	—	—	—
Common stock awards for services	(21,965)	—	—	—	—
RSUs granted	(4,028,424)	—	—	4,028,424	10.52
RSUs vested	—	—	—	(989,314)	36.43
Options granted	(680,788)	680,788	12.60	—	—
Options exercised	—	(27,903)	4.29	—	—
Repurchases of common stock under employee incentive plans	322,163	—	—	—	—
RSUs forfeited	1,126,731	—	—	(1,126,731)	22.92
Options forfeited	265,395	(265,395)	26.90	—	—
Options expired	254,207	(254,207)	27.13	—	—
Balance—December 31, 2023	<u>869,111</u>	<u>3,055,208</u>	\$ 25.21	<u>5,006,775</u>	\$ 19.02

The total intrinsic value of options exercised was \$0.1 million, \$1.6 million and \$42.9 million for the years ended December 31, 2023, 2022 and 2021, respectively.

The total fair value of RSUs vested during 2023 was \$9.5 million. As of December 31, 2023, the total intrinsic value of outstanding RSUs was approximately \$61.6 million and there were \$55.8 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.23 years.

The Company granted performance restricted stock units ("PSUs"), included in RSUs, under the 2014 Plan. The PSUs granted to employees consist of financial and operational metrics to be met over a performance period of 2 years. The number of shares outstanding was 449,983 and 160,538 as of December 31, 2023 and December 31, 2022, respectively. The weighted-average period was 1.01 years and 1.16 years for the years ended December 31, 2023 and 2022, respectively.

Options outstanding that have vested and are expected to vest at December 31, 2023 are as follows:

	Number of Shares Issued (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	1,786	\$ 26.21	6.27	\$ 1,751
Expected to Vest	1,191	23.56	8.59	530
Total	<u>2,977</u>			<u>\$ 2,281</u>

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, 2023 for stock options that were in-the-money.

The weighted-average grant-date fair value of options to purchase common stock granted for the years ended December 31, 2023, 2022 and 2021 using the Black-Scholes Model was \$8.63, \$19.51 and \$52.65, respectively.

The total fair value of options that vested during 2023 was \$18.4 million. As of December 31, 2023, there were approximately \$17.5 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.26 years.

2014 Employee Stock Purchase Plan

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

During the offering period in 2023 that ended on June 30, 2023, 143,817 shares were purchased for aggregate proceeds of \$1.0 million from the issuance of shares, which occurred on July 6, 2023. During the offering period in 2023 that ended on December 31, 2023, 73,759 shares were purchased for aggregate proceeds of \$0.5 million from the issuance of shares, which occurred on January 2, 2024. The Company issued 190,842 shares and 93,422 shares of common stock during the years ended December 31, 2023 and December 31, 2022, respectively, pursuant to the ESPP. The Company received proceeds of \$1.5 million and \$3.0 million from the purchases of shares during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the Company had 583,906 shares available for issuance under the ESPP.

Board of Directors Stock Awards Granted for Services

For the years ended December 31, 2023, 2022 and 2021, 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. As of December 31, 2023, there were a total of 310,609 shares issued to the Company's directors, for a total fair value of \$2.5 million. Stock-based compensation expense associated with the awards was \$0.2 million, \$0.4 million and \$0.3 million for the years ended December 31, 2023, 2022 and 2021, respectively, which was included in general and administrative expense on the consolidated statements of operations.

