2019 Annual Report

Dear Stockholders,

Looking back, I am very proud of the numerous successes our team had in 2019, as we continued to advance CareDx as a true transplant company and an essential partner to transplant patients and caregivers.

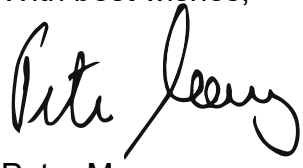
2019 was a very exciting year for CareDx, as unabated momentum for our suite of high-value solutions for transplant patients and caregivers drove robust revenue growth. Our full year revenue was $127 million, representing 66% growth over the prior year.

AlloSure, our surveillance solution for kidney transplant patients, was our key growth driver last year, with more than 150 centers having used AlloSure since its launch. HeartCare, the combination of AlloMap and AlloSure Heart, gained significant traction in the cardiac transplant community. Our multi-modality solutions, together with our registry studies, OKRA and SHORE, and investment in developing clinical data, clearly position CareDx as *the* innovator in transplantation.

With the launch of AlloSeq Tx and AlloSeq cfDNA, we brought novel, next-generation sequencing products to the global transplant community, and with the addition of our digital solutions, through the acquisitions of OttrCare and Xyn Management, we continued to build our platform in transplantation.

Everything we do at CareDx has one focus, and that is to be the leading partner for transplant patients and the transplant ecosystem. Thank you to all the employees and stockholders of CareDx. I look forward to your continued partnership in 2020 and beyond.

With best wishes,



Peter Maag
Chairman & CEO

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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)**

1 Tower Place
South San Francisco, California 94080
(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

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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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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 28, 2019, 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 $1,502 million. Shares of the registrant's common stock held by each executive officer, director and holder of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of the registrant's Common Stock outstanding as of February 25, 2020 was 42,879,426.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2020 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, 2019.

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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," "would," "project," "plan," "expect" and the negative and plural forms of these words and similar expressions are intended to identify forward-looking statements.

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

- our ability to generate revenue and increase the commercial success of our current and future testing services, products and 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 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;
- our ability to integrate our business with the businesses of Ottr Complete Transplant Management, or OttrCare™, and XynManagement, Inc., or XynManagement, to realize the anticipated benefits of the acquisitions;
- 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 defend against or settle any litigation brought against us or other legal matters or disputes; 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 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 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. ("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 healthcare solutions for transplant patients and caregivers. We offer testing services, products, and digital solutions along the pre- and post-transplant patient journey, and is a leading provider of genomics-based information for transplant patients. Our headquarters are in South San Francisco, California. The primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia and Stockholm, Sweden.

Testing Services

Our commercially available testing services consist of AlloSure® Kidney, which is a donor-derived cell-free DNA, or dd-cfDNA, solution for kidney transplant patients, and AlloMap® Heart, which is a gene expression solution for heart transplant patients. During the year 2019, we performed more than 49,000 commercial AlloSure Kidney and AlloMap Heart 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 236 and 137 centers performing kidney and heart transplants, respectively, in the United States.

Kidney

AlloSure Kidney applies proprietary next generation sequencing technology to measure donor-derived cell-free DNA, or dd-cfDNA, in the blood stream emanating from the donor kidney. We believe AlloSure Kidney may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted heart, kidney or other solid organ, irrespective of the type of organ transplanted. We also 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. Effective October 9, 2017, AlloSure Kidney became available for commercial testing with Medicare coverage and reimbursement. The Medicare reimbursement rate for AlloSure Kidney is $2,841. AlloSure Kidney has also received payment from private payers on a case-by-case basis, with the first private payer, BCBS of South Carolina, issuing a positive coverage decision in its October 2019 review.

Prior to the commercialization of AlloSure Kidney, we generated a strong body of clinical evidence. In late 2015, we announced the completion of analytical validation of AlloSure Kidney. A report describing the analytical validation of AlloSure Kidney, including clinical validation detailing the quality, reality and consistency of analytical results information for heart transplant, appeared in the November 2016 issue of The Journal of Molecular Diagnostics. The Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial, sponsored by us, was conducted between April 2015 and January 2018. DART was a 14 center observational study of kidney transplant recipients where blood specimens are drawn periodically after transplant during follow up visits and also after treatment for acute rejection. By the time of completion of the first analysis, 384 patients were followed in DART for up to 24 months. The results demonstrated that increased levels of dd-cfDNA, determined by the AlloSure Kidney assay, discriminated active rejection of a kidney transplant more effectively than serum creatinine values. In collaboration with clinical investigators, we published these findings in the scientific peer-reviewed Journal of the American Society of Nephrology and the Journal of Applied Laboratory Medicine in March 2017. A total of 2,109 patient visits had been accrued in DART by January 2018. We analyzed this data to report on additional findings from this dataset at the American Transplant Congress, or ATC, held in 2019 and intend to continue to report additional findings into the future.

In January 2018, we initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study, or K-OAR, to develop further data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients.

KidneyCare

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.

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 KidneyCare iBox in one surveillance solution. We have not yet made any applications to payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

Heart

Our first commercialized testing solution, the AlloMap Heart transplant molecular test, or 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 for AlloMap Heart 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. In particular, we believe AlloMap Heart can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. AlloMap Heart has received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe acute cellular rejection.

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 from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation, or HCSC, Humana, Kaiser Foundation Health Plan, Inc., and UnitedHealthcare.

We have also successfully completed a number of 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 on the basis of our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am J Transplantation 2006), or CARGO, study, which was published in the American Journal of Transplantation. 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 International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

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.

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 – a measure of graft injury. 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. We have not yet made any applications to private payers for reimbursement coverage of AlloSure Heart except for Medicare. In August 2019, AlloSure Heart received a positive draft Local Coverage Determination, or dLCD, for Medicare coverage.

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. AlloSure Lung applies proprietary next generation sequencing, or NGS, technology to measure dd-cfDNA in the blood stream emanating from the donor lung to monitor graft injury. We have not yet made any applications to payers for reimbursement coverage of AlloSure Lung.

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.

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. Olerup SBT is a complete product range for sequence-based typing of HLA alleles.

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.

As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight® HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. 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.

Digital

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

On May 7, 2019, we acquired 100% of the outstanding common stock of OttrCare. OttrCare was formed in 1993 and is a leading provider of transplant patient tracking software, or the Ottr® software, which provides comprehensive solutions for transplant patient management. 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 Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients, or SRTR, reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

Our software solutions are currently used in 84 transplant centers in the U.S.

Refer to Note 5 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further detail regarding these acquisitions.

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 1 Tower Place, South San Francisco, California and our telephone number is (415) 287-2300.

On June 10, 2014, we acquired ImmuMetrix, Inc., or IMX, a privately held development-stage company focused on dd-cfDNA-based solutions in transplantation and other fields. Through this acquisition, we added to our existing know-how, expertise and intellectual property in applying dd-cfDNA technology to the surveillance of transplant recipients, which has contributed to the development of AlloSure Kidney. The intellectual property rights of IMX included an exclusive license from the Board of Trustees of the Leland Stanford Junior University, or Stanford, to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA.

On April 14, 2016, we acquired Allenex AB, or Allenex. Our combination with Allenex created an international transplant diagnostics company with product offerings along the pre and post-transplant continuum. As a result of the acquisition we now have a presence and direct distribution channels in the U.S. and Europe, with additional third party distributors in Europe and other markets around the world.

On January 20, 2017, we acquired the business assets of Conexio Genomics Pty Ltd, Conexio, to offer a complete product range for sequence-based typing of HLA alleles.

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 the field of bone marrow and solid organ transplantation diagnostic testing.

On April 30, 2019, we entered into a license and collaboration agreement, or the Cibiltech Agreement, with Cibiltech SAS, or Cibiltech, to commercialize Cibiltech's proprietary software and service offering known as KidneyCare iBox for the predictive analysis of post-transplantation kidney allograft loss. We have the right to commercialize KidneyCare iBox in the U.S. for a period of ten years. On September 23, 2019, the KidneyCare iBox validation study from the Paris Transplant Group was

published in the British Medical Journal. On September 18, 2019, we enrolled the first patient in the OKRA clinical study, which incorporates KidneyCare iBox.

On May 7, 2019, we acquired 100% of the outstanding common stock of OttrCare. OttrCare was formed in 1993 and is a leading provider of transplant patient tracking software, or the Ottr software, which provides comprehensive solutions for transplant patient management. 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 Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients, or SRTR, reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

Our software solutions are currently used in 84 transplant centers in the U.S.

