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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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number 001-36536

CAREDX, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**94-3316839**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification Number)**

8000 Marina Boulevard
Brisbane, California 94005
(Address of Principal Executive Offices, Including Zip Code)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, as reported by the Nasdaq Global Market on such date was approximately $1.1 billion. Shares of the registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of the registrant's Common Stock outstanding as of February 23, 2023 was 53,674,392.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2023 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, 2022.

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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:

- the potential impact to our business, revenue, financial condition and employees, including disruptions to our testing services, laboratories, clinical trials, supply chain and operations, due to the COVID-19 global pandemic;
- 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, including Kidney Allograft Outcomes AlloSure Registry, or K-OAR, the Outcomes of KidneyCare™ on Renal Allografts registry study, or OKRA, and the Surveillance HeartCare Outcomes Registry, or SHORE;
- 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, 2022; 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 are 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 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 transplants. 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. In 2019, we began providing digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management, or Ottr, and XynManagement, Inc., or XynManagement. We have since increased our offerings in patient and digital solutions with the 2021 acquisitions of TransChart LLC, or TransChart, MedActionPlan.com, LLC, or MedActionPlan, and The Transplant Pharmacy, or TTP. During 2022, we performed more than 182,000 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 235 and 143 centers performing kidney and heart 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 engineered cell therapies.

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our dd-cfDNA offering built on a Next Generation Sequencing, or NGS, platform. In transplantation, more than 100 papers from over 50 studies globally have shown the value of dd-cfDNA in the management of solid organ transplantation. AlloSure Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA, targeting polymorphisms between donor and recipient. This single-nucleotide polymorphism, or SNPs, approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable, high-quality test to differentiate dd-cfDNA.

AlloSure Kidney has received positive coverage decisions for reimbursement from Medicare. 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.

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

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016 before the commercial launch of AlloSure Kidney, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Bloom et al evaluated 102 kidney recipients and demonstrated that dd-cfDNA levels could discriminate accurately and non-invasively distinguish rejection from other types of graft injury. In contrast, serum creatinine has area under the curve of 50%, showing no significant difference between patients with and without rejection. Multiple

publications and abstracts have shown AlloSure Kidney's value in the management of BK viremia, as well as numerous pathologies that cause molecular inflammation and injury such as DSAs and eGFR decline. Most recently, its utility in the assessment of T-cell mediated rejection (TCMR) 1A and borderline rejection was published in the American Journal of Transplant, or AJT, and the outcomes of 1,000 patients were published in Kidney International.

The prospective multicenter trial, the Kidney Allograft Outcomes AlloSure Kidney Registry study, or K-OAR study, has enrolled over 1,700 patients, with plans to survey patients with AlloSure Kidney for 3 years and provide further 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:

- Implementation of AlloSure surveillance does not adversely impact 12-month eGFR.
- AlloSure is not affected by Interstitial Fibrosis and Tubular Atrophy, or IFTA – higher grades of IF/TA were not associated with increased AlloSure scores.
- Fewer biopsies - fewer patients in the KOAR cohort required one or more allograft biopsies compared to the DART surveillance cohort.
- AlloSure-guided biopsies are higher yield – the number of for-cause (clinically indicated) biopsies performed was similar to that seen in DART, but AlloSure-guided biopsies demonstrated higher yield for actionable findings.
- Higher AlloSure with transplant glomerulopathy – Transplant glomerulopathy relatively uncommon on biopsies within 1 year but a trend towards higher AlloSure scores when identified.
- Excellent graft and patient survival - graft survival slightly higher than contemporary United Network for Organ Sharing (UNOS) patient population, despite being a slightly higher risk cohort.
- Validated, reproducible performance - overall performance of AlloSure similar to that seen in other large cohorts, including DART and ADMIRAL.

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 Outcomes of KidneyCare on Renal Allografts, or 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 K-OAR, 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, or the FDA, for marketing and sale as a test to aid in the identification of heart transplant recipients, who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment. The 510(k) clearance from the FDA is also for an In Vitro Diagnostic Multivariate Index Assay, or IVDMIA. AlloMap Heart Score Variability, or AMV, is an additional service we offer, which provides complementary information to help personalize long-term care of heart transplant recipients. It is available only upon request by clinicians. A patient's AMV is based on the variability of a patient's AlloMap Heart scores over time and may be used as a risk stratification tool in estimating the probability that one or more of the clinical events in heart transplant recipients may occur in the future. AMV may be computed from four AlloMap Heart test results within a 24-month period. In addition, the clinical utility of AlloMap Heart is supported by numerous clinical trials that we have sponsored, the results of which have been published in leading peer-reviewed medical journals.

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

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. AlloSure Heart has received a positive coverage decision from Geisinger Health and is covered for use throughout Kaiser.

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), or CARGO 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), or IMAGE, 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 ISHLT (International Society for Heart and Lung Transplantation) guidelines.

HeartCare

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

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

HeartCare provides robust information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection, or ACR, and Antibody Mediated Rejection, or AMR. In September 2018, we initiated the Surveillance HeartCare™ Outcomes Registry, or SHORE. SHORE is a prospective, multi-center, observational, registry of patients receiving HeartCare for surveillance. Patients enrolled in SHORE will be followed for 5 years with collection of clinical data and assessment of 5-year outcomes.

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

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. One of these studies, launched in April 2020, is the ALARM, or AlloSure Lung Allograft Remote Monitoring, study, with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC is being measured. AlloSure Lung applies proprietary NGS technology to measure dd-cfDNA from the donor lung in the recipient bloodstream to monitor graft injury. In June 2020, we submitted an application to the Palmetto MolDx Technology Assessment program seeking coverage and reimbursement for AlloSure Lung and since then we have been in active discussions with Palmetto. In October 2021, we launched AlloSure Lung as part of the CHEST 2021 Annual Meeting. We have gained early adoption with some commercial payers.

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

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

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

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark authorization on January 10, 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 other solutions on the market and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has simple NGS workflow, with a single tube for processing and steps to reduce errors. AlloSeq Tx 17 received CE mark authorization on May 15, 2020.

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

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

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

Patient and Digital Solutions

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

On May 7, 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.

On August 26, 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, or SRTR, 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. Refer to Note 6 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further detail regarding these acquisitions.

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, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

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

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

In November 2021, we acquired MedActionPlan, 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.

COVID-19 Impact

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, we experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020, we launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests.

There continues to be uncertainty around the COVID-19 pandemic as the Omicron variant, including its sub-variants, has periodically caused increases in COVID-19 cases globally, which in turn impacted the availability of medical personnel in transplant centers and the volume of transplant procedures. A sustained reduction in transplant volume can negatively impact our testing volumes, as we saw in the early part of the first quarter of 2022.

Our product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as we were unable to undertake onsite discussions and demonstrations of our recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. Our product business regained normalized sales volumes during the fourth quarter of 2020.

We are maintaining our testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among our employees. In areas where COVID-19 continues to impact healthcare operations, our field-based sales and clinical support teams are supporting providers through virtual platforms.

In addition, we created, and continue to have, a COVID-19 task force that is responsible for crisis decision making, employee communications, and enforcing all safety, monitoring and testing protocols in line with local regulations.

Due to COVID-19, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, and there may be disruptions in our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities.

In addition, our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or reduced staffing due to staff members contracting COVID-19. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to, or become infected with, COVID-19, may adversely impact our clinical trial operations.

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.

For a further timeline of our history, please refer to our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 28, 2020.

Our software solutions are currently used in over 160 transplant centers in the U.S.

As of December 31, 2022, 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. The estimated U.S. average 2020 charges 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 Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, study evidence 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 could 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 the largest (N =398 patients) prospective, multicenter observational study of dd-cfDNA. Elevations in AlloSure Kidney were found to be strongly correlated with active rejection, especially ABMR. ABMR is increasingly recognized as the form of immune-mediated injury causing long-term graft loss. 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.

The AlloSure Kidney test has been approved for Medicare coverage for clinical use when a physician determines there is a need to assess the probability of allograft rejection in kidney transplant recipients. The DART study suggests that AlloSure Kidney can be used to discriminate the probability of active rejection from absence of rejection in a renal transplant recipient. Use of the test may reduce invasive percutaneous renal biopsy procedures among patients with a suspicion of rejection.

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 1,700 renal transplant recipients who will receive AlloSure Kidney as part of long-term surveillance. The clinical outcomes of these patients will be entered into a registry database as the patients will be surveilled for three years.

The study cohort will include a minimum of 300 patients from centers that use renal surveillance biopsies showing the value of AlloSure Kidney in subclinical rejection. The remaining patients will be from centers that do not perform protocol surveillance biopsies, but for cause biopsies, which is the more common practice. Outcomes in these cohorts will be compared, showing the performance of AlloSure Kidney in all variations of clinical practice. A prospective propensity matched control cohort of 2,000 patients will be retrospectively analyzed from the subset of centers showing 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 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 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.

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 predictive artificial intelligence technology of iBox for a multimodality surveillance solution. We have not yet made any applications to private payers for reimbursement coverage of AlloMap Kidney or KidneyCare.

In December 2021, Kidney International published the article Clinical outcomes from the assessing donor derived cell free DNA monitoring Insights of kidney 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 1092 patients. The high-level summary of the manuscript shows:

- Use in both subclinical and clinical rejection: Elevated AlloSure (≥ 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 ($p=0.001$);
- Associated with development of dnDSA: Elevated AlloSure levels ≥ 0.5% was associated with 3 times increase in the risk of development of dnDSA;
- AlloSure as a leading indicator: AlloSure was elevated 91 days (median) ahead of DSA 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 which 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 multicenter-registry named OAR, which focuses on long-term outcomes of patients. We expect these samples and data to enable further discovery and product development of new biomarkers of organ rejection activity, and new diagnostic solutions. 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.

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 turn-around-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 115 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, a 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 and MedActionPlan and pursuant to our license and collaboration agreement with Cibiltech SAS. 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 $90.4 million, $76.5 million and $48.9 million were incurred during the years ended December 31, 2022, 2021 and 2020, respectively.

Our ongoing efforts include:

- increasing understanding of biological processes of transplant rejection through analysis of genes/metagenes 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 lung, 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 and AlloSure Heart;
- 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 such as AiTraC; 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 a dd-cfDNA-based solution for kidney transplant patients, AlloSure Kidney. DART was the first report to establish clinical performance characteristics for this molecular biomarker in renal transplant patients with an analytically validated assay of dd-cfDNA (N =398 patients) from a prospective, multicenter observational study of dd-cfDNA. The study population is representative of the spectrum renal transplant recipients in the United States. Elevations in AlloSure Kidney were found to be strongly correlated with active rejection, especially with ABMR. ABMR is increasingly recognized as the form of immune-mediated injury causing long-term graft loss.

K-OAR is the next step in the further development of data to support the clinical utility of AlloSure Kidney. The Centers for Medicare & Medicaid Services, or CMS, Medicare Administrative Contractor, or MAC, Palmetto GBA, or Palmetto, in October 2017, recommended Medicare coverage for AlloSure Kidney. The K-OAR study commenced in January 2018. K-OAR is a 1-2 and 3-year post-transplant clinical outcomes study in approximately 1,700 patients managed with AlloSure Kidney surveillance compared to another 300 patients who will serve as a comparative 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 to include multimodality testing with the addition of AlloMap Kidney Gene Expression Profiling and prognostic graft assessment using iBox. The patient transplant registry is statistically powered to determine the utility of KidneyCare and provide real world data on the use of KidneyCare and AlloSure Kidney. OKRA targets more than 50 transplant centers and will enroll approximately 1,500 newly transplanted patients, complementing the K-OAR with 1,500 patients, matching both arms with a total of 1,000 control 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. The use of routine monitoring of AlloSure after kidney transplant may allow clinicians to identify subclinical allograft injury and intervene prior to development of a clinically evident graft injury. To evaluate this, data from 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 (0.5% or more) 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 (hazard ratio 2.71) and were determined to be elevated a median of 91 days (interquartile range of 30-125 days) ahead of donor specific antibody identification. Persistently elevated dd-cfDNA (more than one result above the 0.5% threshold) 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. Thus, persistently low dd-cfDNA levels may accurately identify allograft quiescence or absence of injury, paving the way for personalization of immunosuppression trials.

AlloMap Kidney Gene Expression Tool

The AlloMap Kidney test is a gene expression profile utilizing the RNA-seq platform to measure 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.

dd-cfDNA for Heart Transplants

We believe that the AlloSure Heart dd-cfDNA-based solution provides additional value to AlloMap Heart.

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 could help clinicians identify recipients with a higher probability of rejection and help 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 and HeartCare is included as part of our SHORE registry of dd-cfDNA in association with gene-expression profiling (AlloMap Heart) in heart transplant recipients.

The 2021 ISHLT guidelines published in 2022 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 GEP and dd-cfDNA in the surveilling the transplanted heart for rejection.

HistoMap

We established a strategic research partnership with NanoString Technologies, Inc., or NanoString, dedicated to the development of HistoMap, a gene expression profiling, or GEP, solution to identify allograft rejection types in transplant biopsy tissue. The partnership will combine our clinical expertise and extensive transplant registries with NanoString's technological capabilities to provide solutions that bring precision medicine to histopathology. We will utilize NanoString's nCounter® technology in conjunction with the newly introduced Human Organ Transplant panel, a 770-gene panel designed to evaluate the human immune response in biopsy tissue from a transplanted organ. 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. In 2021, we entered into a collaboration with Arkana Laboratories, a leading kidney pathology laboratory, to develop HistoMap Kidney.

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 of next generation, 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 have been updating, and intend to continue to update, our HLA typing kits with newly identified alleles. QTYPE and AlloSeq Tx use technology platforms that can readily accommodate this increase in HLA allele assays.

The advent of NGS technology has enabled significant improvement in HLA sequencing data. 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. Our HLA typing products are used in labs throughout the world to help determine which organs or bone marrow are a transplantation match between the donor and the recipient.

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. We also introduced AlloSeq Tx at the 2019 ASHI Annual Meeting and continue to improve the product.