Valuation Assumptions

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

	Year Ended December 31,		
	2023	2022	2021
Employee stock options			
Expected term (in years)	5.61	5.96	5.94
Expected volatility	77.86 %	77.62 %	77.70 %
Risk-free interest rate	3.67 %	2.74 %	0.80 %
Expected dividend yield	— %	— %	— %
Employee stock purchase plan			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	75.91% – 93.38%	67.79% – 77.88%	53.10% – 67.79%
Risk-free interest rate	5.26% – 5.47%	2.51% – 4.76%	0.09% – 0.19%
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 nonemployee stock-based awards for the years ended December 31, 2023, 2022 and 2021, included on the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Cost of testing services	\$ 1,854	\$ 1,529	\$ 2,358
Cost of product	1,165	1,120	579
Cost of patient and digital solutions	1,377	1,331	728
Research and development	6,556	7,391	7,126
Sales and marketing	12,470	14,403	10,887
General and administrative	25,664	20,779	14,403
Total	<u>\$ 49,086</u>	<u>\$ 46,553</u>	<u>\$ 36,081</u>

No tax benefit was recognized related to stock-based compensation expense since the Company has never reported taxable income (after net operating loss) and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, stock-based compensation costs were only capitalized under Internal Revenue Code Section 174, capitalized research and development costs for the periods presented.

14. INCOME TAXES

Loss before income taxes for the years ended December 31, 2023, 2022 and 2021 is summarized as follows (in thousands):

	As of December 31,		
	2023	2022	2021
United States	\$ (188,421)	\$ (73,089)	\$ (27,921)
Foreign	(1,722)	(3,145)	(4,167)
Total loss before income taxes	<u>\$ (190,143)</u>	<u>\$ (76,234)</u>	<u>\$ (32,088)</u>

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

	As of December 31,		
	2023	2022	2021
Current			
Federal	\$ (117)	\$ 145	\$ 89
State	186	328	2
Foreign	—	184	(139)
Total current income tax expense (benefit)	<u>69</u>	<u>657</u>	<u>(48)</u>
Deferred			
Federal	184	(130)	(409)
State	(112)	75	(127)
Foreign	—	(223)	(842)
Total deferred income tax expense (benefit)	<u>72</u>	<u>(278)</u>	<u>(1,378)</u>
Income tax expense (benefit)	<u>\$ 141</u>	<u>\$ 379</u>	<u>\$ (1,426)</u>

The Company's actual provision for tax differed from the amounts computed by applying the U.S. federal income tax rates of 21% in each of the years ended 2023, 2022 and 2021, to loss before income taxes as a result of the following:

	Year Ended December 31,		
	2023	2022	2021
Federal tax statutory rate	21.0 %	21.0 %	21.0 %
Stock-based compensation	(3.8)%	(2.8)%	38.8 %
Change in valuation allowance	(18.1)%	(16.9)%	86.4 %
Foreign rate differential	0.2 %	(0.2)%	0.7 %
Non-deductible executive compensation	(0.4)%	(2.1)%	(23.4)%
Research credits	0.4 %	1.8 %	6.9 %
Changes in net operating loss carryforwards, including expirations	0.8 %	(0.5)%	(125.1)%
Other	(0.2)%	(0.8)%	(0.9)%
Effective income tax rate	<u>(0.1)%</u>	<u>(0.5)%</u>	<u>4.4 %</u>

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

	As of December 31, 2023	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 30,260	\$ 26,658
Tax credit carryforwards	10,317	9,138
Accruals	26,256	2,971
Lease liability	7,947	9,250
Section 174 capitalized costs	31,724	20,602
Stock-based compensation	12,799	7,798
Other	1,351	959
Gross deferred tax assets	120,654	77,376
Valuation allowance	(102,865)	(59,499)
Total deferred tax assets	17,789	17,877
Deferred tax liabilities:		
Purchased intangibles	(6,112)	(6,615)
Operating leases right-of-use assets	(6,914)	(8,189)
Property and equipment	(4,443)	(2,548)
Other	(456)	(497)
Total deferred tax liabilities	(17,925)	(17,849)
Net deferred tax (liabilities) assets	\$ (136)	\$ 28

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. The Company has also placed a valuation allowance on the net deferred tax assets of its Swedish operations. The valuation allowance increased by \$43.4 million and \$13.9 million during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company had domestic federal net operating loss carryforwards of \$109.1 million, domestic state net operating loss carryforwards of \$77.6 million, and foreign net operating loss carryforwards of \$12.0 million that can reduce future taxable income. The domestic federal and state net operating loss carryforwards will begin to expire in 2024 and 2030, respectively. The foreign net operating loss carryforwards can be carried forward indefinitely.