As of December 31, 2019, 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 2017 charges for a heart transplant are $1.38 million and for a kidney transplant are $0.41 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 procedure 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.

Our Testing Services, Products and Digital

Testing Services

We develop and provide a diagnostic surveillance testing service for kidney and heart transplant recipients.

Kidney

AlloSure Kidney, our surveillance solution for kidney transplant recipients, applies proprietary next generation sequencing technology to measure dd-cfDNA in the blood stream emanating from the donor organ. The evidence for dd-cfDNA in transplantation has been increasing exponentially. We strongly believe in the added clinical utility AlloSure Kidney brings to clinicians in the assessment of allograft injury, its ability to risk-stratify populations and determine rejection, as well as its response to treatment in a quantifiable manner, has changed the standard of care offered to transplant patients.

AlloSure Kidney has shown to have widespread utility as a leading indicator of allograft injury, with data supporting its use as part of assessment when considering de-novo donor specific antibody formation (dnDSA), estimated glomerular filtration rate (eGFR) decline, and borderline allograft rejection.

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, allowing optimization of therapy and medications, as well as acting early with better surveillance. In particular, we believe AlloSure Kidney can improve patient care by helping healthcare providers to optimize the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

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 KidneyCare iBox in one surveillance solution. We have not yet made any applications to payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

Heart

Our first commercialized testing solution, AlloMap Heart, is a gene expression profiling 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. AlloMap Heart is designed to help health care providers and their patients to better manage long-term care, optimize the use of invasive surveillance biopsies and determine the appropriate dosage levels of immumosuppressant medications. The clinical utility of AlloMap Heart is well established. AlloMap Heart is the first and only non-invasive method recommended in the International Society for Heart & Lung Transplantation, or ISHLT, patient care guidelines as standard care. AlloMap Heart uses a sample of the patient's blood. AlloMap Heart may be used instead of a surveillance heart biopsy to rule out acute cellular rejection in heart transplant recipients. AlloMap Heart offers rapid, high quality results, and we aim to return AlloMap Heart results to the clinician within three business days after the blood draw.

AlloMap Heart has obtained 510(k) clearance from the FDA as an In Vitro Diagnostic Multivariate Index Assay, or IVDMIA. AlloMap Heart Score Variability, or AMV, is an additional service we offer providing 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.

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 activity, and (ii) AlloSure Heart – measures graft injury. HeartCare provides complementary information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection, or ACR, and Antibody Mediated Rejection, or AMR, in heart transplant recipients.

Clinical Trials of AlloSure Kidney and AlloMap Heart

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 reports that increased levels of dd-cfDNA detected using AlloSure Kidney are associated with active rejection of the kidney allograft. The 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 1,500 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 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 1,000 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 estimated glomerular filtration rate (eGFR) with the number of renal allograft biopsies performed during the first year being a secondary outcome. Other endpoints include patient survival, graft survival, change and serum creatinine, evaluated at years 1, 2 and 3 post-transplantation.

In September 2019, we announced the commencement of the OKRA study. OKRA is an extension of K-OAR. OKRA is a prospective, multi-center, observational, registry of patients receiving KidneyCare for surveillance. The patient transplant

registry, will total 4,000 transplant patients, being statistically powered to determine the utility of KidneyCare and AlloSure Kidney to the current standards of care. It will provide real world data, with OKRA targeting more than 50 transplant centers and enrolling a further 1,500 newly transplanted patients. The addition of OKRA to K-OAR and the control arm is how the total of 4,000 is reached.

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 the SHORE registry. 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. 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 – a measure of graft injury. 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. We have not yet made any applications to private payers for reimbursement coverage of AlloSure Heart except for Medicare. In August 2019, AlloSure Heart received a positive draft Local Coverage Determination, or dLCD, for Medicare coverage.

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.

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 polymerase chain reaction, or 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. When transplanting organs from deceased donors it is of great importance to be able to expediently carry out HLA typing to find an appropriate recipient. 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. QTYPE comes with custom software, SCORE6.

Olerup SSP is used to type HLA alleles based on the SSP technology. Olerup SSP is used to type HLA alleles, based on SSP technology. The Olerup SSP product line comprises products for low to high-resolution HLA typing. The product line includes close to 400 different typing products, covering the approximately 17,331 different HLA alleles (gene variants) that have been identified to date. New HLA alleles are identified frequently and the typing kits are routinely updated for new alleles. SCORE6, our custom developed software simplifies interpretation and documentation of laboratory results. We offer one of the most up-to-date and comprehensive libraries of HLA typing kits based on SSP technology.

Olerup SBT is a sequence-based typing product for HLA alleles that uses specifically designed software, Assign SBT, a sequence analysis software program that provides high-resolution HLA typing.

TruSight HLA is high-resolution solution that uses NGS methodology. TruSight HLA is a NGS-based high-resolution typing solution that provides NGS-level resolution to HLA typing. CareDx licensed the exclusive world-wide distribution rights to this product from Illumina in May 2018. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines. 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.

In September 2019, we launched AlloSeq Tx during the American Society for Histocompatibility and Immunogenetics, or ASHI, and Banff Foundation for Allograft Pathology's Joint meeting in Pittsburgh, PA. AlloSeq Tx is a first of its kind NGS HLA typing solution utilizing hybrid capture technology. This technology enables comprehensive sequencing, covering more genes than current solutions, including coverage of non-HLA genes that may impact transplant patient matching and management. AlloSeq Tx has straightforward NGS workflow, with a single tube for processing and steps to reduce errors.

In September 2019, we launched AlloSeq cfDNA during the European Society for Organ Transplantation, or ESOT, Congress. AlloSeq cfDNA has been utilized by beta sites in four countries, and is now commercially available for transplant patients outside of the US. During the ESOT Congress we held a workshop titled "Innovation in Transplant Diagnostic for Improving Patient Care". The workshop featured the clinical utility and evidence of dd-cfDNA as a biomarker and unveiled the European clinical study with AlloSeq cfDNA. On January 10, 2020, AlloSeq cfDNA received CE mark approval.

Digital

Through our acquisition of OttrCare, we provide transplant patient tracking software for transplant patient management. 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.

Through our acquisition of XynManagement, we provide XynQAPI software for transplant quality tracking and SRTR reporting.

Our software solutions are currently used in 84 transplant centers in the U.S.

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.

Research and development activities to integrate recently acquired technology from the acquisitions of OttrCare and XynManagement and our Cibiltech Agreement have also been an area of recent focus. Integration of such technology with our current service offerings aligns an incredibly 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 $30.7 million, $14.5 million and $12.4 million were incurred during the years ended December 31, 2019, 2018 and 2017, respectively.

Our ongoing efforts include:

- increasing understanding of biological processes of transplant rejection through analysis of genes/ metagenes of 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 Kidney for other organs such as lung, pancreas and liver;
- increasing understanding of biological processes of transplant rejection through analysis of genes/ metagenes of archived clinical trials, OAR registry, SHORE registry and commercial laboratory testing to further improve clinical utility of AlloMap 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 Histomap to identify allograft rejection in transplant biopsy tissue;
- developing an NGS transplant genetic matching system that includes critical genes in addition to HLA;
- 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; and
- developing and deploying smart analytics and machine learning artificial intelligence that provide clinical utility with respect to patient health such as AiTraC.

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 clinical study has established the clinical validity of a dd-cfDNA-based solution for kidney transplant patients, AlloSure Kidney. This 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 in the largest (N =398 patients) 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 1,500 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 KidneyCare 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.

dd-cfDNA for Heart Transplants

We believe that the AlloSure Kidney dd-cfDNA-based solution could provide additional value to AlloMap Heart testing for clinicians caring for heart transplant patients, particularly in situations where a recipient's AlloMap Heart score suggests a probability of acute rejection.

Studies have reported that a higher percentage of dd-cfDNA in the blood stream of patients is found with moderate or severe heart rejection compared to patients without rejection. We believe a dd-cfDNA solution such as AlloSure Kidney 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 – measures graft injury. HeartCare provides complementary information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection and Antibody Mediated Rejection 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 now offer AlloSure Heart as a laboratory developed test as part of our SHORE study of dd-cfDNA in association with gene-expression profiling (AlloMap Heart) in heart transplant recipients.