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 transplant. 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 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 Ottr and XynManagement in 2019. These acquisitions have strengthened our growing portfolio of transplant software solutions such as Ottr and XynQAPI. In 2021, we acquired TransChart, MedActionPlan and TTP. We are committed to continue upgrading these software programs, including medication adherence management, and further integrating them into our current testing service offerings to provide a unified user 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 and AlloSure Heart tests performed on patients covered by Medicare. Tests performed on patients covered by Medicare represented 34%, 40% and 48% of all tests in 2022, 2021 and 2020, respectively. Approximately 64%, 68% and 67% of all testing services revenue was derived from Medicare for the years ended December 31, 2022, 2021 and 2020, 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.

Following the assignment of a Category 1 Current Procedural Terminology, or CPT code, for AlloMap Heart in September 2015, CMS issued a proposed Clinical Laboratory Fee Schedule, or CLFS, Preliminary Determinations for calendar year 2016. In October 2016, CMS reversed its preliminary gapfill determination for the 2017 CLFS and restored the final pricing determinations for AlloMap Heart in the 2017 CLFS to $2,821. The Protecting Access to Medicare Act of 2014, or 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 would report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. CMS will 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. The CARES Act freezes current (2020) CMS CLFS rates through 2021. Further, the CARES Act delays the reporting cycle under PAMA to January 1 and March 31, 2025, and the preceding data collection period will become January 1 through June 30, 2024. In December 2021, Congress passed the Protecting Medicare and Medicare Farmers from Sequester Cuts Act.

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.

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. AlloSure Heart has received a positive coverage decision from Geisinger Health and is covered for use throughout Kaiser.

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 to isolate the white blood cells, which are subsequently broken down, frozen and sent via overnight courier to our laboratory. Each of the 20 genes comprising AlloMap Heart is tested in triplicate, and the 11 informative genes are combined to produce the AlloMap Heart score. The remaining 9 genes are used as part of the rigorous quality control testing performed to assess every phase of the test process. The test 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.

When AlloSure Kidney, AlloSure Heart or AlloSure Lung is ordered by a clinician, a blood sample is drawn and sent overnight at ambient temperature to our laboratory. Cell-free DNA is purified from the plasma and the fraction of the total cell-free DNA derived from the transplanted organ, the dd-cfDNA, is quantified and reported as a percentage. Tests 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. 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, a master mix formula 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, XM-One, 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.

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. 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 Viracor, Inc., or Eurofins, 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 in order 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 acquisition of transplant-focused companies One Lambda and Linkage Biosciences. 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 known in the diagnostics industry as “home brews”. 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 include 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. 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

In order 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 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, 2022, we had 20 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have two issued U.S. patents covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart. The expiration dates of these patents range from 2023 to 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, four in 2021 and two in 2022, that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents are expiring between 2030 and 2032.

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

License Agreements

We currently rely on license agreements to obtain rights under certain patents that we believe may be necessary to make, use and sell our AlloSure tests and future solutions. 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 20 existing U.S. patents related to transplant rejection and autoimmunity, nine are the product of exclusive licensing agreements.

In June 2014, we entered into an amended and restated license agreement with Stanford, which granted us an exclusive license to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA and a non-exclusive license to related technology provided by Stanford. Subject to various rights of extension, we are required to achieve certain development and commercialization milestones set forth in the license agreement. Under the terms of the Stanford license, we are required to report and pay royalties in the low single digits on net sales of products incorporating the licensed technology.

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. Two issued patents for HLA genotyping are exclusively licensed as part of this agreement.

On April 30, 2019, we entered into a license and collaboration agreement with Cibiltech SAS, or Cibiltech, pursuant to which we were granted an irrevocable, non-transferable right to commercialize Cibiltech's proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation in the U.S. for a period of ten years.

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, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

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. The FFDCA and its implementing regulations govern, among other things, the following activities relating to our medical devices: preclinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, post-market adverse event reporting, import/export, and advertising and promotion. 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 AlloMap Heart or AlloSure Kidney.

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 the event the FDA changes their policy in regards to “Enforcement discretion” for LDTs, it could require us to modify our business model and incur higher costs in order to maintain compliance with this new policy. 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. 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 clinical trials to demonstrate clinical validity and utility of our test, and submit to the FDA a premarket approval application, or PMA, or 510(k) premarket notification application and obtain approval or clearance for the test subsequent to commercialization. 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.

Sanctions for a violation of the Stark Law include the following:

- denial of Medicare payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $26,125 per service for submitting or causing to be submitted a claim in violation of the Stark Law and an assessment of up to three times the amount claimed;
- exclusion from federal health care programs, including the Medicare and Medicaid programs; and
- a civil penalty of up to $174,172 against parties that enter into a scheme to circumvent the Stark Law's prohibitions.

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 health care 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 the federal health care 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 health care 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 health care 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, health care 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 on April 24, 2020 published a proposed rule to codify new authority in regulation, which the agency proposed would be effective 60 days after it issues a final rule, but in no event before November 2, 2020. The U.S. Department of Health and Human Services Office of Inspector General has not yet issued a final rule.

Anti-Kickback Statutes

The federal health care 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 health care 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 health care 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 health care 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.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $11,803 and $23,607 for each false claim for penalties assessed after December 31, 2021. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits or causes another to submit, a false claim for reimbursement to 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

New 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 take effect in 2023, including Virginia, Colorado, Utah and Connecticut.

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 roll-out 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 change 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 date of certification for our products under the IVDR is currently under review in consultation 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 to IVDR requirements by May 2026.

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, 2022, we had 738 employees, of which 727 were full-time employees. We had 185 employees in manufacturing operations and support, 192 in research and development, 239 in sales and marketing and 122 in general and administrative positions. As of December 31, 2022, 648 employees were located in the United States and 90 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 LinkedIn Learning platform, a learning library and repository for self-guided personal and professional learning opportunities. 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.

In addition, the success of our business is fundamentally connected to the well-being, health and safety of our employees. We are maintaining our testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among our employees. In areas where COVID-19 continues to impact healthcare operations, our field-based sales and clinical support teams are supporting providers through telephone and online platforms.

We also created, and continue to have, a COVID-19 task force that is responsible for crisis decision making, employee communications, and ensuring all safety, monitoring and testing protocols in line with local regulations.

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 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, leaning 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 background 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.

- Our business may be adversely affected by the effects of health epidemics, including the continuing COVID-19 pandemic.
- 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 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 larger and more 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 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.
- In order to operate our laboratory, we have to comply with the CLIA and federal and state laws and regulations governing clinical laboratories and laboratory developed tests, including FDA regulations.
- We are subject to 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

Our business may be adversely affected by the effects of health epidemics, including the continuing COVID-19 pandemic.

Our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations. Additionally, collaborators at research hospitals may be subject to limitations with respect to accessing their laboratories and sample banks, which could impact timelines for research and product development dependent on external collaborations. Limits on the ability of individuals to move freely during a pandemic may also negatively impact recruiting new staff necessary to expand our operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a continued widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Management is actively monitoring the effect of the global situation on our financial condition, liquidity, operations, suppliers, industry and workforce. While the spread of COVID-19 may eventually be contained or mitigated, we cannot predict the timing of the vaccine roll-out globally or the continued efficacy of such vaccines, and we do not yet know how businesses, clinics, patients or our partners will operate in a post COVID-19 environment. The ultimate impact of the COVID-19 pandemic on our business, operations, or the global economy as a whole, remains highly uncertain, and a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results.

Though availability of vaccines and reopening of state and local economies has improved the outlook for recovery from COVID-19's impacts, the impact of the Delta or Omicron variants or other new, more contagious or lethal variants that may emerge, the effectiveness of COVID-19 vaccines against variants and the related responses by governments, including reinstated government-imposed lockdowns or other measures, cannot be predicted at this time. We continue to evaluate and refine our return to work strategy. We also continue to monitor the World Health Organization and Centers for Disease Control and Prevention guidelines, as well as other federal, state and local guidance, as we adapt and as some of our employees have returned to in-person work.

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, 2022, our net loss was $76.6 million. As of December 31, 2022, we had an accumulated deficit of $460.4 million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of 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;
- 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, 2022, revenue from Medicare for AlloMap Heart, AlloSure Kidney and AlloSure Heart represented 64% of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

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

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

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.

If an AlloMap Heart, AlloSure Kidney or AlloSure Heart reimbursement rate that is significantly lower than the current rate is set by CMS or MolDx in the future, it could cause us to discontinue AlloMap Heart, AlloSure Kidney or AlloSure Heart testing for Medicare patients because providing tests at a substantially lowered reimbursement rate may not be economically viable. Given the significant portion of payments represented by Medicare, our remaining test revenue may be insufficient to sustain our operations.

If future reimbursement 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.

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 or AlloSure Heart 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 or AlloSure Heart could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

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

Our financial results currently are largely dependent on sales of AlloSure Kidney, AlloMap Heart 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, 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 be likely not to order a diagnostic test unless third-party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic testing service, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

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

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

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

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

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

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

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

Reimbursement for AlloSure Kidney, AlloMap Heart and AlloSure Heart comes primarily from Medicare and private third party payers such as insurance companies and managed care organizations. The reimbursement process can take six months or more to complete depending on the payer. 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, 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 the CMS, including with respect to coding, 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.

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

We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18, 2020 in the U.S. District Court for the District of Delaware, or the Court, alleging we made false and misleading claims about the performance capabilities of AlloSure. The suit seeks injunctive relief and unspecified monetary relief. On September 30, 2020, Natera requested leave of the Court to amend its counterclaims to include additional allegations regarding purportedly false claims we made with respect to AlloSure, and the Court granted Natera's request. The trial commenced on March 7, 2022 and concluded on March 14, 2022, with the jury awarding us $44.9 million in damages, comprised of $21.2 million in compensatory damages and $23.7 million in punitive damages. As of the date of this report, the post-trial motion practice remains pending. We will not record the award until cash is received or the matter is otherwise resolved.

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 addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13, 2020 in the Court alleging, among other things, that AlloSure infringes Natera's U.S. Patent 10,526,658. This case was consolidated with our patent infringement suit on February 4, 2020. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera's U.S. Patent 10,597,724. The suit seeks a judgment that we have infringed Natera's patents, an order preliminarily and permanently enjoining us from any further infringement of such patents and unspecified damages. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera's U.S. Patents 10,655,180 and 11,111,544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera's U.S. Patent 10,526,658. On July 6, 2022, we moved to dismiss the rest of Natera's claims. On September 6, 2022, we withdrew the motion to dismiss. We intend to defend both of these matters vigorously, and believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

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

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. Plaintiffs' opposition to the motion to dismiss and motion to strike is due on March 13, 2023, and defendants' reply is due on April 13, 2023. We intend to defend ourselves vigorously, and believes 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 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 the Board 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, Ankur Dhingra, Peter Maag and other current and former members of the Company's 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.

We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the Edelman Derivative Action and the Stevenson 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 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, including the continued impact of the COVID-19 pandemic. 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;
- 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 larger and more 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 and Eurofins, 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 2021 to 2022, our revenue grew from $296.4 million to $321.8 million, which represents annual growth of 9%. In the future, our revenue may not grow at all and it may decline. We believe that our future revenue will depend on, among other factors:

- the continued usage and acceptance of our current and future solutions;
- demand for our testing services, 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 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 related or attributable to the COVID-19 pandemic, or related to the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, 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 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, 2022, we had cash, cash equivalents and marketable securities of $293.1 million and an accumulated deficit of $460.4 million. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- develop other solutions for clinical surveillance in transplantation;
- increase our selling and marketing efforts to drive market adoption and address competitive developments;
- expand our clinical laboratory operations;
- fund our clinical 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. Moreover, we have the ability to sell up to $200.0 million of additional shares of our common stock to the public through an “at the market” offering pursuant to a Sales Agreement we entered into with Jefferies, LLC on April 14, 2022. Any shares of common stock issued in the at-the-market offering will result in dilution to our existing 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 (such as COVID-19), 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 be 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.

In addition, we may experience employee turnover as a result of the ongoing "great resignation" occurring throughout the U.S. economy, which has impacted job market dynamics. 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 addition, our ABI 7900 Thermocycler, a real time PCR instrument used in AlloMap Heart, is no longer in production. Thermo Fisher has committed to provide service and support of this instrument through 2023. 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 COVID-19 pandemic or the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, 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 and the global impact of restrictions and sanctions imposed on Russia;
- 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 such as the COVID-19 pandemic 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. On June 23, 2016, the United Kingdom, or the UK, held a referendum pursuant to which voters elected to leave the EU, commonly referred to as Brexit. The UK formally left the EU on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, and the UK is in the process of negotiating trade deals with other countries, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; increased inflation globally and in the U.S. in particular; 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. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our tests and in our ability to raise additional capital when needed on acceptable terms, if at all. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. We

cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

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

We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. 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.

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, 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'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 through 2023 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.

Our License and Commercialization Agreement, or the Cibiltech Agreement, with Cibiltech SAS, or Cibiltech, may not result in material benefits to our business.

The Cibiltech Agreement provides us an exclusive right to commercialize its proprietary software iBox. We have not yet made any applications to payers for reimbursement coverage of iBox. The failure to obtain reimbursement coverage from payers for iBox could result in material amounts of revenue not being recognized for iBox itself.

Risks Related to Billing and Reimbursement

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

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

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

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

Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized 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. 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 any audits or inquiries evaluating the medical necessity of our services 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 ADLTs), private payer payment rates and volumes for their tests. The new PAMA rules took effect January 1, 2018 and used 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

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

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

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

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

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

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

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 were required to conduct additional 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 AlloSure Kidney and other future solutions under development as medical devices, we could be required to conduct additional premarket clinical testing subsequent to commercialization in the case of AlloSure Kidney and/or conduct premarket clinical testing prior to submitting a regulatory application for commercial sales for future products not yet developed. If we are required to conduct premarket clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of 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 health care program, such as the Medicare and Medicaid programs;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services, including clinical laboratory services, reimbursed by Medicare if the physician (or a member of the physician's family);

- has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- state laws regarding prohibitions on fee-splitting;
- the federal health care program exclusion statute; and
- state and foreign law equivalents of each of the above federal laws and regulations, such as anti-kickback, false claims, and self-referral laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. We previously received a civil investigative demand, or CID, from the United States Department of Justice, or DOJ, requesting that we produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the SEC in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. We also previously received an information request from a state regulatory agency. The state regulatory agency recently advised us that it has completed its review of our business practices and determined that no further information or action is required. In late 2022, we received a request for information from a separate state regulatory agency concerning specimen collection by a vendor in the state. We may receive additional requests for information from the DOJ, SEC, or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the SEC subpoena or the state regulatory agency information request raise 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 or SEC investigations, the state regulatory agency information request, or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and 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, the SEC subpoena and other information requests. Any of the foregoing consequences could seriously harm our business and our financial results.