As of December 31, 2023, the Company had credit carryforwards of approximately \$11.5 million and \$11.1 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 2023. California credits have no expiration date.

The Company has recorded a valuation allowance against its deferred tax assets at December 31, 2023 and 2022 because the Company's management believes that it is more likely than not that these assets will not be fully realized. The increase in the valuation allowance is approximately \$43.4 million in the year ended December 31, 2023.

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

	Year Ended December 31,		
	2023	2022	2021
Balance at the beginning of the year	\$ 5,436	\$ 4,156	\$ 4,416
Additions based on tax positions related to the current year	839	1,255	805
Additions based on tax positions related to prior years	—	25	130
Decreases based on tax positions related to prior years	(91)	—	(1,195)
Balance at the end of the year	\$ 6,184	\$ 5,436	\$ 4,156

None of the \$6.2 million of net unrecognized tax benefit as of December 31, 2023, if recognized, would impact the Company's effective tax rate. During the year ended December 31, 2023, given the Company's valuation allowance, the uncertain tax benefits would not have impacted the effective tax rate.

The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2023 and December 31, 2022, the Company had in each year \$0.2 million of cumulative interest and penalties related to unrecognized tax benefits. The Company does not anticipate a significant change in the unrecognized tax benefits over the next twelve months.

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 3 to 6 years.

15. 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 CODM, or decision making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its Office of the Chief Executive Officer as the CODM. In determining its reportable segments, the Company considered the markets and types of customers served and the products or services provided in those markets. The Company operates in a single reportable segment.

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

	Year Ended December 31,		
	2023	2022	2021
Testing services revenue			
United States	\$ 209,158	\$ 262,959	\$ 258,412
Rest of World	527	789	873
	<u>\$ 209,685</u>	<u>\$ 263,748</u>	<u>\$ 259,285</u>
Product revenue			
United States	\$ 19,753	\$ 16,409	\$ 13,512
Europe	9,901	9,081	9,740
Rest of World	3,863	3,761	3,580
	<u>\$ 33,517</u>	<u>\$ 29,251</u>	<u>\$ 26,832</u>
Patient and digital solutions revenue			
United States	\$ 36,719	\$ 28,175	\$ 10,085
Europe	266	468	82
Rest of World	137	151	113
	<u>\$ 37,122</u>	<u>\$ 28,794</u>	<u>\$ 10,280</u>
Total United States	<u>\$ 265,630</u>	<u>\$ 307,543</u>	<u>\$ 282,009</u>
Total Europe	<u>\$ 10,167</u>	<u>\$ 9,549</u>	<u>\$ 9,822</u>
Total Rest of World	<u>\$ 4,527</u>	<u>\$ 4,701</u>	<u>\$ 4,566</u>
Total	<u><u>\$ 280,324</u></u>	<u><u>\$ 321,793</u></u>	<u><u>\$ 296,397</u></u>

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

	December 31, 2023	December 31, 2022
Long-lived assets:		
United States	\$ 34,714	\$ 35,020
Europe	476	405
Rest of World	56	104
Total	<u><u>\$ 35,246</u></u>	<u><u>\$ 35,529</u></u>

16. RESTRUCTURING

In January 2023, the Company announced a restructuring plan that is intended to optimize costs and simplify its organizational and corporate structure. The restructuring plan includes the discontinuation of operations at one of its two locations in Fremantle, Australia. The Company expects to complete the closure of the affected location in June 2024. The Company incurred immaterial restructuring charges for the year ended December 31, 2023.

In May and December 2023, the Company announced a reduction of its workforce to simplify and streamline its organization and strengthen the overall effectiveness of its operations. The restructuring charges are primarily related to employee severance pay and related costs. As a result of this plan, the Company incurred \$2.2 million in restructuring charges for the year ended December 31, 2023.