HistoMap

We have established a strategic partnership with NanoString Technologies, Inc., or NanoString, to develop HistoMap, a gene expression profiling, or GEP, solution to identify allograft rejection in transplant biopsy tissue. NanoString is a leading provider of life science tools for translational research and molecular diagnostic products. The partnership will combine our clinical expertise and extensive transplant registries with NanoString's technological capabilities and development expertise 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.

Product Advancement and Development

Ongoing research and development in the pre-transplant arena encompasses six areas. First, the last decade of next generation 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.

Second, 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. We expanded our market-leading portfolio of transplantation product with the global launch of AlloSeq cfDNA at the ESOT Congress. We estimate this launch will enable access to our cfDNA surveillance technology to an additional 800,000 patients outside the United States. We also introduced AlloSeq Tx at the ASHI Conference. 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.

Third, our AlloSeq Tx NGS testing platform is a technology departure from commonly used approaches for HLA typing. This enables the addition of non-HLA genes critical to transplant outcome. The addition of non-HLA genes will have no impact on workflow and enable the inclusion of increasing content, as new transplant outcome related genes are described.

Fourth, depending on the specific indication, different levels of HLA typing resolution and follow up confirmatory testing are required. Olerup SSP and QTYPE flexible platforms are complemented with Olerup SBT and TruSight HLA, and our research and development staff weave together the four typing product offerings to effectively address laboratory needs.

Fifth, the complexity of the HLA region benefits significantly from interpretive software solutions for the laboratories. We are committed to ongoing upgrades to our software solutions to further simplify the use of the various HLA kits.

Finally, our research and development staff in transplant environment is working closely together to advance the synergies of products across the pre- and post-transplant continuum.

Digital Solutions Business Development

We acquired OttrCare and XynManagement in 2019. These acquisitions have strengthened our growing portfolio of transplant software solutions such as Ottr and XynQAPI. We are committed to continue upgrading these software programs and further integrating them into our current testing service offerings.

We plan to develop, deploy and promote a rational set of analytical tools that provide clinical utility with respect to patient health. Our vision is to add smart analytics and machine learning to artificial intelligence in transplant, which we call AiTraC. Going forward, we will strive to bring our multi-modality testing solutions and machine learning algorithms to the transplant

clinic under our AiTrack 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.

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 and AlloMap Heart tests performed on patients covered by Medicare. Tests performed on patients covered by Medicare represented 49%, 46% and 30% of all tests in 2019, 2018 and 2017, respectively. Approximately 66%, 62% and 27% of all testing services revenue was derived from Medicare for the years ended December 31, 2019, 2018 and 2017, respectively.

Effective October 9, 2017, AlloSure Kidney was reimbursed for kidney transplant patients covered by Medicare. The Medicare reimbursement rate for AlloSure Kidney is currently $2,841. Medicare coverage and reimbursement was determined by the Molecular Diagnostic Services Program, or MolDx, administered by Palmetto.

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. Effective January 1, 2018, Medicare reimburses $3,240 for AlloMap Heart testing of Medicare beneficiaries, which remains applicable through 2021.

In August 2019, AlloSure Heart received a positive draft local coverage determination for Medicare coverage from MolDx.

Private Payers and Medicaid Payers

As of today, there has been one private payer that has adopted a positive coverage policy for AlloSure Kidney, BCBS of South Carolina. 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 for reimbursement have been adopted by many of the largest private payers, including Aetna, Anthem, Cigna, Health Care Services, or HCSC, Humana, Kaiser Foundation Health Plan, Inc., and UnitedHealthcare. Many other payers have positive coverage policies for AlloMap Heart.

For AlloSure Kidney and AlloMap Heart 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 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

Our laboratory operations, where we perform all AlloSure Kidney and AlloMap Heart testing, are headquartered at our Brisbane, California laboratory. Our laboratory holds a certificate of accreditation under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and is accredited by the College of American Pathologists, or CAP. We believe that our laboratory capacity will be adequate to meet demand for AlloSure Kidney, AlloMap Heart, and 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 reported to the ordering clinician by fax or electronically via 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 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 reported to the ordering clinician by fax or electronically within our WebPortal within two business days of receipt.

We rely solely on certain suppliers to provide some of the laboratory instruments and key reagents that we use to perform AlloSure Kidney and AlloMap Heart testing. These sole source suppliers include Thermo Fisher Scientific, which supplies us with instruments, laboratory reagents, a master mix formula and consumables; Roche Molecular Systems, which supplies us with laboratory reagents and consumables; Illumina, which supplies us with instruments, laboratory reagents and consumables; Becton, Dickinson, 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.

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 assure 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 standards ISO 9001:2008 and ISO 13485: 2016. These standards include 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 Olerup SBT and 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 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 Vienna, Austria; Stockholm, Sweden; West Chester Pennsylvania, United States; and Fremantle, Australia, which manage direct sales to customers and sales through third-party distributors.

Digital Solutions Sales and Marketing Team

Our sales teams are located in the United States. They manage customer sales for Ottr software and XynQAPI software. Our strategy includes educating clinicians and care teams at transplant centers through software demos.

Competition

With our comprehensive portfolio of surveillance testing services, diagnostic products and digital business offerings, we face many different types of competition. Our potential competitors may have widespread brand recognition and substantially greater financial, technical and research and development resources and selling and marketing capabilities than we do. Other competitors may develop products with prices lower than ours that could be viewed by clinicians and payers as functionally equivalent to our solution, offer solutions that may be more accurate or effective than our solutions or offer solutions at prices designed to promote market penetration, which could force us to lower the price of our current and future solutions and affect our ability to achieve or maintain profitability.

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, AlloMap 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, so 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 and Linkage Biosciences. In certain HLA tissue typing markets that incorporate a wide variety of technology test platforms, such as SSP, SBT, 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.

Digital Solutions

Competition for our digital solutions include various companies that develop application software and operate in the healthcare field. Our primary competitor in this field is Epic Systems Corporation, or Epic. 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, 2019, we had 25 issued U.S. patents related to transplant rejection and autoimmunity. We have five issued U.S. patents covering methods of diagnosing transplant rejection that use all 11 informative genes measured in AlloMap Heart. The expiration dates of these patents range from 2021 to 2024. We have five additional patents covering additional genes or gene variants for diagnosing transplant rejection. In connection with our June 2014 acquisition of IMX, we obtained an exclusive license from Stanford to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This patent has an expiration date of November 5, 2030. A second patent included in the license from Stanford was issued in December 2017 and further covers the use of dd-cfDNA to diagnose and predict transplant status or outcome. A third and fourth patent were issued from this Stanford set in June 2019 and December 2019, respectively, covering the use of dd-cfDNA to diagnose and predict transplant status or outcome. Both patents have the same 2030 expiration date as the original Stanford patent.

As part of our April 2016 acquisition of Allenex, we obtained an additional five U.S. patents on donor matching technology and treatment for antibody mediated transplant rejection.

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, Olerup SSP, Olerup XM-ONE, 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.

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.

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, KidneyCare 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.

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. Almost all 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 in 2018 and recertified under the CLIA as a result of passing that inspection.

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 it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. 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 Verifying Accurate Leading-edge IVCT Development Act of 2018. For AlloSure Kidney and other similar testing solutions, 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 to comply with 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 or a significant breach to protected health information, or PHI, may occur.

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 to comply with health information privacy requirements to which we are aware that we are subject.

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 comply with the requirements of the applicable exceptions to the Stark Law and PORA. 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 $15,000 for each service arising out of the prohibited referral;
- exclusion from federal healthcare programs, including the Medicare and Medicaid programs; and
- a civil penalty of up to $100,000 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 Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal healthcare programs. 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 been recent public announcements by members of the U.S. Congress and President Trump and his administration regarding their plans to repeal and replace the Affordable Care Act. We cannot predict the ultimate form or timing of any repeal or replacement of the Affordable Care Act or the effect such repeal or replacement would have on our business.

Anti-Kickback Statutes

The federal healthcare programs' Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

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's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered businesses, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, 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 referral of recipients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Federal False Claims Act

The False Claims Act's "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 a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the 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 False Claims Act, and many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program.

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 $5,500 and $11,000 for each separate instance of false claim. 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 causing physicians to order excessive or unnecessary services, providing false documentation in support of claims, kickbacks, off-label promotion of products, Stark Law violations and other improper referrals and CLIA violations, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. Our future activities relating to billing, compliance with the CLIA 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.