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

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, 2022, we had 20 issued U.S. patents related to transplant rejection and autoimmunity. Among those, we have two issued U.S. patents covering methods of diagnosing transplant rejection using all 11 informative genes measured in AlloMap Heart. The expiration dates of these patents range from 2023 to 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, four in 2021 and two in 2022, that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents are expiring between 2030 and 2032.

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. 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 United States Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. In the Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015) case, a federal court recently determined that a cfDNA product for fetal testing was not eligible for patent protection. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a "sufficient" additional feature for this purpose is uncertain. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. In particular, in September 2011, the United States Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms United States patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This has not yet had a material impact on the operation of our business and the protection and enforcement of our intellectual property, but it may in the future. The AIA and its implementation could still increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Patent applications in the United States and many foreign jurisdictions are not published until at least eighteen months after filing, and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent is issued on the application. In addition, publications in the scientific literature often lag behind actual discoveries.

We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we or our licensors, as applicable, were the first to invent the technology

(pre-AIA) or first to file (post-AIA). 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 PTO or a court to determine priority of invention in the United States for pre-AIA applications and patents.

For post-AIA applications and patents, we 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 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.

For example, we became aware that in October 2020, prior to terminating employment and joining a competitor of ours with which we are in current litigation, a former employee of ours downloaded certain of our confidential and privileged information without permission. After our claims against this former employee were filed, the former employee subsequently brought various claims against us. We are in the process of reviewing and, with the assistance of counsel, are continuing to conduct certain interviews and gather information. We intend to vigorously pursue and defend against these matters. Although we believe we have strong claims against, and good and substantial defenses to the claims made by, the former employee, there is no guarantee that we will prevail in these matters. 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, Olerup XM-ONE, 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. In connection with our acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to one U.S. patent issued in April 2014 relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. Additional patents from Stanford included in the exclusive license were issued, including one in 2017, two in 2019, four in 2021 and two in 2022 that further cover the use of dd-cfDNA to diagnose and predict transplant status or outcome. These patents are expiring between 2030 and 2032. As mentioned above, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid, and all three of such patents are licensed to us under the Stanford license. The Court's finding does not have any impact on our ability to continue providing AlloSure. We are actively renegotiating the terms of our license agreement with Stanford.

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

On April 30, 2019, we entered into the Cibiltech Agreement, pursuant to which we were granted an irrevocable, non-transferable right to commercialize Cibiltech's proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation in the U.S. for a period of ten years.

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, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system.

Our rights to use this 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, following the COVID-19 pandemic, 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, which became effective on January 1, 2023, and Colorado passed the Colorado Privacy Act, Utah passed the Consumer Privacy Act, and Connecticut passed the Connecticut Data Privacy Act, all of which will become effective in 2023. 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 2022, our closing stock price ranged from $10.88 to $46.60 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 such as the COVID-19 pandemic;
- 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, including the COVID-19 pandemic; 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 58.0% of our common stock as of February 23, 2023. 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.

We currently have effective registration statements registering shares of our common stock for resale, and such shares are currently freely tradable in the public market. 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, 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 U.S. 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.

In the event we make any 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. 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. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management concluded that we had the following material weaknesses as of December 31, 2022:

- **General Information Technology Controls**. We 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, 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 ("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 the 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 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 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 are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries 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 may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine 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 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, 2022:

Location	Function	Square Footage
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	101,004
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 23, 2023, 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.

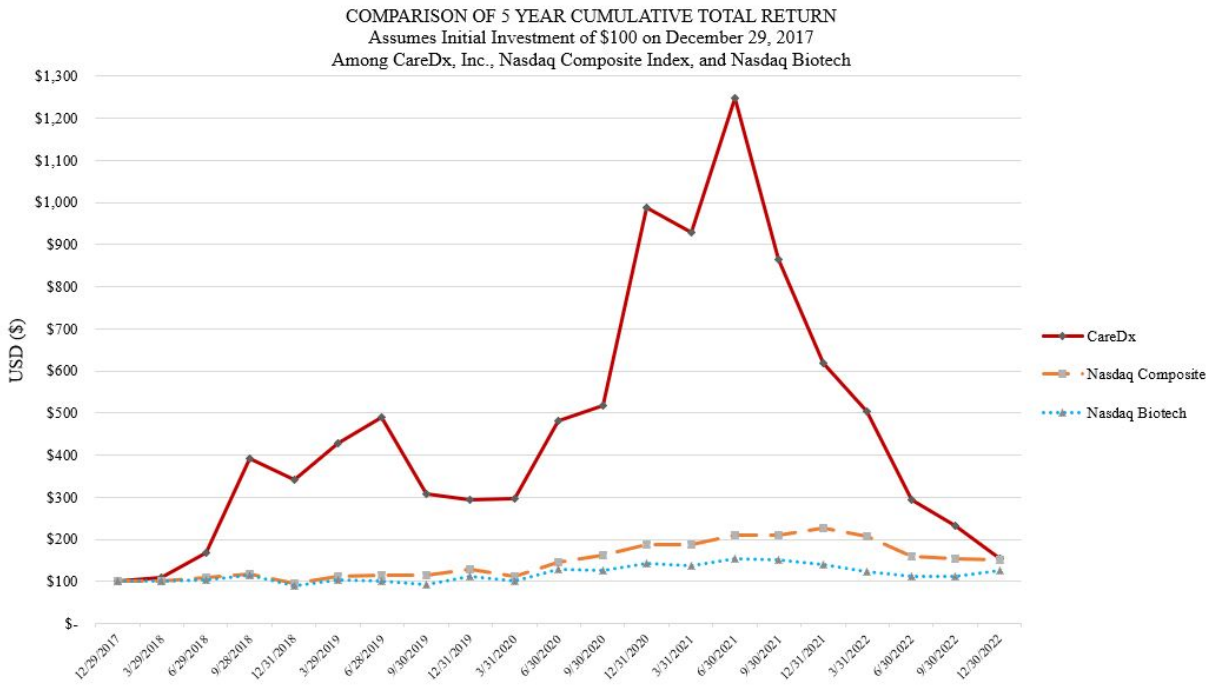
Dividend Policy

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 29, 2017 through December 30, 2022 against the Nasdaq Market Composite Index and Nasdaq Biotech Index, assuming a $100 investment made on December 29, 2017. 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 2022.

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, 2022, 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, 2022 were as follows:

	Total Number of Shares Purchased or Withheld	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (in millions)
October 1, 2022 - October 31, 2022	5,858 (1)	$ 6.22	—	$ —
November 1, 2022 - November 30, 2022	19,143 (1)	5.89	—	—
December 1, 2022 - December 31, 2022	70,898 (2)	12.58	50,051 (3)	49.4 (3)
Total	95,899		50,051 (3)	

(1) Represents shares of our common stock withheld from employees for the payment of taxes. Average price paid per share with respect to withheld shares represents fair market value of our common stock on the date of withholding.

(2) Comprised of: (a) 20,847 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 $6.17, which represents fair market value of our common stock on the date of withholding, and (b) 50,051 shares of our common stock repurchased pursuant to our stock repurchase program at an average price per repurchased share of $12.82.

(3) 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, block trades and in privately negotiated transactions.

ITEM 6. [RESERVED]

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

Kidney

AlloSure Kidney, our transplant surveillance solution, was commercially launched in October 2017 and is our dd-cfDNA offering built on a NGS platform. In transplantation, more than 100 papers from over 50 studies globally have shown the value of dd-cfDNA in the management of solid organ transplantation. AlloSure Kidney is able to discriminate dd-cfDNA from recipient-cell-free DNA, targeting polymorphisms between donor and recipient. This SNP approach across all the somatic chromosomes is specifically designed for transplantation, allowing a scalable, high-quality test to differentiate dd-cfDNA.

AlloSure Kidney has received positive coverage decisions for reimbursement from Medicare. 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.

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

Since the analytical validation paper in the Journal of Molecular Diagnostics in 2016 before the commercial launch of AlloSure Kidney, there has been an increasing body of evidence supporting the use of AlloSure Kidney dd-cfDNA in the assessment and surveillance of kidney transplants. Bloom et al evaluated 102 kidney recipients and demonstrated that dd-cfDNA levels could discriminate accurately and non-invasively distinguish rejection from other types of graft injury. In contrast, serum creatinine has area under the curve of 50%, showing no significant difference between patients with and without rejection. Multiple publications and abstracts have shown AlloSure Kidney's value in the management of BK viremia, as well as numerous pathologies that cause molecular inflammation and injury such as DSAs and eGFR decline. Most recently, its utility in the assessment of T-cell mediated rejection (TCMR) 1A and borderline rejection was published in the American Journal of Transplant, or AJT, and the outcomes of 1,000 patients were published in Kidney International.

The prospective multicenter trial, the K-OAR study, has enrolled over 1,700 patients, with plans to survey patients with AlloSure Kidney for 3 years and provide further clinical utility of AlloSure Kidney in the surveillance of kidney transplant recipients.

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 K-OAR, 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 to aid in the identification of heart transplant recipients, 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.

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

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. AlloSure Heart has received a positive coverage decision from Geisinger Health and is covered for use throughout Kaiser.

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 ISHLT (International Society for Heart and Lung Transplantation) guidelines.

HeartCare

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

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

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

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

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. One of these studies, launched in April 2020, is the ALARM, or AlloSure Lung Allograft Remote Monitoring, study with Johns Hopkins University, where the impact of AlloSure Lung combined with RemoTraC is being measured. AlloSure Lung applies proprietary NGS technology to measure dd-cfDNA from the donor lung in the recipient bloodstream to monitor graft injury. In June 2020, we submitted an application to the Palmetto MolDx Technology Assessment program seeking coverage and reimbursement for AlloSure Lung and since then we have been in active discussions with Palmetto. In October 2021, we launched AlloSure Lung as part of the CHEST 2021 Annual Meeting. We have gained early adoption with some commercial payers.

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, or 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 historical product portfolio includes QTYPE and Olerup SSP. QTYPE enables HLA typing at a low to intermediate resolution for samples that require a fast turn-around-time and uses real-time PCR methodology. 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, Inc., or Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS products and technologies for use in transplantation diagnostic testing.

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

In September 2019, we commercially launched AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and we received CE mark authorization on January 10, 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 other solutions on the market and adding coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has simple NGS workflow, with a single tube for processing and steps to reduce errors. AlloSeq Tx 17 received CE mark authorization on May 15, 2020.

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

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

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

Patient and Digital Solutions

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

On May 7, 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.

On August 26, 2019, we acquired 100% of the outstanding common stock of XynManagement. XynManagement provides two unique solutions, XynQAPI and XynCare. XynQAPI simplifies transplant quality tracking and SRTR 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, closely follow and assist patients through the transplant waitlist process, and ultimately, through transplantation.

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

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

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

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

COVID-19 Impact

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, we experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020, we launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests.

There continues to be uncertainty around the COVID-19 pandemic as the Omicron variant, including its sub-variants, has periodically caused increases in COVID-19 cases globally, which in turn impacted the availability of medical personnel in transplant centers and the volume of transplant procedures. A sustained reduction in transplant volume can negatively impact our testing volumes, as we saw in the early part of the first quarter of 2022.

Our product business experienced a reduction in forecasted sales volume throughout the second and third quarters of 2020, as we were unable to undertake onsite discussions and demonstrations of our recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. Our product business regained normalized sales volumes during the fourth quarter of 2020.

We are maintaining our testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among our employees. In areas where COVID-19 continues to impact healthcare operations, our field-based sales and clinical support teams are supporting providers through virtual platforms.

In addition, we created, and continue to have, a COVID-19 task force that is responsible for crisis decision making, employee communications, and enforcing all safety, monitoring and testing protocols in line with local regulations.

Due to COVID-19, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur or could impact personnel at third-party suppliers in the

United States and other countries, or the availability or cost of materials, and there may be disruptions in our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities.

In addition, our clinical studies may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or reduced staffing due to staff members contracting COVID-19. Some patients may not be able to comply with clinical study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to, or become infected with, COVID-19, may adversely impact our clinical trial operations.

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 82%, 87% and 85% of our total revenues for the years ended December 31, 2022, 2021 and 2020, 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.

We currently market testing services to healthcare providers through our direct sales force that targets transplant centers and their physicians, coordinators and nurse practitioners as well as general nephrologists managing transplant recipients. The healthcare providers that order the tests and on whose behalf we provide our testing services are generally not responsible for the payment of these services. Amounts received by us vary from payer to payer based on each payer's internal coverage practices and policies. We generally bill third-party payers upon delivery of a test result report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

Product Revenue

Our product revenue is derived primarily from sales of AlloSeq Tx, Olerup SSP and QTYPE products. Product revenue represented 9%, 9% and 10% of total revenue for the years ended December 31, 2022, 2021 and 2020, 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, 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 9%, 3% and 5% of total revenue for the years ended December 31, 2022, 2021 and 2020, 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. 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.

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 (customers). 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 remeasured 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 remeasure 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 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 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 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, 2022, 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, 2022, 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, 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 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, 2022, 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

COVID-19 Pandemic

COVID-19 may impact personnel at third-party suppliers in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and testing activities. Clinical trials, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able to

comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

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.

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 guidelines, 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.

The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS would report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued 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 freezes current (2020) CMS CLFS rates through 2021. Further, the CARES Act delays the reporting cycle under PAMA to January 1 and March 31, 2022. The next data collection period will become 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. 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.

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 turn-around-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. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines in the field of bone marrow and solid organ transplantation on diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA

typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, a NGS solution for chimerism testing for stem cell transplant recipients.

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

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

In June 2020, we commercially launched AlloSeq HCT, a 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.