17. SUBSEQUENT EVENTS

Litigation

As discussed in Note 9, *Commitment and Contingencies*, Natera filed claims against the Company alleging that AlloSure infringes Natera's U.S. Patents 10,655,180 and 11,111,544. On January 26, 2024, following a five-day trial, a jury concluded that the Company did not infringe Natera's U.S. Patent 10,655,180 but did infringe Natera's U.S. Patent 11,111,544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera's U.S. Patent 11,111,544 expires in September 2026. The Company anticipates continued litigation as to whether its current AlloSure process infringes the patent. Natera may also move for injunctive relief. The Company intends to seek judicial review of the verdict and contest any potential claims of ongoing infringement and any motion for injunctive relief. The Company intends to defend these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company recorded the damages of \$96.3 million as other liabilities on the consolidated balance sheets as of December 31, 2023 and as litigation expense under the operating expense on the consolidated statements of operations for the year ended December 31, 2023.

Derivative Action

On February 8, 2024, Christian Jacobsen filed a stockholder derivative action complaint in the U.S. District Court for the Northern District of California against the Company as nominal defendant and Dr. Seeto, Mr. Dhingra, Dr. Maag, and other current and former members of the Company's Board of Directors (the "Jacobsen Derivative Action"). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and/or officers of the Company, violated Section 14(a) of the Exchange Act, are liable for contribution under Sections 10(b) and 21(D) of the Exchange Act, engaged in unjust enrichment, waste of corporate assets, aiding and abetting, insider trading, and misappropriation of information, and/or are liable for indemnification. The suit seeks declaratory relief, disgorgement, and to recover alleged damages sustained by the Company as a result of the alleged violations, along with plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. The Jacobsen Derivative Action was designated related to the consolidated derivative action.

As discussed in Note 9, *Commitment and Contingencies*, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action. On February 13, 2024, the parties in the consolidated derivative action filed a joint status statement and administrative motion with the court.

Securities Class Action

As discussed in Note 9, *Commitment and Contingencies*, on May 3, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action against the Company and Reginald Seeto, Ankur Dhingra, and Peter Maag. The parties filed a joint status statement with the court on February 15, 2024.

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as such terms are defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of December 31, 2023. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Based on such evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, in light of the material weaknesses identified in our internal control over financial reporting, our disclosure controls and procedures were not effective at the reasonable assurance level and are not effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act, is (i) recorded, processed, summarized and reported as and when required and (ii) accumulated and communicated to our management, including the principal executive officer and principal financial officer, as appropriate to allow timely discussion regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Management, including our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in the 2013 Internal Control-Integrated Framework. Based on our assessment, management has concluded that our system of internal control over financial reporting was not effective due to the material weaknesses described below. However, after giving full consideration to these material weaknesses, and the additional analyses and other procedures we performed to ensure that our consolidated financial statements included in this Annual Report on Form 10-K were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, our management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with GAAP.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2023, the following material weaknesses have been identified:

General Information Technology Controls. We did not design and maintain effective general information technology controls, or GITCs, for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology, or IT, program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) computer and network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement account balances and disclosures.

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

COSO Framework. We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the

organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an adequate process in place to complete its assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner.

Remediation of Prior Year Material Weaknesses

As disclosed in Part II, Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on February 27, 2023, we previously identified material weaknesses related to GITCs, purchase order approval workflow and the COSO framework.

During the fiscal year ended December 31, 2023, we implemented an intensive program to remediate the previously identified material weaknesses, which included expanding resources, including hiring a Chief Information and Security Officer in the third quarter of 2023, enhancing our control activities for key systems and business processes, and providing training. In addition, we performed manual procedures to validate the completeness and accuracy of the reports generated from the systems that are relevant to the preparation of the consolidated financial statements that did not have effective GITCs.