CCPA

The California Consumer Privacy Act, or the CCPA, was enacted in 2018 and took effect on January 1, 2020. This piece of legislation secures new privacy rights for California consumers. The CCPA grants consumers the right to:

- know the types of personal information that are collected, used, shared or sold, both as to the categories and specific pieces of personal information;
- have personal information held by businesses and, by extension, a business's service provider deleted;

- opt-out of the sale of personal information. Consumers are able to direct a business that sells personal information to stop selling that information. Children under the age of 16 must provide opt in consent, with a parent or guardian consenting for children under 13; and
- non-discrimination in terms of price or service when a consumer exercises a privacy right under the CCPA.

The CCPA applies to certain businesses and such businesses must create procedures to respond to requests from consumers to opt-out, know and delete.

For requests to opt-out, businesses must provide a "Do Not Sell My Info" link on their website or mobile app. Under the CCPA, we are required to:

- respond to requests from consumers to know, delete and opt-out within specific time frames;
- verify the identity of consumers who make requests to know and to delete, whether or not the consumer maintains a password-protected account with us;
- maintain records of requests and how we responded for 24 months in order to demonstrate our compliance;
- treat user-enabled privacy settings that signal a consumer's choice to opt-out as a validly submitted opt-out request;
- disclose financial incentives offered in exchange for the retention or sale of a consumer's personal information and explain how we calculate the value of the personal information; and
- explain how these incentives are permitted under the CCPA.

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.

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

The General Data Protection Regulation (EU) 2016/679, or the GDPR, is a regulation on data protection and privacy in the European Union, or 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.

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

principles and provide safeguards to protect data (for example, using pseudonymization or full anonymization where appropriate). Data controllers and processors must design information systems with privacy in mind; for instance using the highest-possible privacy settings by default, so that the datasets are not publicly available, and cannot be used to identify a subject. 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. 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. Public authorities, and businesses whose core activities consist of regular or systematic processing of personal data, are required to employ a data protection officer, who is responsible for managing compliance with the GDPR. Businesses must report data breaches to national supervisory authorities within 72 hours if they have an adverse effect on user privacy. In some cases, violators of the 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

At December 31, 2019, we had 386 employees, of which 306 were full-time employees. We had 132 employees in manufacturing operations and support, 83 in research and development; 102 in sales and marketing and 69 in general and administrative positions. As of December 31, 2019, 309 employees were located in the United States and 77 were located outside of the United States.

From time to time, we also employ independent contractors, consultants and temporary employees to support our operations. Currently, the CareDx 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.

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.

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

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 follows risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business

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

We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the year ended December 31, 2019, our net loss was $22.0 million. As of December 31, 2019, we had an accumulated deficit of $333.8 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 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 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 may require additional financing.

As of December 31, 2019, we had cash and cash equivalents of $38.2 million and an accumulated deficit of $333.8 million. We may require additional financing in the future to fund working capital, pay our obligations as they come due and fund our acquisitions of complementary businesses and assets. Additional financing might include issuance of equity securities, debt, cash from collaboration agreements, or a combination of these. However, 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 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, 2019, revenue from Medicare for AlloMap Heart and AlloSure represented 66% 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 includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS report initially and then on a subsequent three-year basis thereafter (or annually for advanced diagnostic

laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 and the new market based rates took effect January 1, 2018. The Centers for Medicare & Medicaid Services, or 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. 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.

If an AlloMap Heart or AlloSure Kidney 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 or AlloSure Kidney 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 or AlloSure Kidney 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 and AlloMap 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 and AlloMap Heart 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.

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.

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 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 alleging CareDx made false and misleading claims about the performance capabilities of AlloSure. In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13th, 2020, in the U.S. District Court for the District of Delaware alleging, among other things, that AlloSure infringes Natera's U.S. Patent 10,526,658. The suit seeks a judgment that we have infringed Natera's patent, an order preliminarily and permanently enjoining us from any further infringement of such patent and unspecified damages. We intend to defend both of these matters vigorously, and believe we have good and substantial defenses to the claims alleged in the suits, 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 elsewhere in this Annual Report on Form 10-K. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

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

The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations that could make AlloSure Kidney, AlloMap Heart and our other products and digital solutions, including those in development, outdated. We must continually innovate, expand and update our test offerings to address unmet needs in monitoring transplant related conditions. AlloSure Kidney, AlloMap Heart, and our other products and digital solutions, including those in development, could become obsolete unless we continually innovate, enhance and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloSure Kidney, AlloMap Heart, our other products and digital solutions and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our tests, products, 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 digital solutions, and demonstrate the clinical and diagnostic benefits of these services, products and digital solutions. We believe that clinicians, transplant centers and laboratories may not use our services, products 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 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, AlloMap 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 and AlloMap 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, AlloMap Heart, and our other products 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, AlloMap 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 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 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 digital solutions would suffer and our business would be harmed. While we have had success in generating peer-reviewed publications regarding AlloSure Kidney and AlloMap Heart, additional peer-reviewed publications regarding AlloSure Kidney, AlloMap Heart and our future products 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 digital solutions or the technology underlying AlloSure Kidney, AlloMap Heart, or our future products 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, AlloMap 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 and AlloMap Heart in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloSure Kidney or AlloMap 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, 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, we launched QTYPE in September 2016 and QTYPE competes with other quantitative polymerase chain reaction products including products offered by Thermo Fisher Scientific, Inc., or Thermo Fisher, as well as alternatives to polymerase chain reaction, or 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 digital solutions include various companies that develop application software and operate in the healthcare field. Our primary competitor in this field is Epic Systems Corporation, or Epic. 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 and AlloMap 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, AlloMap Heart and our products 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 and AlloMap Heart depends, in large part, on our ability to perform AlloSure Kidney and AlloMap 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, AlloMap 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 2018 to 2019, our revenue grew from $76.6 million to 127.1 million, which represents annual growth of 66%. 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 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 and AlloMap 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, AlloMap 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, wildfires, flooding and power outages, which 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,AlloMap 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, AlloMap Heart, or future solutions and comply with the required procedures, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms.

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 affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis.

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

We rely on third-party laboratory services providers to draw and partially process the patient blood samples that are analyzed in our Brisbane, California laboratory. Our business will suffer if these service providers do not support AlloSure Kidney, AlloMap Heart 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.

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, KidneyCare, AlloMap Heart, HeartCare, our products, and digital solutions or enhancements to those tests, products 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. 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. For example, we have the ability to sell up to $50.0 million of additional shares of our common stock to the public through an "at the market" offering pursuant to the Sales Agreement we entered into with Jefferies, LLC, on August 31, 2018. Any shares of common stock issued in the at-the-market offering will result in dilution to the 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, 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.

In addition, our success depends on our ability to attract and retain laboratory and field personnel with extensive experience in transplant recipient care and surveillance and close relationships with clinicians, pathologists and other hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of AlloSure Kidney, AlloMap Heart, or our future solutions, if any. 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, such as the recall that occurred in April 2016 with respect to one of the Olerup products, and may damage our customers' businesses and harm our reputation. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim, product recall or similar occurrence may cause us to incur significant expense, decrease market acceptance of our products and adversely impact our business and operating results.

In addition, the marketing, sale and use of AlloSure Kidney, AlloMap Heart 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 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, 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. We do not have guaranteed supply agreements with Thermo Fisher, Becton, Dickinson and Company, or Qiagen N.V., 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 2020. We believe that there are relatively few suppliers other than Thermo Fisher, 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 Therapak Corporation, or Therapak Corporation encounters delays or difficulties in securing from Qiagen N.V., 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.

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.

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, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions.

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 billing agent, 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.

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. The CCPA, among other things, requires 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 CCPA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the CCPA on our business.

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

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 currently have a commercial agreement for the promotion of AlloMap Heart in Europe with Eurobio Scientific, or Eurobio (formerly known as Diaxonhit SA). We also currently distribute products directly in Germany, UK, New Zealand, Sweden, Austria, Belgium, Netherlands and Australia and sell products via sub-distributors, in Canada and in significant markets in Europe such as France, Italy, UK and Turkey, and to certain countries in 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;
- 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 coronavirus 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 left the EU on January 31, 2020. Although the effects of Brexit will depend on any agreements between the UK and the EU, 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.