Development of Additional Services and Products

Our development pipeline includes other transplant diagnostic 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 products. Our success in developing new products and services will be important in our efforts to grow our business by expanding the potential market for our services and products 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, 2022 and 2021

(In thousands)

	Year Ended December 31,		
	2022	2021	Change
Revenue:			
Testing services revenue	$ 263,748	$ 259,285	$ 4,463
Product revenue	29,251	26,832	2,419
Patient and digital solutions	28,794	10,280	18,514
Total revenue	321,793	296,397	25,396
Operating expenses:			
Cost of testing services	72,286	71,251	1,035
Cost of product	17,639	18,930	(1,291)
Cost of patient and digital solutions	22,287	7,208	15,079
Research and development	90,388	76,525	13,863
Sales and marketing	96,027	77,245	18,782
General and administrative	100,397	74,964	25,433
Total operating expenses	399,024	326,123	72,901
Loss from operations	(77,231)	(29,726)	(47,505)
Other income (expense):			
Interest income, net	3,762	160	3,602
Change in estimated fair value of common stock warrant liabilities	107	106	1
Other expense, net	(2,872)	(2,628)	(244)
Total other income (expense)	997	(2,362)	3,359
Loss before income taxes	(76,234)	(32,088)	(44,146)
Income tax (expense) benefit	(379)	1,426	(1,805)
Net loss	$ (76,613)	$ (30,662)	$ (45,951)

Testing Services Revenue

Testing services revenue increased by $4.5 million, or 2%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. The increase in testing revenue was driven by the increase in patient results of 28,000 year over year, however majority of these tests were covered by commercial payers that have limited coverage resulting in lower revenue per test.

Product Revenue

Product revenue increased by $2.4 million, or 9%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to growth from the NGS typing products.

Patient and Digital Solutions Revenue

Patient and digital solutions revenue increased by $18.5 million, or 180%, during the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to the acquisitions of TTP and MedActionPlan during the fourth quarter of 2021.

Cost of Testing Services

Cost of testing services increased by $1.0 million, or 1%, for the year ended December 31, 2022, compared to the year ended December 31, 2021. The increase is primarily due to an increase in personnel-related costs of $1.7 million, partially offset by a decrease in stock-based compensation expense of $0.8 million.

Cost of Product

Cost of product decreased by $1.3 million, or (7)%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to lower standard cost and decreased freight costs.

Cost of Patient and Digital Solutions

Cost of patient and digital solutions increased by $15.1 million, or 209%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to the acquisition of TTP and MedActionPlan during the fourth quarter of 2021.

Research and Development

Research and development expenses increased by $13.9 million, or 18%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to an increase in headcount and personnel-related costs of $4.5 million, an increase in consulting and professional fees of $5.6 million, an increase in stock-based compensation expense of $0.3 million and an increase in software expense of $2.1 million.

Sales and Marketing

Sales and marketing expenses increased by $18.8 million, or 24%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to an increase in headcount and personnel-related costs of $10.9 million, an increase in stock-based compensation expense of $3.5 million, an increase in travel costs of $2.5 million and an increase in tradeshows and events of $1.3 million.

General and Administrative

General and administrative expenses increased by $25.4 million, or 34%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to an increase in legal expenses of $11.8 million, an increase in consulting and professional fees of $4.0 million, an increase in stock-based compensation expense of $6.4 million, an increase in software expense of $1.7 million and an increase in travel expenses of $0.3 million, offset by a decrease in personnel-related costs of $1.2 million.

Interest Income, Net

Interest income, net, increased by $3.6 million for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to interest income earned on U.S. agency securities and corporate debt securities.

Other Expense, Net

Other expense, net, increased by $0.2 million, or 9%, for the year ended December 31, 2022, compared to the year ended December 31, 2021, primarily due to an increase in other business expense of $0.9 million, partially offset by a decrease in unrealized loss on our investment in Miromatrix Medical, Inc., or Miromatrix, of $0.6 million.

Income Tax (Expense) Benefit

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 effective tax rate for the year ended December 31, 2022 differs from the federal statutory tax rate 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, 2021, we recorded an income tax benefit of $1.4 million on a loss before income taxes of $32.1 million, primarily attributable to the recognition of deferred tax assets from foreign losses and recognition of previous unrecognized tax benefits. The effective tax rate for the year ended December 31, 2021 differs from the federal statutory tax rate as a result of the income tax expense related to non-deductible executive compensation and the increase in valuation allowance.

Comparison of the Years Ended December 31, 2021 and 2020

For a discussion regarding our financial condition and results of operations for the year ended December 31, 2021 as compared to the year ended December 31, 2020, please refer to the discussion under the heading “Results of Operations—Comparison of the Years Ended December 31, 2021 and 2020” in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 24, 2022.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $460.4 million at December 31, 2022. As of December 31, 2022, we had cash, cash equivalents and marketable securities of $293.1 million, and no debt outstanding.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a continued widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity.

Since March 31, 2020, and in response to the outbreak of the COVID-19 pandemic, we have increased our cash and cash equivalents. 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.

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services, or CMS, expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, we received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on our consolidated balance sheet.

During December 2020, we reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021. We recorded the amount as Refund liability - CMS advance payment on the consolidated balance sheet as of December 31, 2021.

January 2021 Underwritten Public Offering of Common Stock

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

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

At-the-Market Equity Offering

On April 14, 2022, we entered into a sales agreement, or the Sales Agreement, with Jefferies, LLC as sales agent ("Jefferies"), pursuant to which we may offer and sell, from time to time, through Jefferies, up to $200.0 million in shares of our common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Jefferies is entitled to compensation for its services equal to 3% of the gross proceeds of any shares of common stock sold through Jefferies under the Sales Agreement. Any shares of common stock offered and sold pursuant to the Sales Agreement will be issued and sold pursuant to our Registration Statement on Form S-3ASR (File No. 333-239049), filed with the SEC on June 9, 2020, including a base prospectus dated June 9, 2020, and a prospectus supplement dated April 14, 2022.

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, block trades and in privately negotiated transactions. In 2022, we purchased an aggregate of 50,051 shares of our common stock under the Repurchase Program for an aggregate purchase price of $0.6 million. As of December 31, 2022, $49.4 million remained available for future share repurchase under the Repurchase Program.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2022, 2021 and 2020:

	Year Ended December 31,		
	2022	2021	2020
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (25,239)	$ (19,294)	$ 33,431
Investing activities	(228,502)	47,712	(100,394)
Financing activities	(4,535)	185,642	163,149
Effect of exchange rate changes on cash, cash equivalents and restricted cash	23	(303)	274
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (258,253)	$ 213,757	$ 96,460

Cash Flows from Operating Activities

Net cash (used in) provided by 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, 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.

Net cash used in operating activities for the year ended December 31, 2021 was $19.3 million. Our net loss of $30.7 million was our primary use of cash in operating activities. Our net loss also included the following noncash items: $36.1 million in stock-based compensation expense, $8.8 million of depreciation and amortization expense, amortization of right-of-use assets of $3.1 million, loss on disposal of property and equipment of $2.4 million, unrealized loss on long-term marketable equity securities of $1.7 million and amortization of premium on short-term marketable securities, net of $1.1 million. Cash used in operating activities was also due to an increase in accounts receivable of $24.4 million and a decrease in Refund liability - CMS advance payment of $20.5 million. Cash used in operating activities was partially offset by an increase in net operating assets of $3.9 million.

Cash Flows from Investing Activities

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.

For the year ended December 31, 2021, net cash provided by investing activities was $47.7 million and primarily related to proceeds of $88.9 million for the maturities of short-term marketable securities. These proceeds were partially offset by the acquisitions, net of cash acquired, for TransChart, MedActionPlan and TTP of $15.4 million, $5.5 million related to the purchase of long-term marketable securities, $13.6 million related to additions of capital expenditures, net and $6.7 million related to payments for acquired intangibles.

Cash Flows from Financing Activities

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.

Net cash provided by financing activities for the year ended December 31, 2021 was $185.6 million and primarily related to $188.9 million of proceeds from the issuance of shares of common stock in an underwritten offering, net of issuance costs, proceeds from exercises of stock options of $12.8 million and proceeds from issuances of shares of common stock under our employee stock purchase plan of $2.1 million. These proceeds were partially offset by taxes paid related to net share settlements of restricted stock units of $18.1 million.

For a discussion regarding our cash flows for the year ended December 31, 2020, 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, 2021, filed with the SEC on February 24, 2022.

Contractual Obligations

For a discussion regarding our significant contractual obligations as of December 31, 2022 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.

Off-Balance Sheet Arrangements

Not required.

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 $293.1 million at December 31, 2022, which consisted of bank deposits and money market funds, and we had cash, cash equivalents and marketable securities of $348.5 million at December 31, 2021, which consisted of bank deposits, money market funds and corporate debt securities. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 100 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of $2.9 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, 2022, would have negatively impacted our financial results for the year ended December 31, 2022 by $0.3 million and our product revenue by $1.3 million. Currently, we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility. We will continue to reassess our approach to managing our risk relating to fluctuations in foreign currency exchange rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CareDx, Inc.
Index to Consolidated Financial Statements

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 27, 2023, expressed an adverse opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit 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 a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue Recognition - Testing Services Revenue — Refer to Note 2 to the consolidated financial statements

Critical Audit Matter Description

During the year ended December 31, 2022, the Company's revenue from testing services was $263.7 million. As discussed in Note 2, the Company's testing services revenue is recognized upon the delivery of test results to the prescribing physician, at which time the Company bills for its services. The Company recognizes revenue related to billings based on transaction prices estimated as the amount that will ultimately be realized.

The transaction price estimate represents the estimated consideration the Company expects to receive based on historical collection experience and other anticipated adjustments, including anticipated payer denials. In determining the amount to recognize for a delivered test, the Company considers factors such as payment history, amount collected per test, payer coverage, and whether there is a reimbursement contract between the payer and the Company. 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, which is an estimate that requires significant judgment by the Company.

We identified management's estimation of the transaction price for revenue recorded as a critical audit matter due to the significant judgments required by management to estimate payer behavior. 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 judgments in the estimate of transaction prices for testing services revenue, included the following, among others:

- We understood and tested the design, implementation, and operating effectiveness of controls over management's determination of the assumptions used and the related review and approval of the transaction price estimate.
- We tested the methodology used by the Company to estimate transaction prices by independently recalculating the estimated transaction prices.
- We tested the assumptions used by management to calculate transaction prices by:
    - Testing the mathematical accuracy of management's calculation.
    - Testing the historical cash receipts from 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 2022.
    - Evaluating trends in revenue and accounts receivable compared to previous periods to identify any evidence that may contradict management's assertion regarding estimated transaction price.

Impact on Financial Statements of Material Weaknesses in Internal Control Over Reporting - Refer to Management's 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 27, 2023

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, 2022, 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, 2022, 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, 2022, of the Company and our report dated February 27, 2023, 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, 2022, of the Company, and this report does not affect our report on such financial statements.

/s/ Deloitte & Touche LLP

San Jose, California
February 27, 2023

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

	As of December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 89,921	$ 348,485
Marketable securities	203,168	—
Accounts receivable	66,312	59,761
Inventory	19,232	17,186
Prepaid and other current assets	9,216	7,928
Total current assets	387,849	433,360
Property and equipment, net	35,529	22,044
Operating leases right-of-use assets	34,689	17,993
Intangible assets, net	43,051	50,195
Goodwill	37,523	36,983
Restricted cash	522	211
Other assets	3,828	5,835
Total assets	$ 542,991	$ 566,621
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,942	$ 13,337
Accrued compensation	16,902	26,042
Accrued and other liabilities	49,131	37,922
Total current liabilities	75,975	77,301
Deferred tax liability	—	415
Common stock warrant liability	32	139
Deferred payments for intangible assets	2,418	5,041
Operating lease liability, less current portion	33,406	17,394
Other liabilities	249	455
Total liabilities	112,080	100,745
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at December 31, 2022 and 2021; 53,583,301 and 52,923,360 shares issued at December 31, 2022 and 2021, respectively; 53,533,250 and 52,923,360 shares outstanding at December 31, 2022 and 2021, respectively	52	52
Additional paid-in capital	898,806	853,683
Accumulated other comprehensive loss	(7,503)	(4,670)
Accumulated deficit	(460,444)	(383,189)
Total stockholders' equity	430,911	465,876
Total liabilities and stockholders' equity	$ 542,991	$ 566,621

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,		
	2022	**2021**	**2020**
Revenue:			
Testing services revenue	$ 263,748	$ 259,285	$ 163,610
Product revenue	29,251	26,832	19,302
Patient and digital solutions	28,794	10,280	9,282
Total revenue	321,793	296,397	192,194
Operating expenses:			
Cost of testing services	72,286	71,251	43,932
Cost of product	17,639	18,930	13,847
Cost of patient and digital solutions	22,287	7,208	5,338
Research and development	90,388	76,525	48,941
Sales and marketing	96,027	77,245	53,858
General and administrative	100,397	74,964	48,806
Total operating expenses	399,024	326,123	214,722
Loss from operations	(77,231)	(29,726)	(22,528)
Other income (expense):			
Interest income, net	3,762	160	271
Change in estimated fair value of common stock warrant liability	107	106	(1,495)
CARES Act Provider Relief Fund	—	—	4,813
Other expense, net	(2,872)	(2,628)	(811)
Total other income (expense)	997	(2,362)	2,778
Loss before income taxes	(76,234)	(32,088)	(19,750)
Income tax (expense) benefit	(379)	1,426	1,036
Net loss	$ (76,613)	$ (30,662)	$ (18,714)
Net loss per share (Note 3):			
Basic	$ (1.44)	$ (0.59)	$ (0.40)
Diluted	$ (1.44)	$ (0.59)	$ (0.40)
Weighted-average shares used to compute net loss per share:			
Basic	53,321,625	52,241,076	46,481,772
Diluted	53,321,625	52,241,076	46,481,772

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,		
	2022	**2021**	**2020**
Net loss	$ (76,613)	$ (30,662)	$ (18,714)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	(2,833)	(2,574)	3,109
Net comprehensive loss	$ (79,446)	$ (33,236)	$ (15,605)