While we believe that we have completed updates to the control design for the majority of our systems and purchase order approval workflow in response to the identified material weaknesses, the redesigned controls did not operate for a sufficient period of time for management to reach a conclusion regarding the operating effectiveness of the controls that were redesigned in the fiscal year ended December 31, 2023.

However, our management concluded these material weaknesses did not result in any material misstatement in our financial statements or disclosures for the fiscal year ended December 31, 2023.

Our management is committed to maintaining a strong internal control environment. In response to the material weaknesses described above, our management is continuing to take actions to remediate the material weaknesses in internal control over financial reporting, which include but are not limited to the following:

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

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

Attestation Report of the Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, which has expressed an adverse opinion, as stated in their report, which appears herein.

Changes in Internal Control over Financial Reporting

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

ITEM 9B. OTHER INFORMATION

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

ITEM 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, 2023 in connection with the Annual Meeting of Stockholders to be held in 2024, or the 2024 Proxy Statement. To the extent that we do not file the 2024 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.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2024 Proxy Statement. The 2024 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023. To the extent that we do not file the 2024 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 to from the information contained in the 2024 Proxy Statement. The 2024 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023. To the extent that we do not file our 2024 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 to from the information contained in our 2024 Proxy Statement. The 2024 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023. To the extent that we do not file the 2024 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 2024 Proxy Statement. The 2024 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023. To the extent that we do not file the 2024 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 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).

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>Incorporated by Reference</u>		
			<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>
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 CareDx, Inc., 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 CareDx, Inc., effective as of March 24, 2023.	8-K	001-36536	3.1	3/28/2023
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 CareDx, Inc.				
10.1#	Form of Change of Control and Severance Agreement between the Registrant and each of its executive officers.	S-1	333-196494	10.11	6/3/2014
10.2#	Promotion Letter, dated May 21, 2022, by and between the Registrant and Abhishek Jain.	10-Q	001-36536	10.3	8/14/2022
10.3#	Promotion Letter, dated July 12, 2021, between the Registrant and Alex Johnson.	8-K	001-36536	10.1	7/20/2021
10.4#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-196494	10.1	6/3/2014
10.5#	Executive Incentive Compensation Plan.	10-K	001-36536	10.19	3/31/2015
10.6#	Outside Director Compensation Policy, last amended December 21, 2023.	8-K	001-36536	10.1	12/22/2023
10.7	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
10.8+	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

<u>Exhibit Number</u>	<u>Description</u>	<u>Form</u>	<u>Incorporated by Reference</u>		
			<u>File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>
10.9+	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
10.10+	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
10.11+	Lease, dated February 28, 2022, by and between the Registrant and One Miracle Place, LLC.	10-Q	001-36536	10.1	11/3/2022
10.12†	License and Commercialization Agreement, dated May 4, 2018, between the Registrant and Illumina, Inc.	10-Q/A	001-36536	10.3	10/9/2018
10.13	Sales Agreement, dated April 14, 2022, by and between the Registrant and Jefferies LLC.	8-K	001-36536	1.1	4/15/2022
10.14#+	Separation Agreement, dated September 20, 2023, by and between CareDx, Inc. and Abraham Ronai.	10-Q	001-36536	10.1	11/8/2023
10.15#+	Legal Consulting Agreement, dated September 20, 2023, by and between CareDx, Inc. and Abraham Ronai.	10-Q	001-36536	10.2	11/8/2023
10.16+##	Consulting Agreement, dated October 30, 2023, by and between CareDx, Inc. and Reginald Seeto, MBBS.				
10.17+##	Separation Agreement, dated November 1, 2023, by and between CareDx, Inc. and Reginald Seeto, MBSS.				
10.18+##	Retention Bonus Letter, dated December 1, 2023, by and between CareDx, Inc. and Alex Johnson.				
10.19+##	Retention Bonus Letter, dated December 1, 2023, by and between CareDx, Inc. and Abhishek Jain.				
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 Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).				
97*	CareDx, Inc. Clawback Policy				
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				