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; inflation; 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. 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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, the Tax Act, was signed into law, making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017. We calculated the impact of the Tax Act in our 2018 year end income tax provision in accordance with our understanding of the Tax Act and guidance available as of the date of the filing of our Annual Report on Form 10-K for the year ended December 31, 2018, which did not result in any additional income tax expense in the fourth quarter of 2017. The enactment of the Tax Act also requires companies to recognize the effects of changes in tax laws and rates on deferred tax assets and liabilities and the retroactive effects of changes in tax laws in the period in which the new legislation is enacted. Consequently, we accounted for a provisional estimated reduction of the U.S. deferred tax assets from $72.5 million to approximately $45.9 million with a corresponding decrease of $27.0 million to our valuation allowance in 2018. We completed our analysis of the impacts of the 2017 Tax Act in the fourth quarter of 2018 with no change to our provisional estimates.

The Tax Cuts and Jobs Act of 2017 also implemented global intangible low tax income, or GILTI, which is a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations as well as the new base erosion anti-abuse tax, or BEAT, under the Tax Act. GILTI will be effectively taxed at a tax rate of 10.5%. Due to the complexity of the GILTI tax rules, companies are allowed to make an accounting policy choice of either (1) treating taxes due on future U.S. inclusions in taxable income related to GILTI as a current-period expense when incurred or (2) factoring such amounts into a company's measurement of its deferred taxes. We have not made an election with respect to GILTI as it is not applicable to us in 2019. We will continue to review the GILTI and BEAT rules to determine their applicability to us and the impact that the rules may have on our results of operations of financial condition.

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 successfully integrate our business with the business of Ottr Complete Transplant Management, or OttrCare, or XynManagement, Inc., or XynManagement, and we may not be able to achieve the anticipated strategic benefits from our acquisition of OttrCare.

The integration of OttrCare, XynManagement and any other 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, which includes, with respect to OttrCare, the complementary Ottr software, and, with respect to XynManagement, XynQAPI, and in each case significant cross-selling opportunities. The failure to successfully integrate the combined operations, including retention of key employees, could impact our ability to realize the

full benefits of our acquisition of OttrCare, XynManagement or any other businesses or assets we may acquire. 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 integration or 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, Inc., or 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 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 KidneyCare iBox. We have not yet made any applications to payers for reimbursement coverage of KidneyCare iBox. The failure to obtain reimbursement coverage from payers for KidneyCare iBox could result in material amounts of revenue not being recognized, and failure to successfully integrate predictive artificial intelligence technology with our existing tests.

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. These billing complexities, and the resulting uncertainty in obtaining payment for AlloSure Kidney, AlloMap Heart and future solutions, could negatively affect our revenue, cash flows and profitability.

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 and AlloMap 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;
- lead to improved patient outcomes;
- appropriate for the specific recipient;
- cost-saving or cost-effective; and
- supported by peer-reviewed publications.

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 believe 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 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, AlloMap Heart, or future solutions will be provided in the future by any third-party payer.

Reimbursement for AlloSure Kidney and AlloMap 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, including Aetna, Anthem, Cigna, Health Care Services Corporation, Humana, Kaiser Foundation Health Plan, Inc., and UnitedHealthcare. 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.

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

There have been recent public announcements by members of the U.S. Congress and President Trump and his administration regarding their plans to repeal and replace the Affordable Care Act. We cannot predict the ultimate form or timing of any repeal or replacement of the Affordable Care Act or the effect such repeal or replacement would have on our business. Regardless of the impact of any or repeal or replacement 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 and our future diagnostic solutions, increase costs, divert management's attention and adversely affect our ability to generate revenue and achieve profitability.

Risks Related to the Healthcare Regulatory Environment

In order to operate our laboratory, we have to comply with the CLIA and state laws governing clinical laboratories.

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 February 2018 as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in 2020. 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 or AlloSure Kidney, 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 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 and AlloMap 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. Our employees, consultants, principal investigators and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. In addition to the CLIA regulation, other federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

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

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. 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 healthcare 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. Any of the foregoing consequences could seriously harm our business and our financial results.

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.

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions.

Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our current and future solutions. In March 2010, the Affordable Care Act became law. This law substantially changed the way healthcare is financed by both governmental and private insurers, and contained a number of provisions that have impacted our business and operations, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse enforcement. Further, our combination with Allenex will also change how these provisions could impact our business.

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.

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.

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 resting leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes. As of December 31, 2019, we had 25 issued U.S. patents related to transplant rejection and autoimmunity. We have five 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 2021 to 2024. We have five additional patents covering additional genes or gene variants for diagnosing transplant rejection.

In connection with our June 2014 acquisition of ImmuMetrix, Inc., we obtained an exclusive license from Stanford to a U.S. patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This patent has an expiration date of November 5, 2030. A second patent included in the license from Stanford was issued in December 2017 and further covers the use of dd-cfDNA to diagnose and predict transplant status or outcome. A third and fourth patent were issued from this Stanford set in June 2019 and December 2019, respectively, covering the use of dd-cfDNA to diagnose and predict transplant status or outcome. Both patents have the same expiration 2030 date as the original Stanford patent.

As part of our April 2016 acquisition of Allenex, we obtained an additional five U.S. patents on donor matching technology treatment for antibody mediated transplant rejection.

Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. 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 dd-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. 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."

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.

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

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

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

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

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

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

In addition to seeking patents for some of our technologies and solutions, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot be certain that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures we have followed to prevent such disclosure are, or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

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

AlloMap, AlloSure, Olerup SSP, 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 a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This technology is critical to AlloSure Kidney under the terms of the Stanford license, we are required to report and pay an annual license maintenance fee, six milestone payments and royalties in the low single digits on net sales of products incorporating the licensed technology. This patent has an expiration date of November 5, 2030. A second patent included in the license from Stanford was issued in December 2017 and further covers the use of dd-cfDNA to diagnose and predict transplant status or outcome. A third and fourth patent was issued from this Stanford set in June 2019 and December 2019, respectively, covering the use of dd-cfDNA to diagnose and predict transplant status or outcome. Both patents have the same 2030 expiration date as the original Stanford patent.

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. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line.

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, KidneyCare 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.

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 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 2019, our closing stock price ranged from $19.24 to $40.08 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; 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; 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, and entities affiliated with them, beneficially own in the aggregate approximately 30.26% of our common stock as of December 31, 2019. 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 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 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.

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.

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 preliminary review of our equity transactions since inception, we believe a portion of our NOLs may be limited due to the equity financings that we have completed. Utilization of our NOLs may be subject to a substantial annual limitation 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.

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.

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);
- stockholders are not permitted to cumulate their votes for the election of directors; and
- stockholders may amend our bylaws and certain provisions of our certificate of incorporation only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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.

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

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock

short. These short attacks have, in the past, led to selling of shares in the market. We believe that our securities have in the past been, and may continue to be, the subject of short selling. Reports and information have been published about us that we believe are mischaracterized or incorrect, and which have in the past been followed by a decline in our stock price.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters are located in South San Francisco, 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, 2019:

Location	Function	Square Footage
United States		
South San Francisco, California	Corporate headquarters	28,968
Brisbane, California	Research & development and clinical laboratory	46,000
West Chester, Pennsylvania	Sales office and distribution	6,336
Omaha, Nebraska	Digital solutions office	13,132
Europe		
Stockholm, Sweden	Research & development and product manufacturing	23,874
Vienna, Austria	Sales office and distribution	1,744
Australia		
Fremantle	Research & development and product manufacturing	10,265

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

In response to our false advertising suit filed against 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 alleging CareDx made false and misleading claims about the performance capabilities of AlloSure. In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13th, 2020, in the U.S. District Court for the District of Delaware alleging, among other things, that AlloSure infringes Natera’s U.S. Patent 10,526,658. The suit seeks a judgment that we have infringed Natera’s patent, an order preliminarily and permanently enjoining us from any further infringement of such patent and unspecified damages. We intend to defend both of these matters vigorously, and believe we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail.

From time to time, we may become subject to legal proceedings and claims that arise in the ordinary course of business. Although we do not believe that any matters presently pending will have a material adverse effect, individually or in the aggregate, on our financial position, results of operations or liquidity, legal matters and proceedings are inherently unpredictable and subject to significant uncertainties, some of which are beyond our control. As such, there can be no assurance that the final outcome of these matters will not materially and adversely affect our financial position, results of operations or liquidity.

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 is traded 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 25, 2020, there were approximately 93 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.