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				
Balance at December 31, 2019	42,498,430	$ 42	$ 437,976	$ (5,205)	$ (333,813)	$ 99,000
Issuance of common shares through public equity offering, net of commissions and offering costs of $9,166	4,492,187	4	134,580	—	—	134,584
Issuance of common shares in connection with "at-the-market" equity offering, net of commissions and offering costs of $785	1,000,000	1	23,450	—	—	23,451
Issuance of common stock under employee stock purchase plan	76,723	—	1,393	—	—	1,393
RSU settlements, net of shares withheld	333,178	—	(4,529)	—	—	(4,529)
Issuance of common stock for services	11,116	—	315	—	—	315
Issuance of common stock for cash upon exercise of stock options	691,318	1	8,006	—	—	8,007
Issuance of common stock for cash upon exercise of warrants	338,214	1	8,007	—	—	8,008
Employee stock-based compensation expense	—	—	23,055	—	—	23,055
Foreign currency translation adjustment	—	—	—	3,109	—	3,109
Net loss	—	—	—	—	(18,714)	(18,714)
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 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	52	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	$ 52	$ 898,806	$ (7,503)	$ (460,444)	$ 430,911

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,		
	2022	**2021**	**2020**
Operating activities:			
Net loss	$ (76,613)	$ (30,662)	$ (18,714)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Stock-based compensation	46,553	36,081	23,401
Asset impairments and write-downs	840	2,437	—
Depreciation and amortization	11,595	8,797	7,006
Amortization of right-of-use assets	4,412	3,088	2,538
Unrealized loss on long-term marketable equity securities	1,181	1,743	—
Revaluation of common stock warrant liability to estimated fair value	(107)	(106)	1,495
Revaluation of contingent consideration to estimated fair value	727	(609)	309
Amortization of premium on short-term marketable securities, net	390	1,129	—
Other non-cash items	—	(222)	—
Changes in operating assets and liabilities:			
Accounts receivable	(6,660)	(24,416)	(10,402)
Inventory	(2,859)	(6,927)	(3,196)
Prepaid and other assets	(1,049)	(5,144)	(41)
Accounts payable	(2,054)	1,789	4,389
Accrued compensation	(9,251)	7,516	5,737
Accrued and other liabilities	11,327	10,690	2,911
Operating lease liabilities, net	(3,456)	(2,603)	(1,475)
Refund liability - CMS advance payment	—	(20,496)	20,496
Change in deferred taxes	(215)	(1,379)	(1,023)
Net cash (used in) provided by operating activities	(25,239)	(19,294)	33,431
Investing activities:			
Maturities of short-term marketable securities	111,587	88,905	—
Purchases of short-term marketable securities	(315,145)	—	—
Purchases of long-term marketable securities	—	(5,500)	(90,034)
Additions of capital expenditures	(21,234)	(13,559)	(7,110)
Acquisition of intangible assets	(3,100)	(6,700)	(3,250)
Acquisition of business, net of cash acquired	(610)	(15,434)	—
Net cash (used in) provided by investing activities	(228,502)	47,712	(100,394)
Financing activities:			
Proceeds from issuance of common shares in public equity offering, net of issuance costs paid	—	188,855	134,684
Proceeds from issuance of common shares in "at-the-market" equity offering, net of issuance costs paid	—	—	23,451
Payment of contingent consideration	(2,625)	—	—
Principal payments on finance lease obligations	—	(66)	(183)
Repurchase and retirement of common stock	(642)	—	—
Proceeds from exercise of warrants	—	4	352
Proceeds from exercise of stock options	2,435	12,775	8,006
Proceeds from issuance of common stock under employee stock purchase plan	2,230	2,139	1,368
Taxes paid related to net share settlement of restricted stock units	(5,933)	(18,065)	(4,529)
Net cash (used in) provided by financing activities	(4,535)	185,642	163,149
Effect of exchange rate changes on cash and cash equivalents	23	(303)	274
Net (decrease) increase in cash, cash equivalents and restricted cash	(258,253)	213,757	96,460
Cash, cash equivalents, and restricted cash at beginning of period	348,696	134,939	38,479
Cash, cash equivalents, and restricted cash at end of period	$ 90,443	$ 348,696	$ 134,939
Supplemental disclosures of cash information			
Cash paid for interest	$ 8	$ 1	$ 10
Cash paid for income taxes	$ 392	$ 14	$ 80
Supplemental disclosures of cash flow information			
Shares issued in lieu of payment	$ 319	$ 296	$ 315
Operating lease right-of-use assets	$ 22,267	$ 6,079	$ 55
Purchases of capital expenditures in accounts payable and accrued liabilities	$ 1,423	$ 3,953	$ 274
Employee stock purchase plan shares included in accrued compensation	$ 686	$ 1,521	$ 800
Contingent consideration	$ —	$ 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. See also Note 16.

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.

Testing Services

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.

In October 2020, the Company received a final Palmetto MolDx Medicare coverage decision for AlloSure Heart. In November 2020, Noridian Healthcare Solutions, the Company's 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.

In May 2021, the Company purchased a minority investment of common stock in the biotechnology company Miromatrix for $5.0 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.

Clinical Studies

In January 2018, the Company initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study ("K-OAR"), to develop additional data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients. K-OAR is a multicenter, non-blinded, prospective observational cohort study which has enrolled more than 1,700 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 February 2019, AlloSure® Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. In June 2020, the Company submitted an AlloSure Lung application to the Palmetto MolDx Technical Assessment program seeking coverage and reimbursement for Medicare beneficiaries.

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.

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 Tx Access, a cloud-based service that allows nephrologists and dialysis centers to electronically submit referrals to transplant programs, 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 to develop clinical decision support tools across the transplant patient journey. Together, the Company and OrganX will develop advanced analytics that integrate AlloSure, the first transplant specific dd-cfDNA assay, with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation beyond multi-modality by incorporating a variety of clinical inputs to create a universal composite scoring system. The Company has agreed to potential future milestone payments.

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

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.

COVID-19 Pandemic

The full impact of the continued COVID-19 pandemic, including the impact associated with preventative and precautionary measures that the Company, other businesses and governments have taken and may take, continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company, but the pandemic may materially affect the Company's financial condition, liquidity and future results of operations.

In the final weeks of March and during April 2020, with hospitals increasingly caring for COVID-19 patients, hospital administrators chose to limit or even defer, non-emergency procedures. Immunosuppressed transplant patients either self-prescribed or were asked to avoid transplant centers and caregiver visits to reduce the risk of contracting COVID-19. As a result, with transplant surveillance visits down, the Company experienced a slowdown in testing services volumes in the final weeks of March and during April 2020. As a response to the COVID-19 pandemic, and to enable immune-compromised transplant patients to continue to have their blood drawn, in late March 2020, the Company launched RemoTraC, a remote home-based blood draw solution using mobile phlebotomy for AlloSure and AlloMap surveillance tests, as well as for other standard monitoring tests.

There continues to be uncertainty around the COVID-19 pandemic as the Omicron variant, including its sub-variants, has periodically caused increases in COVID-19 cases globally, which in turn impacted the availability of medical personnel in transplant centers and the volume of transplant procedures. A sustained reduction in transplant volume can negatively impact the Company's testing volumes, as the Company saw in the early part of the first quarter of 2022.

The Company's product business experienced a reduction in sales volume throughout the second and third quarters of 2020, as it was unable to undertake onsite discussions and demonstrations of its recently launched NGS products, including AlloSeq Tx 17, which was awarded CE mark authorization in May 2020. The Company's product business regained normalized sales volumes during the fourth quarter of 2020.

The Company is maintaining its testing, manufacturing, and distribution facilities while implementing specific protocols to reduce contact among employees. In areas where COVID-19 continues to impact healthcare operations, the Company's field-based sales and clinical support teams are supporting providers through virtual platforms.

In addition, the Company created, and continues to have, a COVID-19 task force that is responsible for crisis decision making, employee communications, and enforcing all safety, monitoring and testing protocols in line with local regulations.

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 $460.4 million at December 31, 2022. As of December 31, 2022, the Company had cash and cash equivalents and marketable securities of $293.1 million.

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020 the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”). Pursuant to the CARES Act, the Centers for Medicare & Medicaid Services (“CMS”) expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million, and recorded the payment as Deferred revenue - CMS advance payment on the Company's consolidated balance sheet. During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021. Refer to Note 8, Balance Sheet Components, for further explanation.

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.

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 revenue; standalone fair value of patient and digital solutions revenue performance obligations; accrued expenses for clinical studies; inventory valuation; the fair value of issued common stock warrants and embedded derivatives; the fair value of assets and liabilities acquired in a business combination or an assets 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, 2022, 2021 and 2020, approximately 53%, 59% and 57%, respectively, of total revenue was billed to Medicare. No other payers represented more than 10% of total revenue for the years ended December 31, 2022, 2021 and 2020.

As of December 31, 2022 and 2021, approximately 27% and 27%, respectively, of accounts receivable was due from Medicare. No other payer represented more than 10% of accounts receivable at either December 31, 2022 or 2021.

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 $0.5 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, 2022, 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, 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, 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, 2022, the Company's long-term marketable securities consisted of corporate equity securities. The long-term marketable securities are classified as other assets on the consolidated balance sheet.

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

The Company records its long-term marketable equity securities at fair market value. Unrealized gains and losses from the remeasurement of the long-term marketable equity securities to fair value are included in other income (expense), net, in 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, 2022, 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, 2022, 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, 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 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 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, 2022, no impairment of acquired in-process technology assets 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, 2022, the Company’s leases had remaining terms of 0.92 years to 10.09 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.

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 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 the Company's customers for this class of revenue. The main performance obligations in connection with the Company's 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, 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

In November 2021, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*, which contains amendments that require annual disclosures about transactions with a government that are accounted for by applying a grant or contribution accounting model. The disclosures include (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The amendments set forth in this ASU are effective for all entities for annual periods beginning after December 15, 2021. Early application of the amendments in this ASU is permitted. The amendments in this ASU should be applied either (1) prospectively to all transactions within the scope of the amendments that are reflected in financial statements at the date of initial application and new transactions that are entered into after the date of initial application or (2) retrospectively to those transactions. The Company adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In October 2021, the FASB issued ASU No. 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires that an entity recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). At the acquisition date, an acquirer should account for the related revenue contracts in accordance with ASC 606 as if it had originated the contracts. The amendments set forth in this ASU are effective for fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The amendments in this ASU should be applied prospectively to business combinations occurring on or after the effective date of the amendments. The Company adopted the standard prospectively on January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*, which contains amendments that clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The amendments set forth in this ASU are effective for all entities for annual periods beginning after December 15, 2021. Early application of the amendments in this ASU is permitted for all entities. The amendments in this ASU should be applied prospectively. The Company adopted the standard prospectively on

January 1, 2022. The adoption of this new standard had no impact on the Company's consolidated financial statements and disclosures.

In October 2020, the FASB issued ASU No. 2020-10, *Codification Improvements,* which contains amendments that improve the consistency of the ASC by including all disclosure guidance in the appropriate Disclosure Section (Section 50). The FASB provided transition guidance for all the amendments in this ASU. The amendments in Sections B and C (Section A has been removed) of this ASU are effective for annual periods beginning after December 15, 2020 for public business entities. Early application of the amendments in this ASU is permitted for public business entities for any annual or interim period for which financial statements have not been issued. The amendments in this ASU should be applied retrospectively. The Company adopted the standard on January 1, 2021. The adoption of the new standard did not have an impact on the Company's consolidated financial statements and disclosures.

3. NET LOSS PER SHARE

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

For the years ended December 31, 2022, 2021 and 2020, 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,		
	2022	2021	2020
Numerator:			
Net loss used to compute basic net loss per share	$ (76,613)	$ (30,662)	$ (18,714)
Net loss used to compute diluted net loss per share	$ (76,613)	$ (30,662)	$ (18,714)
Denominator:			
Weighted-average shares used to compute basic net loss per share	53,321,625	52,241,076	46,481,772
Weighted-average shares used to compute diluted net loss per share	53,321,625	52,241,076	46,481,772
Net loss per share:			
Basic	$ (1.44)	$ (0.59)	$ (0.40)
Diluted	$ (1.44)	$ (0.59)	$ (0.40)

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

	Year Ended December 31,		
	2022	2021	2020
Shares of common stock subject to outstanding options	2,921,925	1,863,633	2,670,398
Shares of common stock subject to outstanding common stock warrants	3,132	3,132	6,264
Restricted stock units	3,092,467	2,047,657	1,878,866
Total common stock equivalents	6,017,524	3,914,422	4,555,528

During April 2020, the Company issued and sold 1,000,000 shares of its common stock under the Sales Agreement pursuant to an "at-the-market" equity offering.

On June 15, 2020, the Company completed an underwritten public offering pursuant to which the Company sold 4,492,187 shares of common stock.

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, 2022 and 2021 (in thousands):

	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

	December 31, 2021			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Cash equivalents:				
Money market funds	$ 335,107	$ —	$ —	$ 335,107
Marketable securities:				
Corporate equity securities	3,257	—	—	3,257
Corporate debt securities	—	500	—	500
Total	$ 338,364	$ 500	$ —	$ 338,864
Liabilities				
Short-term liabilities:				
Contingent consideration	$ —	$ —	$ 2,114	$ 2,114
Long-term liabilities:				
Contingent consideration	—	—	3,227	3,227
Common stock warrant liability	—	—	139	139
Total	$ —	$ —	$ 5,480	$ 5,480

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):

Common Stock Warrant Liability and Contingent Consideration	(Level 3)
Balance at December 31, 2020	$ 447
Exercise of warrants	(202)
Change in estimated fair value of common stock warrant liability	(106)
Change in estimated fair value of contingent consideration	5,341
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

As of December 31, 2022, the Company had one investment in convertible preferred shares carried at cost. In the event the Company had to calculate the fair value of this investment, it would be based on Level 3 inputs. This investment is not considered material to the Company's consolidated financial statements.