† 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 28, 2024

By: /s/ ALEXANDER L. JOHNSON

Alexander L. Johnson

President of Patient and Testing Services

(Principal Executive Officer)

By: /s/ ABHISHEK JAIN

Abhishek Jain

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 Alexander L. Johnson and Abhishek Jain, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ ALEXANDER L. JOHNSON</u> Alexander L. Johnson	President of Patient and Testing Services (Principal Executive Officer)	February 28, 2024
<u>/s/ ABHISHEK JAIN</u> Abhishek Jain	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2024
<u>/s/ GEORGE W. BICKERSTAFF, III</u> George W. Bickerstaff, III	Director	February 28, 2024
<u>/s/ FRED E. COHEN</u> Fred E. Cohen	Director	February 28, 2024
<u>/s/ GRACE COLÓN</u> Grace Colón	Director	February 28, 2024
<u>/s/ CHRISTINE M. COURNOYER</u> Christine M. Cournoyer	Director	February 28, 2024
<u>/s/ MICHAEL D. GOLDBERG</u> Michael D. Goldberg	Director	February 28, 2024
<u>/s/ WILLIAM HAGSTROM</u> William Hagstrom	Director	February 28, 2024
<u>/s/ PETER MAAG, PH.D.</u> Peter Maag, Ph.D.	Director	February 28, 2024
<u>/s/ ARTHUR TORRES</u> Arthur Torres	Director	February 28, 2024
<u>/s/ HANNAH VALANTINE</u> Hannah Valantine	Director	February 28, 2024

CORPORATE INFORMATION

Board of Directors

Michael D. Goldberg, MBA
Chair of the Board
Audit and Finance Committee
Compensation/Human Cap Committee
Governance & Nominating Committee

George W. Bickerstaff, III
Partner & Managing Director
MM Dillon & Co.
Audit and Finance Committee
Governance & Nominating Committee

Fred E. Cohen, MD, DPhil
Founder and Chairman
Monograph Capital Partners
Compensation/Human Cap Committee
Science and Technology Committee

Grace Colón, PhD
Compensation/Human Cap Committee
Science and Technology Committee*

Christine M. Cournoyer
Audit and Finance Committee
Science and Technology Committee
Compensation/Human Cap Committee*

William Hagstrom
Founder and Chairman and previous
CEO, Octave Bioscience
Audit and Finance Committee
Compensation/Human Cap Committee

John W. Hanna
President and Chief Executive Officer
CareDx, Inc.

Peter Maag, PhD
CEO, Kyverna Therapeutics, Inc.
Science and Technology Committee

R. Bryan Riggsbee
Audit and Finance Committee*

Arthur A. Torres
Governance & Nominating Committee*

Hannah A. Valantine, MD
Professor of Medicine
Stanford University
Science and Technology Committee
Governance & Nominating Committee

Executive Team

John W. Hanna
President and Chief Executive Officer

Abhishek Jain
Chief Financial Officer

Alex Johnson
President of Patient and Testing Services

Jeff Novack
General Counsel and Secretary

Annual Stockholders Meeting

June 13, 2024 at 10AM PST
Virtual Meeting via live webcast at:
<http://www.virtualshareholdermeeting.com/CDNA2024>

Exchange

Nasdaq Global Market

Ticker Symbol CDNA

Transfer Agent

Computershare Trust Company, N.A.
PO Box 30170
College Station, TX 77842

Legal Counsel

Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019

Independent Registered

Public Accounting Firm

Deloitte
555 Mission Street, Suite 1400
San Francisco, CA 94105

Investor Relations

Greg Chodaczek
investor@CareDx.com

Note on Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of the federal securities laws. Results could differ materially. Further information on factors that could affect results is included in the 2023 Form 10-K included in this annual report.

*Indicates Chairperson of the Committee

CareDx, Inc

8000 Marina Blvd, 4th Floor
Brisbane, CA 94005
Tel 415.287.2300
Fax 415.287.2450
WWW.CAREDX.COM