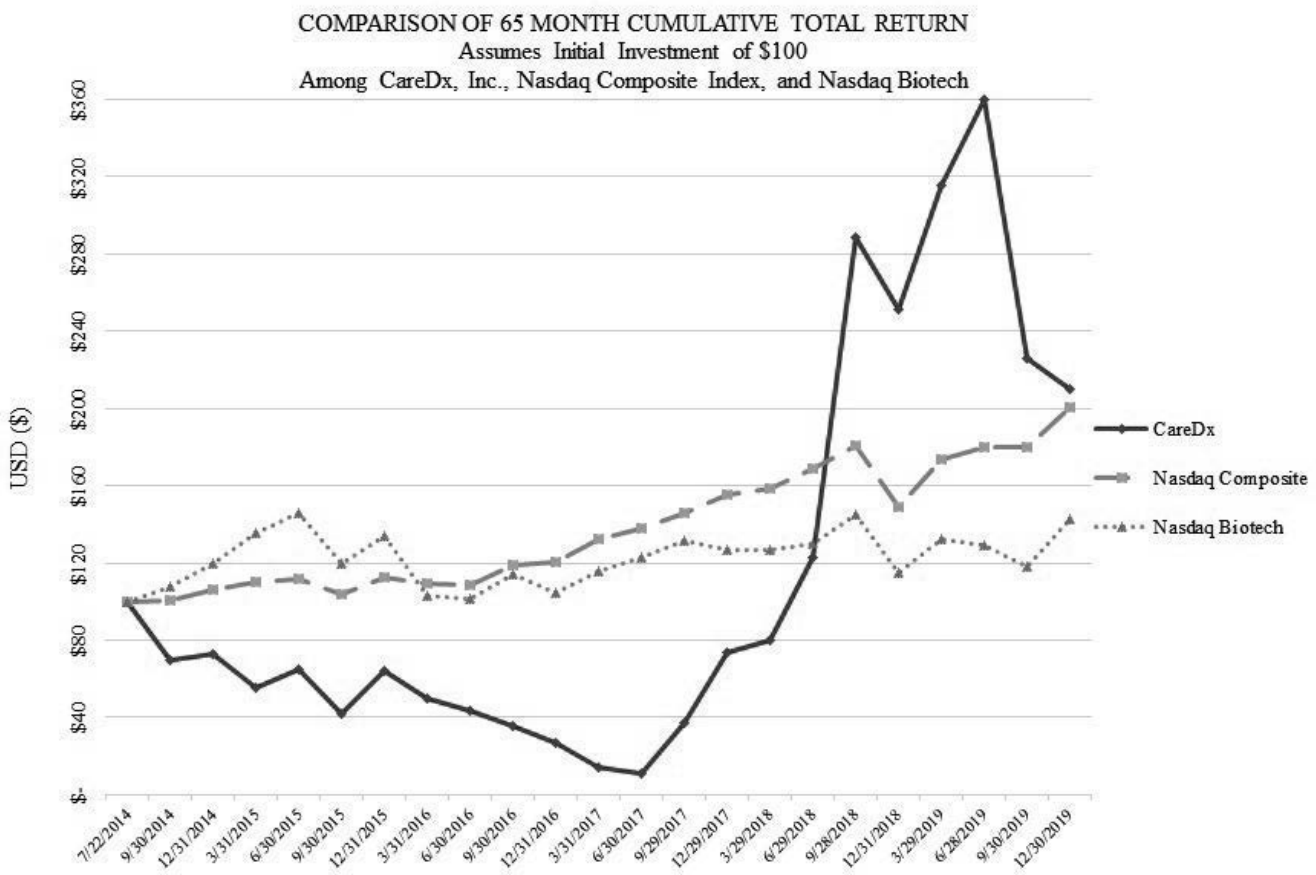
Dividend Policy

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 or 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 July 22, 2014 (the date of our initial public offering) through December 31, 2019 against the Nasdaq Market Composite Index and Nasdaq Biotech Index, assuming a $100 investment made on July 22, 2014. 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 2019.

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 Purchases of Equity Securities

We satisfy 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. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding obligations during the three months ended December 31, 2019:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid per Share (or Unit)
October 1, 2019 - October 31, 2019	1,469	(1)	5.25
November 1, 2019 - November 30, 2019	4,401	(1)	8.9
December 1, 2019 - December 31, 2019	985	(1)	2.50
Total	6,855		—

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

ITEM 6. SELECTED FINANCIAL DATA

The following selected historical financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data at December 31, 2019 and 2018 and the selected statements of operations data for each of the years ended December 31, 2019, 2018 and 2017 have been derived from our audited consolidated financial statements that are included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data at December 31, 2017, 2016 and 2015 and the selected statements of operations data for each of the years ended December 31, 2016 and 2015 were derived from our audited consolidated financial statements that are not included in this Annual Report on Form 10-K. The financial data included in this report are historical and are not necessarily indicative of results to be expected in any future period.

Statements of Operations Data:

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands, except share and per share data)				
Revenue:					
Testing services revenue	$ 104,550	$ 60,300	$ 33,106	$ 29,680	$ 27,881
Product revenue	18,279	15,674	14,634	10,715	—
Digital and other revenue	4,239	595	584	236	263
Total revenue	127,068	76,569	48,324	40,631	28,144
Cost of revenue	45,455	32,987	21,371	21,122	10,273
Gross profit	81,613	43,582	26,953	19,509	17,871
Operating expenses:					
Research and development	30,711	14,514	12,388	12,385	9,333
Sales and marketing	38,894	21,670	12,808	11,166	8,349
General and administrative	36,540	22,976	20,093	20,269	12,121
Goodwill impairment	—	—	1,958	13,021	—
Total operating expenses	106,145	59,160	47,247	56,841	29,803
Loss from operations	(24,532)	(15,578)	(20,294)	(37,332)	(11,932)
Other income (expense):					
Interest income (expense), net	985	(3,701)	(5,863)	(1,860)	(1,587)
Debt extinguishment expenses	—	(5,780)	(459)	—	—
Change in estimated fair value of common stock warrant and derivative liabilities	319	(22,978)	(29,622)	(250)	—
Other expense, net	(719)	(178)	(1,031)	(1,920)	(188)
Total other income (expense)	585	(32,637)	(36,975)	(4,030)	(1,775)
Loss before income taxes	(23,947)	(48,215)	(57,269)	(41,362)	(13,707)
Income tax benefit	1,979	1,434	1,709	1,606	—
Net loss	(21,968)	(46,781)	(55,560)	(39,756)	(13,707)
Net loss attributable to noncontrolling interest	—	(25)	(91)	(287)	—
Net loss attributable to CareDx, Inc.	$ (21,968)	$ (46,756)	$ (55,469)	$ (39,469)	$ (13,707)
Net loss per share:					
Basic	$ (0.52)	$ (1.31)	$ (2.38)	$ (2.39)	$ (1.16)
Diluted	$ (0.52)	$ (1.31)	$ (2.38)	$ (2.39)	$ (1.16)
Shares used to compute net loss per share:					
Basic	42,151,617	35,638,956	23,332,503	16,496,911	11,860,885
Diluted	42,151,617	35,638,956	23,332,503	16,496,911	11,860,885

Balance Sheet Data:

	As of December 31,				
	2019	2018	2017	2016	2015
	(In thousands)				
Cash and cash equivalents	$ 38,223	$ 64,616	$ 16,895	$ 17,258	$ 29,888
Working capital	37,094	61,610	(16,139)	(14,159)	24,210
Total Assets	151,736	130,697	83,565	76,730	55,638
Long term debt, net of current portion	—	—	18,338	1,098	12,887
Accumulated (deficit)	(333,813)	(311,845)	(268,022)	(212,553)	(173,084)
Total CareDx, Inc. stockholders' equity (deficit)	99,000	95,928	(5,954)	19,761	29,494

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction 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 healthcare solutions for transplant patients and caregivers. We offer testing services, products, and digital solutions along the pre- and post-transplant patient journey, and is a leading provider of genomics-based information for transplant patients.

Testing Services

Kidney

AlloSure Kidney, our transplant surveillance solution which was commercially launched in October 2017, applies proprietary next generation sequencing technology to measure donor-derived cell-free DNA, or dd-cfDNA, in the blood stream emanating from the donor kidney. We believe AlloSure Kidney may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted heart, kidney, or other solid organ, irrespective of the type of organ transplanted. We also 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. Effective October 9, 2017, AlloSure Kidney became available for commercial testing with Medicare coverage and reimbursement. The Medicare reimbursement rate for AlloSure Kidney is $2,841. AlloSure Kidney has also received payment from private payers on a case-by-case basis, with the first private payer, BCBS of South Carolina, issuing a positive coverage decision in its October 2019 review.