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, 2022 and 2021, money market funds were included as cash and cash equivalents in the consolidated balance sheets.
- *Short-term marketable securities* — Investments in short-term marketable securities are classified within Level 2. The securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

- *Long-term marketable equity and debt securities* — Investments in long-term marketable equity securities are classified within Level 1. The securities are recorded at fair value based on readily available quoted market prices in active markets. Investments in long-term marketable debt securities are classified within Level 2. The securities are recorded at fair value based on observable inputs for quoted prices for identical or similar assets in markets that are not active. Long-term marketable securities are located within other assets on the 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 multiplied by management's estimate of the probability of success at a discounted rate of 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 a component of operating expenses 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. Prior to fiscal year 2022, the Company utilized a binomial lattice pricing model (the "Monte Carlo Simulation Model"), which involves a market condition simulation to estimate the fair value of the warrants. The application of the Monte Carlo Simulation Model requires the use of a number of complex assumptions, including the Company's stock price, expected life of the warrants, stock price volatility determined from the Company's historical stock prices, and risk-free rates based on the implied yield currently available in the U.S. Treasury zero-coupon issues with a remaining term equal to the expected life of the warrants. The change in valuation method does not have material financial impact.

Common Stock Warrant Liability Valuation Assumptions:

	December 31,	
	2022	2021
Private Placement Common Stock Warrant Liability		
Stock Price	$ 11.41	$ 45.48
Exercise Price	$ 1.12	$ 1.12
Remaining term (in years)	0.28	1.28
Volatility	N/A	66.00 %
Risk-free interest rate	N/A	0.49 %

Warrant liabilities exercised during 2021 were remeasured at the exercise date. Their fair value approximates their intrinsic value, which was recorded to additional paid in capital in the consolidated statements of stockholders' equity. There were no warrant liabilities exercised during 2022.

The Company's liabilities classified as Level 3 were valued based on unobservable inputs and management's judgment due to the absence of quoted market prices, inherent lack of liquidity and the long-term nature of the financial instruments.

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, 2022	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 89,921	$ 348,485	$ 134,669
Restricted cash	522	211	270
Total cash, cash equivalents, and restricted cash at the end of the period	$ 90,443	$ 348,696	$ 134,939

Marketable Securities

All short-term marketable securities were considered held-to-maturity at December 31, 2022. At December 31, 2022, 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, 2022. 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 at December 31, 2022.

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

	December 31, 2021		
	Amortized Cost	Unrealized Holding Losses	Fair Value
Long-term marketable securities:			
Corporate equity securities	$ 5,000	$ (1,743)	$ 3,257
Corporate debt securities	500	—	500
Total long-term marketable securities	$ 5,500	$ (1,743)	$ 3,757

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

	December 31, 2022
Within one year	$ 203,168
After one year through five years	—
Total	$ 203,168

6. BUSINESS COMBINATIONS

The Transplant Pharmacy

In December 2021, the Company acquired TTP, a transplant focused pharmacy located in Mississippi. The Company acquired TTP with a combination of cash consideration paid upfront and contingent consideration with a fair value of $1.3 million. TTP provides individualized transplant pharmacy services for patients at multiple transplant centers located throughout the U.S.

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

Goodwill of $5.5 million arising from the acquisition primarily consists of additional growth opportunities within the pharmacy sector. The integration of TTP into the Company's portfolio is expected to continue to increase the transplant ecosystem for patients and make medication more accessible. The Company estimated net deferred tax liabilities of approximately $0.6 million arising from temporary differences related to the assets acquired and liabilities assumed. 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 value of the intangible asset acquired as of the acquisition date ($ in thousands):

	Estimated Fair Value	Estimated Useful Life (Years)
Trademark	$ 2,080	10

The trademark acquired consists primarily of the TTP brand and markings. The fair value of the trademark was 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 rate of 2% was used to estimate the fair value of the trademark.

A discount rate of 13.5% was utilized in estimating the fair value of the trademark.

The pro forma impact of the TTP 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.

MedActionPlan

In November 2021, the Company acquired MedActionPlan, a New Jersey-based provider of medication safety, medication adherence and patient education. The Company acquired MedActionPlan with a combination of cash consideration paid upfront and contingent consideration with a fair value of $3.5 million. MedActionPlan is a leader in patient medication management for transplant patients and beyond.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Acquisition-related costs of $0.6 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 $4.9 million arising from the acquisition primarily consists of synergies from integrating the MedActionPlan technology with the current testing and digital solutions offered by the Company. The integration of MedActionPlan into centers with the Company's other software platforms will continue to increase the standard of care for transplant patient safety, increase efficiency and facilitate medication compliance. 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	$ 2,590	10
Developed technology	1,090	10
Trademarks	80	5
Total	$ 3,760	

Customer relationships acquired by the Company represent the fair value of future projected revenue that is expected to be derived from sales of MedActionPlan'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 MedActionPlan's proprietary software. The trademark acquired consists primarily of the MedActionPlan 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 15% and 1% were used to estimate the fair value of the developed technology and the trademark, respectively.

A discount rate of 40.0% was utilized in estimating the fair value of these three intangible assets.

The pro forma impact of the MedActionPlan 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.

TransChart LLC

In January 2021, the Company acquired TransChart for cash. TransChart provides EMR software to hospitals throughout the U.S. to care for patients who have or may need an organ transplant. As a result of the acquisition, the Company recognized goodwill of $2.2 million and intangible assets of $2.0 million.

The pro forma impact of the TransChart 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 TransChart, TTP and MedActionPlan, 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	$ 17,166
Total consideration	$ 17,166
Recognized amounts of identifiable assets acquired and liabilities assumed	
Current assets	$ 3,444
Fixed assets	23
Identifiable intangible assets	7,860
Other assets	2
Current liabilities	(3,915)
Noncurrent liabilities	(2,883)
Total identifiable net assets acquired	4,531
Goodwill	12,635
Total consideration	$ 17,166

The allocation of the purchase price to assets acquired and liabilities assumed was based on the Company's best estimate of the fair value of such assets and liabilities as of the acquisition date.

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. There were no indicators of impairment in the year ended December 31, 2022.

The following table presents details of the Company's goodwill as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Balance as of January 1,	$ 36,983	$ 23,857
Goodwill acquired	540	13,126
Balance as of December 31,	$ 37,523	$ 36,983

On December 1, 2022, 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, 2022, no impairment of goodwill has been identified.

Intangible Assets

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	73,764	(27,175)	(4,788)	41,801	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	$ 75,014	$ (27,175)	$ (4,788)	$ 43,051	

The following table presents details of the Company's intangible assets as of December 31, 2021 ($ in thousands):

	December 31, 2021				
	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	$ 35,874	$ (12,088)	$ (1,513)	$ 22,273	8.1
Customer relationships	21,898	(6,024)	(1,210)	14,664	9.9
Commercialization rights	10,579	(2,030)	—	8,549	7.6
Trademarks and tradenames	4,540	(988)	(155)	3,397	9.5
Other	250	(188)	—	62	0.2
Total intangible assets with finite lives	73,141	(21,318)	(2,878)	48,945	
Acquired in-process technology	1,250	—	—	1,250	
Total intangible assets	$ 74,391	$ (21,318)	$ (2,878)	$ 50,195	

Acquisition of intangible assets

In June 2021, the Company acquired commercialization rights in an exclusive partnership for comprehensive data analytics in relation to NGS-based metagenomics testing for infectious diseases. During the year ended December 31, 2022, the Company incurred additional costs related to this partnership of $1.0 million. These are included within commercialization rights as of December 31, 2022.

In June 2021, the Company acquired the Transplant Hero patient application. The patient application is included in Acquired and developed technology as of December 31, 2022.

In the fourth quarter of 2021, acquisition of intangible assets increased $13.4 million primarily from business combinations. These acquisitions included $4.7 million of Acquired and developed technology, $2.5 million of Commercialization rights, $3.7 million of Customer relationships, $2.2 million of Trademarks and tradenames and $0.3 million of Other intangible assets.

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,		
	2022	2021	2020
Cost of testing services	$ 1,316	$ 1,316	$ 1,316
Cost of product	1,716	1,905	1,665
Cost of patient and digital solutions	945	684	345
Sales and marketing	2,252	1,891	1,472
Total	$ 6,229	$ 5,796	$ 4,798

The following table summarizes the Company’s estimated future amortization expense of intangible assets with finite lives as of December 31, 2022 (in thousands):

Years Ending December 31,	Cost of Testing Services	Cost of Product	Cost of Patient and Digital Solutions	Sales and Marketing	Total
2023	$ 1,316	$ 1,675	$ 945	$ 2,211	$ 6,147
2024	1,316	1,675	709	2,211	5,911
2025	1,316	1,675	540	2,211	5,742
2026	1,316	743	540	2,209	4,808
2027	1,316	743	540	2,195	4,794
Thereafter	2,825	3,294	1,180	7,100	14,399
Total future amortization expense	$ 9,405	$ 9,805	$ 4,454	$ 18,137	$ 41,801

8. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Finished goods	$ 2,962	$ 3,911
Work in progress	4,306	2,828
Raw materials	11,964	10,447
Total inventory	$ 19,232	$ 17,186

Property and Equipment, Net

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

	December 31,	
	2022	2021
Leasehold improvements	$ 17,389	$ 8,466
Machinery and equipment	16,294	12,091
Internally developed software	10,893	3,746
Construction in progress	7,639	10,925
Computer and office equipment	5,570	5,454
Furniture and fixtures	2,168	943
Property and equipment	59,953	41,625
Less: Accumulated depreciation and amortization	(24,424)	(19,581)
Property and equipment, net	$ 35,529	$ 22,044

Depreciation expense was $5.2 million, $2.7 million and $1.9 million for the years ended December 31, 2022, 2021 and 2020, respectively.

There were no assets purchased under finance leases during 2022. Accumulated depreciation was $0.6 million and $0.5 million at December 31, 2022 and 2021, respectively. Related amortization expense, included in depreciation and amortization expense, was $0.1 million for each of the three years ended December 31, 2022, 2021 and 2020.

Accrued and Other Liabilities

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

	December 31,	
	2022	2021
Clinical studies	$ 14,816	$ 10,653
Professional fees	6,115	5,780
Short-term lease liability	5,591	3,958
Deferred revenue	5,342	4,208
Accrued royalty	4,633	1,664
Laboratory processing fees and materials	2,189	1,664
Deferred payments for intangible assets	2,062	2,000
Capital expenditures	1,316	2,612
Contingent consideration	1,025	2,114
License and other collaboration fees	1,000	—
Accrued shipping expenses	489	668
Other accrued expenses	4,553	2,601
Total accrued and other liabilities	$ 49,131	$ 37,922

CMS Accelerated and Advance Payment Program for Medicare Providers

On March 27, 2020, the U.S. government enacted the CARES Act. Pursuant to the CARES Act, CMS expanded its Accelerated and Advance Payment Program in order to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. CMS was authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider who submitted a request to the appropriate Medicare Administrative Contractor and met the required qualifications. During April 2020, the Company received an advance payment from CMS of approximately $20.5 million and recorded the payment as Deferred revenue - CMS advance payment on the Company's consolidated balance sheet. During December 2020, the Company reassessed the Deferred revenue - CMS advance payment and repaid the entire amount in January 2021.

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, 2022, the carrying value of the ROU asset was $34.7 million. The related current and non-current liabilities as of December 31, 2022 were $5.6 million and $33.4 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):

	2022	2021	2020
Operating lease cost	$ 6,716	$ 5,134	$ 4,441
Finance lease cost	—	53	205
Total lease cost	$ 6,716	$ 5,187	$ 4,646

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

Other information:	
Weighted-average remaining lease term - Operating leases (in years)	6.26
Weighted-average discount rate - Operating leases (%)	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.

As of December 31, 2022, the ROU assets and lease liabilities for lease agreements which commenced in July 2022 aggregated to $14.3 million and $15.3 million, respectively.

As of December 31, 2022, the ROU assets and lease liabilities for lease agreements which commenced in August 2022, amounted to $5.8 million and $6.0 million, respectively.

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

	2022	2021	2020
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows used for operating leases	$ 3,665	$ 2,580	$ 934
Operating cash flows used for finance leases	—	63	199
Total	$ 3,665	$ 2,643	$ 1,133

Maturities of operating lease liabilities as of December 31, 2022, are as follows (in thousands):

Years ending December 31,	Operating Leases
2023	$ 7,807
2024	7,903
2025	7,651
2026	7,019
2027	7,166
Thereafter	10,605
Total lease payments	48,151
Less imputed interest	9,154
Present value of future minimum lease payments	38,997
Less operating lease liability, current portion	5,591
Operating lease liability, long-term portion	$ 33,406

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.

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.

Cibiltech Commitments

Pursuant to that certain license and commercialization agreement that the Company entered into with Cibiltech SAS ("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.

Tax Commitments

As of December 31, 2022, the Company had gross unrecognized tax benefits of $5.4 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 through 2023.

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 awarding the Company $44.9 million in damages, comprised of $21.2 million in compensatory damages and $23.7 million in punitive damages. Post-trial motion practice remains pending. The Company will not record the award until cash is received or the matter is otherwise resolved.

On July 19, 2022, the United States Court of Appeals for the Federal Circuit affirmed the Court's judgment dismissing the Company's patent infringement suit against Natera.

In addition, in response to the Company's patent infringement suit filed against Natera on March 26, 2019, 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. The Company intends to defend both of these matters vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suits, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for these suits.

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 ("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. The Company also received an information request from a state regulatory agency. The state regulatory agency recently advised the Company that it has completed its review of the Company's business practices and determined that no further information or action is required. In late 2022, the Company received a request for information from a separate state regulatory agency concerning specimen collection by a vendor in the state. The Company may receive additional requests for information from the DOJ, SEC, or other regulatory and governmental agencies regarding similar or related subject matters. The Company does not believe that the CID, the SEC subpoena or the state regulatory agency information request raise any issues regarding the safety or efficacy of any of the Company's products or services and are cooperating fully with the investigations and the request for information. Although the Company remains committed to compliance with all applicable laws and regulations, it cannot predict the outcome of the DOJ or SEC investigations, the state regulatory agency information request, 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.