Prior to the commercialization of AlloSure Kidney, we generated a strong body of clinical evidence. In late 2015, we announced the completion of analytical validation of AlloSure Kidney. A report describing the analytical validation of AlloSure Kidney including clinical validation detailing the quality, reality and consistency of analytical results information for heart transplant, appeared in the November 2016 issue of The Journal of Molecular Diagnostics. The Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial, sponsored by us, was conducted between April 2015 and January 2018. DART is a 14 center observational study of kidney transplant recipients where blood specimens are drawn periodically after transplant during follow up visits and also after treatment for acute rejection. By the time of completion of the first analysis, 384 patients were followed in DART for up to 24 months. The results demonstrated that increased levels of dd-cfDNA, determined by the AlloSure Kidney assay, discriminated active rejection of a kidney transplant more effectively than serum creatinine values. In collaboration with clinical investigators, we published these findings in the scientific peer-reviewed Journal of the American Society of Nephrology and the Journal Applied Laboratory Medicine in March 2017. A total of 2,109 patient visits had been accrued in DART by January 2018. We analyzed this data to report on additional findings from this dataset at the American Transplant Congress, or ATC, held in 2019 and intend to continue to report additional findings into the future.

In 2018, we initiated the Kidney Allograft Outcomes AlloSure Kidney Registry, or K-OAR study, to develop further data on the clinical utility of AlloSure Kidney for surveillance of kidney transplant recipients.

KidneyCare

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.

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 KidneyCare iBox in one surveillance solution. We have not yet made any applications to payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

Heart

Our first commercialized testing solution, the AlloMap Heart transplant molecular test, or 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 for AlloMap Heart 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. In particular, we believe AlloMap Heart can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. AlloMap Heart has received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe acute cellular rejection.

AlloMap Heart has received positive coverage decisions for reimbursement from Medicare. 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, including Aetna, Anthem, Cigna, HCSC, Humana, Kaiser Foundation Health Plan, Inc., and UnitedHealthcare.

We have also successfully completed a number of 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 on the basis of our Cardiac Allograft Rejection Gene Expression Observational (Deng, M. et al., Am J Transplantation 2006), or CARGO, study, which was published in the American Journal of Transplantation. 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 International Society for Heart and Lung Transplantation, or ISHLT, guidelines.

HeartCare

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.

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 – a measure of graft injury. 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. We have not yet made any applications to private payers for reimbursement coverage of AlloSure Heart except for Medicare. In August 2019, AlloSure Heart received a positive draft Local Coverage Determination, or dLCD, for Medicare coverage.

Lung

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies. AlloSure Lung applies proprietary next generation sequencing, or NGS, technology to

measure dd-cfDNA in the blood stream emanating from the donor lung to monitor graft injury. We have not yet made any applications to payers for reimbursement coverage of AlloSure Lung.

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 to these recipients.

QTYPE enables 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. QTYPE received CE mark certification on April 10, 2018. Olerup SSP is used to type HLA alleles based on the SSP technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles.

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.

As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines. 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.

Digital

On May 7, 2019, we acquired 100% of the outstanding common stock of OttrCare for total consideration of $16.1 million. OttrCare was formed in 1993 and is a leading provider of transplant patient tracking software, or the Ottr software, which provides comprehensive solutions for transplant patient management. Ottr software enable 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 with a combination of cash consideration of $2.0 million paid upfront and contingent consideration with a fair value of $1.4 million. XynManagement provides two unique solutions, XynQAPI software, or XynQAPI, and Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients, or SRTR, reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility. XynManagement products have been added to the CareDx digital solutions portfolio and will be integrated with current offerings, including Ottr software and patient care managers.

Our software solutions are currently used in 84 transplant centers in the U.S.

Refer to Note 5 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for further detail regarding these acquisitions.

Financial Operations Overview

Revenue

We derive our revenue from testing services, products sales and digital and other 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 and AlloMap Heart tests, which represented 82%, 79% and 69% of our total revenues for the years ended December 31, 2019, 2018 and 2017, 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; (v) our ability to expand into markets outside of the United States; and (vi) 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. 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 Olerup SSP, QTYPE, Olerup SBT and TruSight products. Product revenue represented 15%, 20% and 30% of total revenue for the years ended December 31, 2019, 2018 and 2017, 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.

Digital and Other Revenue

Our digital and other revenue is mainly derived from sales of our Ottr software and XynQAPI licenses and services and other licensing agreements. Digital and other revenue represented 3% of total revenue for the year ended December 31, 2019, and 1% of total revenue for each of the years ended December 31, 2018 and 2017.

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, products and digital and other revenue in the amount that reflects the consideration which it expects to be entitled in exchange for goods or services as it transfers control to its customers. Revenue is recorded considering a five-step 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

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 a contract. Testing services are performed in our laboratory. Testing services represent one performance obligation in a contract and revenue is recorded when results of the test are provided to the healthcare provider, at a point of 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 test result to the healthcare provider. Amounts received may vary amongst payers based on coverage practices and policies of the payer. We determine an estimate of a transaction price by financial class of payers. Transaction prices are determined for each financial

class using history of reimbursements, including analysis of an average reimbursement per test and a percentage of tests reimbursed. We estimate revenue for non-contracted payers and self-payers using this methodology. The estimate requires significant judgment. 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 process for determining the appropriate transaction price involves judgment, and considers such factors as, historical payment trends, current economic conditions and regulatory changes. The ultimate amounts of collections could be different from the amounts we estimate.

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. 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.

Digital and Other Revenue

Digital revenue is mainly derived from perpetual software license agreements entered into with various transplant centers (customers). The main performance obligations in connection with our 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 ("PCS"). 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 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. We record 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 recognize revenue over the contractual term, as performance obligations are fulfilled.

In addition, we derive digital revenue from software subscriptions. We generally bill software subscription fees in advance. Revenue from software subscriptions is deferred and recognized ratably over the subscription term.

Business Combinations

In accordance with ASC Topic 805, *Business Combinations*, we determine and allocate the purchase price of an acquired business to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the business combination date, including identifiable intangible assets that either arise from a contractual or legal right or 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 we expect to make as of the acquisition date. We remeasured this liability each reporting period and record changes in the fair value as a component of general and administrative expenses.

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

Acquired Intangible Assets

Amortizable intangible assets may include customer relationships, developed technology, trademarks, contracts and acquired in-process technology assets as part of a business combination. 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. Accordingly, amortization of the acquired in-process technology assets will not occur until the products reach commercialization.

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, 2019, we performed a qualitative assessment at the consolidated level taking into consideration past, current and projected future earnings, recent trends and market conditions; and its 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, 2019, 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.

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. Where indicators of impairment exist, 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 such impairment losses to date.

Common Stock Warrant Liability

Common stock warrants issued with debt, equity or as standalone financing instruments are recorded as either liabilities or equity in accordance with the respective accounting guidance. Warrants recorded as equity are recorded at their relative fair value determined at the issuance date and are not remeasured after that. Warrants recorded as liabilities are recorded at their fair

value and remeasured on each reporting date with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the consolidated statements of operations.

We utilize a binomial-lattice pricing model, or the Monte Carlo Simulation Model, that 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 our stock price, expected life of the warrants, stock price volatility determined from our historical stock prices and stock prices of peer companies in the diagnostics industry, 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. Increases (decreases) in these assumptions result in a directionally similar impact to the fair value of the common stock warrant liability. Refer to Note 4 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for key assumptions used to value outstanding warrant liability.

Recently Issued Accounting Standards

Refer to Note 2, Summary of Significant Accounting Policies - Recent Accounting Pronouncements, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a description of recently issued accounting pronouncements, including the expected dates of adoption and estimated effects on our results of operations, financial position and cash flows.

Factors Affecting Our Performance

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

The growth of our testing services business is tied to the number of AlloSure Kidney and AlloMap 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.

The Number of Diagnostic Products We Sell

The growth of our product revenues is tied to the sales of the Olerup SSP, QTYPE, Olerup SBT, TruSight HLA and AlloSeq product lines. The product sales organizations are located in Stockholm, Sweden; Vienna, Austria; Fremantle, Australia and West Chester, Pennsylvania. Products are sold directly to customers in 22 countries. We also use distributors to sell products in approximately 46 countries.