Olymbios Matter

On April 15, 2022, a complaint was filed by Michael Olymbios against the Company in the Superior Court of the State of California for the County of San Mateo (the "San Mateo County Court"). The complaint alleges that the Company failed to pay certain fees and costs required to continue an arbitration proceeding against Dr. Olymbios, and that the Company has defamed Dr. Olymbios. Dr. Olymbios also seeks to void restrictive covenants previously agreed to by him in favor of the Company and to recover damages purportedly incurred by Dr. Olymbios. The Company filed a motion to compel arbitration and dismiss the case. On April 25, 2022, the San Mateo County Court granted the Company's *ex parte* application to stay the case and advance the hearing date to June 10, 2022 for the motion to compel arbitration and dismiss. At the June 10, 2022 hearing, the San Mateo County Court found that the decision should be made by the arbitrator, and stayed the case. On July 19, 2022, Olymbios filed a motion to withdraw from arbitration before JAMS, which was denied on August 18, 2022. The arbitration hearing is currently set for June 26, 2023. The Company intends to defend itself vigorously. The Company believes it has good and substantial defenses to the claims alleged in the suit, but there is no guarantee that the Company will prevail if the case continues. The Company has not recorded any liabilities for this suit.

Securities Class Action

On May 23, 2022, Plumbers & Pipefitters Local Union #295 Pension Fund filed a federal securities class action in the U.S. District Court for the Northern District of California against the Company, Reginald Seeto, its 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 Board 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 complaints on November 28, 2022. On January 27, 2023, defendants moved to dismiss all claims and to strike certain allegations in the amended complaint. Plaintiffs' opposition to the motion to dismiss and motion to strike is due on March 13, 2023, and defendants' reply is due on April 13, 2023. The Company intends to defend itself vigorously, and believes that the Company has good and substantial defenses to the claims alleged in the suit, but there is no guarantee that the Company will prevail. The Company has not recorded any liabilities for this suit.

Derivative Action

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 Reginald Seeto, its President, Chief Executive Officer and member of the Company's Board of Directors, Ankur Dhingra, its former Chief Financial Officer, Peter Maag, its former President, former Chief Executive Officer, former Chairman of the Board and current member of the Company's Board of Directors, 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 twenty (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.

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.

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. In 2022, the Company purchased an aggregate of 50,051 shares of its common stock under the Repurchase Program for an aggregate purchase price of $0.6 million. As of December 31, 2022, $49.4 million remained available for future share repurchase under the Repurchase Program. See also Note 16.

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, 2022, 2021 and 2020.

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 $1.8 million, $1.4 million and $0.7 million for the years ended December 31, 2022, 2021 and 2020, 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, 2022, no warrants to purchase shares of common stock were exercised.

During the year ended December 31, 2021, warrants to purchase approximately 3,000 shares of common stock were exercised for cash proceeds of $4 thousand.

As of December 31, 2022, outstanding warrants to purchase common stock were:

	Classified as	Original Term	Exercise Price	Number of Shares Underlying Warrants
Original issue date:				
April 2016	Liability	7 years	$ 1.12	3,132
				3,132

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 1,297,408 shares of common stock reserved for future issuance under the 2014 Plan as of December 31, 2022.

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, 2022.

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 130,302 shares of common stock reserved for future issuance under the 2019 Plan as of December 31, 2022.

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, 2021	2,066,529	1,863,633	$ 29.33	2,047,657	$ 50.21
Additional options authorized	2,116,934	—	—	—	—
Common stock awards for services	(12,764)	—	—	—	—
RSUs granted	(2,397,369)	—	—	2,397,369	27.79
RSUs vested	—	—	—	(643,892)	42.59
Options granted	(1,864,465)	1,864,465	28.35	—	—
Options exercised	—	(142,579)	17.07	—	—
Repurchases of common stock under employee incentive plans	211,265	—	—	—	—
RSUs forfeited	706,738	—	—	(706,738)	43.80
Options forfeited	554,427	(554,427)	34.12	—	—
Options expired	109,167	(109,167)	33.96	—	—
Balance—December 31, 2022	1,490,462	2,921,925	$ 28.13	3,094,396	$ 37.39

The total intrinsic value of options exercised was $1.6 million, $42.9 million and $19.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

The total fair value of RSUs vested during 2022 was $20.0 million. As of December 31, 2022, the total intrinsic value of outstanding RSUs was approximately $37.1 million and there were $74.7 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 2.55 years.

Options outstanding that have vested and are expected to vest at December 31, 2022 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	1,186	$ 25.39	5.72	$ 1,558
Expected to Vest	1,592	30.37	8.94	—
Total	2,778			$ 1,558

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, 2022 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, 2022, 2021 and 2020 using the Black-Scholes Model was $19.51, $52.65 and $18.97, respectively.

The total fair value of options that vested during 2022 was $10.6 million. As of December 31, 2022, there were approximately $27.7 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 2.97 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 2022 that ended on June 30, 2022, 67,570 shares were purchased for aggregate proceeds of $1.2 million from the issuance of shares, which occurred on July 1, 2022. During the offering period in 2022 that ended on December 31, 2022, 47,025 shares were purchased for aggregate proceeds of $0.5 million from the issuance of shares, which occurred on January 2, 2023. The Company issued 93,422 shares and 45,464 shares of common stock during the years ended December 31, 2022 and December 31, 2021, respectively, pursuant to the ESPP. The Company received proceeds of $3.0 million and $2.1 million from the purchases of shares during the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company had 640,847 shares available for issuance under the ESPP.

Board of Directors Stock Awards Granted for Services

For the years ended December 31, 2022, 2021 and 2020, 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, 2022, there were a total of 289,480 shares issued to the Company's directors, for a total fair value of $2.3 million. Stock-based compensation expense associated with the awards was $0.4 million, $0.3 million and $0.3 million for the years ended December 31, 2022, 2021 and 2020, respectively, which was included in general and administrative expense in 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,		
	2022	2021	2020
Employee stock options			
Expected term (in years)	5.96	5.94	5.98
Expected volatility	77.62 %	77.70 %	75.56 %
Risk-free interest rate	2.74 %	0.80 %	0.69 %
Expected dividend yield	— %	— %	— %
Employee stock purchase plan			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	67.79% – 77.88%	53.10% – 67.79%	62.56% – 93.17%
Risk-free interest rate	2.51% – 4.76%	0.09% – 0.19%	0.17% – 1.57%
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, 2022, 2021 and 2020, included in the consolidated statements of operations as follows (in

thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of testing services	$ 1,529	$ 2,358	$ 1,493
Cost of product	1,120	579	391
Cost of patient and digital solutions	1,331	728	449
Research and development	7,391	7,126	4,676
Sales and marketing	14,403	10,887	5,795
General and administrative	20,779	14,403	10,597
Total	$ 46,553	$ 36,081	$ 23,401

No tax benefit was recognized related to stock-based compensation expense since the Company has never reported taxable income and has established a full valuation allowance to offset all of the potential tax benefits associated with its deferred tax assets. In addition, no amounts of stock-based compensation costs were capitalized for the periods presented.

14. INCOME TAXES

Loss before income taxes for the years ended December 31, 2022, 2021 and 2020 is summarized as follows (in thousands):

	As of December 31,		
	2022	2021	2020
United States	$ (73,089)	$ (27,921)	$ (14,233)
Foreign	(3,145)	(4,167)	(5,517)
Total loss before income taxes	$ (76,234)	$ (32,088)	$ (19,750)

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

	As of December 31,		
	2022	2021	2020
Current			
Federal	$ 145	$ 89	$ (58)
State	328	2	1
Foreign	184	(139)	160
Total current income tax expense (benefit)	657	(48)	103
Deferred			
Federal	(130)	(409)	91
State	75	(127)	(52)
Foreign	(223)	(842)	(1,178)
Total deferred income tax benefit	(278)	(1,378)	(1,139)
Income tax expense (benefit)	$ 379	$ (1,426)	$ (1,036)

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 2022, 2021 and 2020, to loss before income taxes as a result of the following:

	Year Ended December 31,		
	2022	2021	2020
Federal tax statutory rate	21.0 %	21.0 %	21.0 %
Stock-based compensation	(2.8)%	38.8 %	13.5 %
Change in valuation allowance	(16.9)%	86.4 %	(34.4)%
Foreign rate differential	(0.2)%	0.7 %	1.8 %
Warrant revaluation	— %	— %	(1.7)%
Interest expense	— %	— %	(0.3)%
Non-deductible executive compensation	(2.1)%	(23.4)%	(6.8)%
Research credits	1.8 %	6.9 %	3.9 %
Changes in net operating loss carryforwards, including expirations	(0.5)%	(125.1)%	6.9 %
Other	(0.8)%	(0.9)%	1.2 %
Effective income tax rate	(0.5)%	4.4 %	5.2 %

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

	As of December 31, 2022	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 26,658	$ 30,234
Tax credit carryforwards	9,138	7,185
Accruals	2,971	6,054
Property and equipment	—	1,043
Lease liability	9,250	4,639
Section 174 capitalized costs	20,602	—
Stock-based compensation	7,798	7,401
Other	959	587
Gross deferred tax assets	77,376	57,143
Valuation allowance	(59,499)	(45,635)
Total deferred tax assets	17,877	11,508
Deferred tax liabilities:		
Purchased intangibles	(6,615)	(7,439)
Operating leases right-of-use assets	(8,189)	(3,828)
Property and equipment	(2,548)	—
Other	(497)	(656)
Total deferred tax liabilities	(17,849)	(11,923)
Net deferred tax assets (liabilities)	$ 28	$ (415)

The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (i) cumulative results of operations in recent years, (ii) sources of recent losses, (iii) estimates of future taxable income and (iv) the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets. The Company has also placed a valuation allowance on the net deferred tax assets of its Australian operations. Accordingly, the U.S. and Australia net deferred tax assets have been offset by a full valuation allowance. The valuation allowance increased by $13.9 million and decreased by $27.2 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had domestic federal net operating loss carryforwards of $90.5 million, domestic state net operating loss carryforwards of $61.9 million, and foreign net operating loss carryforwards of $13.6 million that can reduce future taxable income. The domestic federal and state net operating loss carryforwards will begin to expire in 2033 and 2030, respectively. The foreign net operating loss carryforwards can be carried forward indefinitely.

As of December 31, 2022, the Company had credit carryforwards of approximately $6.5 million and $10.2 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 2033. California credits have no expiration date.

The Company has recorded a valuation allowance against its deferred tax assets at December 31, 2022 and 2021 because the Company's management believes that it is more likely than not that these assets will not be fully realized. The decrease in the valuation allowance of approximately $27.2 million in the year ended December 31, 2021 primarily relates to the loss of net operating loss carryforwards and research and development (“R&D”) credits due to Section 382 of the Internal Revenue Code and similar provisions under state law. Section 382 of the Internal Revenue Code and similar provisions under state law limit the utilization of U.S. and state net operating loss carryforwards following certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%. Based on the Company's analysis under Section 382 as of December 31, 2022, the Company believes that there are no additional ownership changes that would result in further adjustments to the $158.4 million of its federal net operating loss (“NOL”) carryforwards and $50.5 million of its state NOL carryforwards. $3.9 million of its R&D credit carryforwards were determined to be limited by Section 382 and similar provisions under state law as of December 31, 2021, and these amounts were written off in the year ended December 31, 2021. The remaining unused carryforwards and credits remain available for future periods. Due to the Company's full valuation

allowance, the write off of net operating loss carryforwards and R&D credits did not have any impact to the statements of operations and comprehensive loss.

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

	Year Ended December 31,		
	2022	2021	2020
Balance at the beginning of the year	$ 4,156	$ 4,416	$ 3,650
Additions based on tax positions related to the current year	1,255	805	824
Additions based on tax positions related to prior years	25	130	—
Decreases based on tax positions related to prior years	—	(1,195)	(58)
Balance at the end of the year	$ 5,436	$ 4,156	$ 4,416

None of the $5.4 million of net unrecognized tax benefit as of December 31, 2022, if recognized, would impact the Company's effective tax rate. During the year ended December 31, 2022, 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, 2022 and December 31, 2021, 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 Chief Operating Decision Maker ("CODM"), or decision making group, whose function is to allocate resources to and assess the performance of the operating segments. The Company has identified its Chief Executive Officer as the CODM. In determining its reportable segments, the Company considered the markets and types of customers served and the products or services provided in those markets. The Company operates in a single reportable segment.

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

	Year Ended December 31,		
	2022	2021	2020
Testing services revenue			
United States	$ 262,959	$ 258,412	$ 163,221
Rest of World	789	873	389
	$ 263,748	$ 259,285	$ 163,610
Product revenue			
United States	$ 16,409	$ 13,512	$ 9,219
Europe	9,081	9,740	7,475
Rest of World	3,761	3,580	2,608
	$ 29,251	$ 26,832	$ 19,302
Patient and digital solutions revenue			
United States	$ 28,175	$ 10,085	$ 9,063
Europe	468	82	87
Rest of World	151	113	132
	$ 28,794	$ 10,280	$ 9,282
Total United States	$ 307,543	$ 282,009	$ 181,503
Total Europe	$ 9,549	$ 9,822	$ 7,562
Total Rest of World	$ 4,701	$ 4,566	$ 3,129
Total	$ 321,793	$ 296,397	$ 192,194

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

	December 31, 2022	December 31, 2021
Long-lived assets:		
United States	$ 35,020	$ 21,444
Europe	405	403
Rest of World	104	197
Total	$ 35,529	$ 22,044

16. SUBSEQUENT EVENTS

Business Combination

In January 2023, the Company acquired a software system company based in the U.S. The acquisition will be accounted for as a business combination. The purchase price will be allocated to the assets acquired and liabilities assumed based upon their estimated fair values. The purchase price allocation will be determined when additional information becomes available.

Restructuring Plan

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 its operations in Fremantle, Australia, terminating its employees in that location and vacating its facilities there. The Company expects to complete the closure of its Australia location in June 2024.

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 Reginald Seeto, Ankur Dhingra, Peter Maag, 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. The Company intends to defend itself vigorously, and believes the Company has good and substantial defenses to the claims alleged in this suit, but there is no guarantee that the Company will prevail.

Stock Repurchase

Subsequent to December 31, 2022 and through filing of this Annual Report on Form 10-K, the Company repurchased 25,622 shares of its common stock, for an aggregate purchase price of $13.53 per share, under the Repurchase Program.

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 Chief Executive Officer and Chief 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, 2022. 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 Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, 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 Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Management’s Annual Report on Internal Control over Financial Reporting

Management, including our Chief Executive Officer and Chief 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 the Company's internal control over financial reporting as of December 31, 2022. 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 the Company’s annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2022, the following material weaknesses have been identified:

General Information Technology Controls. 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 account balances 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, and 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.

Management's Plan to Remediate the Material Weaknesses

Our management has been engaged in developing and implementing remediation plans to address the material weaknesses described above. These remediation efforts are ongoing and are expected to include the following:

- Enhancing the design and control procedures of the GITCs to ensure that the control activities related to GITCs are functioning appropriately;
- Improving the control environment in relation to personnel training and accountability of Sarbanes-Oxley Act of 2002 control activities;
- Hiring additional personnel in the IT and Finance and Accounting departments with an appropriate level of knowledge and experience to effectively execute our processes and procedures; and
- Expanding controls and/or applying appropriate procedures to address the design and operation of internal controls related to the procure-to-pay process.

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

Attestation Report of the Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2022 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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, 2022 in connection with the Annual Meeting of Stockholders to be held in 2023, or the 2023 Proxy Statement. To the extent that we do not file the 2023 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 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 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 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file our 2023 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 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 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 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022. To the extent that we do not file the 2023 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).

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	001-36536	3.1	8/28/2014
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of CareDx, Inc., filed June 17, 2021.	8-K	001-36536	3.1	6/21/2021
3.3	Amended and Restated Bylaws of the Registrant.	8-K	001-36536	3.2	6/21/2021
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	Form of Warrant.	8-K	001-36536	10.3	4/14/2016
4.7#	2019 Inducement Equity Incentive Plan.	10-Q	001-36536	4.7	7/29/2021
4.8*	Description of Securities of CareDx, Inc.				
10.1#	Offer Letter, dated November 13, 2018, between the Registrant and Reginald Seeto, MBBS.	8-K	001-36536	10.1	11/26/2018
10.2#	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
10.3#	Amendment to Change of Control and Severance Agreement, dated October 29, 2020, by and between the Registrant and Reginald Seeto, MBBS.	8-K	001-36536	10.1	10/29/2020
10.4#	Promotion Letter, dated May 21, 2022, by and between the Registrant and Abhishek Jain.	10-Q	001-36536	10.3	8/14/2022
10.5	Consulting Agreement, dated May 20, 2022, by and between the Registrant and Ankur Dhingra.	10-Q	001-36536	10.2	8/14/2022
10.6#	Promotion Letter, dated July 12, 2021, between the Registrant and Alex Johnson.	8-K	001-36536	10.1	7/20/2021
10.7#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-196494	10.1	6/3/2014
10.8#	Executive Incentive Compensation Plan.	10-K	001-36536	10.19	3/31/2015
10.9#	Outside Director Compensation Policy.	10-K	001-36536	10.10	2/28/2020
10.10	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

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.11+	Second Amendment to Lease, dated January 2, 2020, by and between the Registrant and BMR-Bayshore Boulevard LP (formerly known as BMR-Bayshore Boulevard LLC), for office and laboratory space located at 3260 Bayshore Boulevard, Brisbane, California 94005.	10-Q	001-36536	10.1	4/30/2020
10.12+	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
10.13+	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
10.14+	Lease, dated February 28, 2022, by and between the Registrant and One Miracle Place, LLC.	10-Q	001-36536	10.1	11/3/2022
10.15	Amended and Restated Exclusive Agreement, dated January 27, 2014, by and between the Board of Trustees of the Leland Stanford Junior University and ImmuMetrix, Inc.	10-Q	001-36536	10.1	8/14/2022
10.16†	License and Commercialization Agreement, dated May 4, 2018, between the Registrant and Illumina, Inc.	10-Q/A	001-36536	10.3	10/9/2018
10.17	Sales Agreement, dated April 14, 2022, by and between the Registrant and Jefferies LLC.	8-K	001-36536	1.1	4/15/2022
21.1*	Subsidiaries of the Registrant.				
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (see page 133 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).				
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.

‡ Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by 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.

By: /s/ Reginald Seeto, MBBS
Reginald Seeto, MBBS
President and Chief Executive Officer

Date: February 27, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Reginald Seeto 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.

Signature	Title	Date
/s/ REGINALD SEETO, MBBS Reginald Seeto, MBBS	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 27, 2023
/s/ ABHISHEK JAIN Abhishek Jain	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2023
/s/ GEORGE W. BICKERSTAFF, III George W. Bickerstaff, III	Director	February 27, 2023
/s/ FRED E. COHEN Fred E. Cohen	Director	February 27, 2023
/s/ GRACE COLÓN Grace Colón	Director	February 27, 2023
/s/ CHRISTINE M. COURNOYER Christine M. Cournoyer	Director	February 27, 2023
/s/ MICHAEL D. GOLDBERG Michael D. Goldberg	Director	February 27, 2023
/s/ WILLIAM HAGSTROM William Hagstrom	Director	February 27, 2023
/s/ PETER MAAG, PH.D. Peter Maag, Ph.D.	Director	February 27, 2023
/s/ ARTHUR TORRES Arthur Torres	Director	February 27, 2023
/s/ HANNAH VALANTINE Hannah Valantine	Director	February 27, 2023

Exhibit 4.8

Description of Securities of CareDx., Inc.

The authorized capital stock of CareDx, Inc., a Delaware corporation (the "***Company***"), consists of:

- 100,000,000 shares of common stock, $0.001 par value per share ("***Common Stock***"); and
- 10,000,000 shares of preferred stock, $0.001 par value per share ("***Preferred Stock***").

Common Stock

- ***Voting rights.*** Each holder of Common Stock is entitled to one vote for each share on all matters to be voted upon by the stockholders. No share of Common Stock affords any cumulative voting rights. This means that the holders of a majority of the voting power of the shares voting for the election of directors can elect all directors to be elected if they choose to do so, subject to any voting rights granted to holders of any outstanding Preferred Stock. Generally, except as discussed under the heading "Effect of Certain Provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the Delaware Anti-Takeover Statute" below, all matters to be voted on by stockholders must be approved by a majority of the total voting power of the Common Stock present in person or represented by proxy at a meeting at which a quorum exists, subject to any voting rights granted to holders of any outstanding Preferred Stock. Except as otherwise provided by law or in the Company's Amended and Restated Certificate of Incorporation, as amended (the "***Certificate of Incorporation***") (as further discussed under the heading "Effect of Certain Provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the Delaware Anti-Takeover Statute" below), and subject to any voting rights granted to holders of any outstanding Preferred Stock, amendments to the Certificate of Incorporation must be approved by a majority of the votes entitled to be cast by the holders of Common Stock.
- ***Dividend rights.*** Subject to any preferential rights of any outstanding Preferred Stock, holders of Common Stock are entitled to receive ratably the dividends, if any, as may be declared from time to time by the Company's board of directors (the "***Board***") out of funds legally available therefor. The Company has never declared or paid any cash dividend on the capital stock and does not anticipate paying any cash dividends in the foreseeable future.
- ***Liquidation Rights.*** In the event of a liquidation, dissolution or winding up, holders of Common Stock are entitled to share ratably in the Company's assets remaining after the payment of liabilities and any preferential rights of any outstanding Preferred Stock.
- ***No preemptive or similar rights.*** Holders of Common Stock have no preemptive or conversion rights or other subscription rights, and there are no redemption or sinking fund provisions applicable to the Common Stock.
- ***Fully paid and non-assessable.*** The outstanding shares of Common Stock are fully paid and non-assessable.
- ***Preferred Stock.*** The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that the Company may designate and issue in the future.
- ***Anti-Takeover Provisions.*** See the below section titled "Effect of Certain Provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the Delaware Anti-Takeover Statute".

Listing

The Common Stock is listed on the Nasdaq Global Market under the symbol "CDNA."

Preferred Stock

The Board is authorized, subject to limitations prescribed by Delaware law, to issue up to 10,000,000 shares of Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each series, and to fix the designation, powers, preferences, and rights of the shares of each series and any of its qualifications, limitations or restrictions, in each case without further vote or action by the stockholders. The Board can also increase or decrease the number of shares of any series of Preferred Stock, but not below the number of shares of that series then outstanding, without any further vote or action by the stockholders. The Board may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of the Company and might adversely affect the market price of the Common Stock and the voting and other rights of the holders of Common Stock.

Warrants

As of December 31, 2022, the Company had outstanding warrants to purchase an aggregate of 3,132 shares of Common Stock with an exercise price of $1.12, all of which are currently exercisable (subject to certain beneficial ownership limitations) and expire on June 16, 2023.

All of the outstanding warrants contain provisions for the adjustment of the exercise price in the event of stock dividends, stock splits or similar transactions. All of the warrants also contain priced-based adjustment provisions, pursuant to which the exercise price of the warrants may be adjusted downward in the event of certain dilutive issuances by the Company. In addition, all of the warrants contain a "cashless exercise" feature that allows the holders thereof to exercise the warrants without a cash payment to the Company under certain circumstances. All of the warrants also contain provisions that provide certain rights to warrantholders in the event of a fundamental transaction, including a merger or consolidation with or into another entity, such as:

- The right to receive the same amount and kind of consideration paid to the holders of Common Stock in the fundamental transaction; and
- The right to require the Company to repurchase the unexercised portion of certain warrants at the warrant's respective fair value using the Black Scholes option pricing formula.

Effect of Certain Provisions of the Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and the Delaware Anti-Takeover Statute

Certain provisions of Delaware law, along with certain provisions of the Certificate of Incorporation and the Company's Amended and Restated Bylaws (the "***Bylaws***"), may have the effect of delaying, deferring or discouraging another person from acquiring control of the Company and could make the following transactions more difficult:

- acquisition of the Company by means of a tender offer;
- acquisition of the Company by means of a proxy contest or otherwise; or
- removal of the Company's incumbent officers and directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in the Company's management. These provisions are also designed, in part, to encourage persons seeking to acquire control of the Company to first negotiate with the Board. However, these provisions could have the effect of deferring hostile takeovers or delaying, discouraging or preventing attempts to acquire the Company, which could deprive the stockholders of opportunities to sell their shares of Common Stock at prices higher than prevailing market prices.

The Certificate of Incorporation and the Bylaws

The Certificate of Incorporation and the Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes relating to the control of the Board or management team, including the following:

- *Board of Directors Vacancies*. The Certificate of Incorporation and the Bylaws authorize only the Board to fill vacant directorships, including newly created seats. In addition, the number of directors constituting the Board can be set only by a resolution adopted by a majority vote of the entire Board. These provisions would prevent a stockholder from increasing the size of the Board and then gaining control of the Board by filling the resulting vacancies with the stockholder's own nominees. This makes it more difficult to change the composition of the Board and promotes continuity of management.
- *Classified Board*. The Certificate of Incorporation provides that the Board is classified into three classes of directors. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of the Company as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.
- *Stockholder Action; Special Meeting of Stockholders*. The Certificate of Incorporation provides that the stockholders may not take action by written consent, but may only take action at annual or special meetings of the stockholders. As a result, a holder controlling a majority of the Company's capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of the stockholders called in accordance with the Bylaws. The Bylaws further provide that special meetings of the stockholders may be called only by a majority of the Board, the Chairperson of the Board, or the Company's Chief Executive Officer or President, thus prohibiting a stockholder (in the capacity as a stockholder) from calling a special meeting. These provisions might delay the ability of the stockholders to force consideration of a proposal or for stockholders controlling a majority of the capital stock to take any action, including the removal of directors.
- *Advance Notice Requirements for Stockholder Proposals and Director Nominations*. The Bylaws provide advance notice procedures for stockholders seeking to bring business before the Company's annual meeting of stockholders or to nominate candidates for election as directors at the annual meeting of stockholders. The Bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude the stockholders from bringing matters before the annual meeting of stockholders or from making nominations for directors at the annual meeting of stockholders if the proper procedures are not followed. The Company expects that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.
- *No Cumulative Voting*. The General Corporation Law of the State of Delaware (the "***DGCL***") provides that stockholders may cumulate votes in the election of directors if the corporation's certificate of incorporation allows for such mechanism. The Certificate of Incorporation does not provide for cumulative voting.

- *Directors Removed Only for Cause*. The Certificate of Incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least 66 2/3% in voting power of the stock entitled to vote thereon.
- *Issuance of Undesignated Preferred Stock*. The Board has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated Preferred Stock with rights and preferences, including voting rights, designated from time to time by the Board. The existence of authorized but unissued shares of Preferred Stock would enable the Board to render more difficult or to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or other means.
- *Exclusive Forum.* The Bylaws provide that, unless the Company consents 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. 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. 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 the Company or its 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. If a court were to find this provision of the Bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect its business, financial condition or operating results.

Delaware Anti-Takeover Statute

The Company is subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, those provisions prohibit a public 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:

- the transaction is approved by the board of directors before the date the interested stockholder attained that status;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or after the date of the transaction, the transaction is approved by the board of directors and authorized at a meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines a business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning, or who within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any such entity or person.

A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, the Company has not opted out of, and does not currently intend to opt out of, this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire the Company.

Exhibit 21.1

Subsidiaries of CareDx, Inc.

Name	State or Jurisdiction of Incorporation or Organization
CareDx AB	Sweden
CareDx Lab Solutions, Inc.	Delaware
CareDx Transplant Management, Inc.	Nebraska
CareDx Pty Ltd.	Australia
The Transplant Pharmacy	Mississippi

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 Nos. 333-211700 and 333-239049, and on Form S-8 Nos. 333-197493, 333-203128, 333-211538, 333-217462, 333-225991, 333-231523, 333-233710, 333-239277, and 333-258577 of our reports dated February 27, 2023, relating to the financial statements of CareDx, Inc., and the effectiveness of CareDx, Inc.'s internal control over financial reporting, appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Deloitte & Touche LLP

San Jose, California
February 27, 2023

Exhibit 31.1

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

I, Reginald Seeto, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 27, 2023

By: /s/ Reginald Seeto

Reginald Seeto
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Abhishek Jain, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date:February 27, 2023

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of CareDx, Inc. (the "Company") for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to their knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Reginald Seeto
Reginald Seeto
President and Chief Executive Officer
(Principal Executive Officer)
February 27, 2023

By: /s/ Abhishek Jain
Abhishek Jain
Chief Financial Officer
(Principal Financial and Accounting Officer)
February 27, 2023

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.