Continued Adoption of and 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 Medicare provided reimbursement and payers adopt coverage policies and fewer payers 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 reimbursement, achieve broader reimbursement from third party payers and to expand the number of tests per patient and the base of healthcare providers.

The Protecting Access to Medicare Act of 2014, or PAMA, includes 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 $2,840. AlloMap Heart has also received positive coverage decisions for reimbursement from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation (HCSC), Humana, Kaiser Foundation Health Plan, Inc., and UnitedHealthcare.

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.

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.

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 polymerase chain reaction, or PCR, methodology. QTYPE received CE mark certification on April 10, 2018. Olerup SSP is used to type HLA alleles based on the SSP technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles.

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. As a result, on June 1, 2018, we became the exclusive worldwide distributor of Illumina's TruSight HLA product line. TruSight HLA is a high-resolution solution that uses NGS methodology. In addition, we were granted the exclusive right to develop and commercialize other NGS product lines for use in the field of bone marrow and solid organ 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.

Continued Growth of Software Sales

The growth of our digital revenues is tied to the successful implementation of our Ottr and XynQAPI software businesses, as well as continued support and maintenance of existing OttrCare and XynManagement customers. The Ottr software and XynQAPI are currently implemented in multiple locations in the U.S. The Ottr software and XynQAPI implementation and support teams are based in Omaha, Nebraska.

Development of Additional Products

We rely on sales of AlloSure Kidney, AlloMap Heart, Olerup SSP, Olerup SBT, QTYPE and TruSight HLA to generate the majority of our revenue. 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 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, 2019 and 2018

(In thousands)

	Year Ended December 31,		
	2019	2018	Change
Revenue:			
Testing services revenue	$ 104,550	$ 60,300	$ 44,250
Product revenue	18,279	15,674	2,605
Digital and other revenue	4,239	595	3,644
Total revenue	127,068	76,569	50,499
Cost of revenue	45,455	32,987	12,468
Gross profit	81,613	43,582	38,031
Operating expenses:			
Research and development	30,711	14,514	16,197
Sales and marketing	38,894	21,670	17,224
General and administrative	36,540	22,976	13,564
Total operating expenses	106,145	59,160	46,985
Loss from operations	(24,532)	(15,578)	(8,954)
Other income (expense):			
Interest income (expense), net	985	(3,701)	4,686
Debt extinguishment expenses	—	(5,780)	5,780
Change in estimated fair value of common stock warrant and derivative liabilities	319	(22,978)	23,297
Other expense, net	(719)	(178)	(541)
Total other income (expense)	585	(32,637)	33,222
Loss before income taxes	(23,947)	(48,215)	24,268
Income tax benefit	1,979	1,434	545
Net loss	(21,968)	(46,781)	24,813
Net loss attributable to noncontrolling interest	—	(25)	25
Net loss attributable to CareDx, Inc.	$ (21,968)	$ (46,756)	$ 24,788

Testing Services Revenue

Testing services revenue increased by $44.3 million, or 73%, for the year ended December 31, 2019, compared to the same period in 2018. This increase is mainly due to an increase of 21,472 test results provided during the year ended December 31, 2019, compared to the year ended December 31, 2018.

Product Revenue

Product revenue increased by $2.6 million, or 17%, for the year ended December 31, 2019, compared to the same period in 2018. The increase was due to sales of the TruSight HLA products related to the License Agreement with Illumina signed in May 2018, and increased sales of QTYPE, partially offset by a decrease in sales of Olerup SSP and Olerup SBT products.

Digital and Other Revenue

Digital and other revenue increased by $3.6 million for the year ended December 31, 2019, compared to the same period in 2018, primarily due to the acquisition of OttrCare in May 2019 and XynManagement in August 2019.

Cost of Revenue

Cost of revenue increased by approximately $12.5 million, or 38%, for the year ended December 31, 2019, compared to the same period in 2018, primarily due to higher testing volume, increased product sales, and the acquisitions of OttrCare in May 2019 and XynManagement in August 2019.

Gross profit increased by $38.0 million, or 87%, for the year ended December 31, 2019, compared to the same period in 2018, primarily due and increase in revenue and an improvement in gross profit margins resulting from efficiencies in testing services laboratory operations.

Research and Development

Research and development expenses increased by $16.2 million, or 112%, for the year ended December 31, 2019, compared to the same period in 2018. This increase is primarily due to an increase of $8.9 million in personnel costs, an increase of $2.7 million in stock-based compensation expense, an increase of $1.4 million in consulting and professional fees, and an increase of $1.3 million in external clinical studies expense.

Sales and Marketing

Sales and marketing expenses increased by approximately $17.2 million, or 79%, for the year ended December 31, 2019, compared to the same period in 2018, primarily due to an increase in personnel-related expenses of $7.8 million, an increase in stock-based compensation expenses of $3.0 million, an increase in tradeshow and marketing costs of $2.8 million and an increase in travel costs of $2.0 million.

General and Administrative

General and administrative expenses increased by $13.6 million, or 59%, for the year ended December 31, 2019, compared to the same period in 2018, primarily due to an increase of $8.2 million in stock-based compensation expense, an increase of $2.1 million in consulting services, an increase of $1.2 million in personnel-related expenses, and an increase of $1.2 million in legal fees.

Interest Income (Expense), Net

Interest income of $1.0 million for the year ended December 31, 2019, related to interest earned by our money market accounts.

Interest expense of $3.7 million for the year ended December 31, 2018 consisted of $2.5 million of interest expense and debt discount amortization related to the convertible debt with JGB Collateral LLC and certain of its affiliates, or the JGB Debt, $1.2 million of interest expense and debt amortization recorded in relation to the Perceptive Credit Agreement entered into on April 17, 2018 and $0.2 million of interest expense recorded in relation to other debt. These interest expense amounts were partially offset by interest income of $0.2 million earned on cash and cash equivalent balances.

Debt Extinguishment Expenses

There were no debt extinguishment expenses for the year ended December 31, 2019. For the year ended December 31, 2018, debt extinguishment expenses were $5.8 million related to a loss recorded on the conversion of the JGB Debt, calculated as the difference between the value of the shares of common stock issued on the days of conversion and the amount of principal debt converted on those days, net of the allocated debt discount and derivative liability balances.

Change in Estimated Fair Value of Common Stock Warrant and Derivative Liabilities

The expense for the change in estimated fair value of common stock warrants decreased by $23.3 million, or 101%, for the year ended December 31, 2019, compared to the same period in 2018. The income in 2019 was $0.3 million, comprised of a a $3.4 million remeasurement gain related to the change in fair value of our common stock warrant liability, partially offset by a $3.1 million remeasurement charge for warrants exercised during the period.

The $23.0 million expense for the year ended December 31, 2018 consisted of a $25.6 million remeasurement charge related to the change in fair value of our common stock warrant liability, partially offset by a $2.6 million gain recorded for the changes in fair value of the JGB Debt embedded derivative between January 1, 2018 and the conversion date of March 27, 2018.

Other Expense, Net

Other expense, net increased by $0.5 million in the year ended December 31, 2019, compared to the same period in 2018, primarily due to recording of accretion expense of $0.3 million and foreign exchange losses of $0.1 million.

Income Tax Benefit

For the year ended December 31, 2019, we recorded an income tax benefit of $2.0 million on a loss before income taxes of $23.9 million primarily attributable to the recognition of deferred tax assets from foreign losses and recognition of previous unrecognized tax benefits. For the year ended December 31, 2018, we recorded an income tax benefit of $1.4 million on a loss

before income taxes of $48.2 million primarily attributable to the tax impact of the losses related to our foreign operations. The effective tax rate for the year ended December 31, 2019 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, 2018 and 2017

For a discussion regarding our financial condition and results of operations for the year ended December 31, 2018 as compared to the year ended December 31, 2017, please refer to the discussion under the heading "Results of Operations—Comparison of the Ended December 31, 2018 and 2017" in Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 6, 2019.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $333.8 million at December 31, 2019. As of December 31, 2019, we had cash and cash equivalents of $38.2 million, and no debt outstanding.

Going Concern

As of December 31, 2019, we had cash and cash equivalents of $38.2 million. We may require future additional financing to fund working capital and pay our obligations as they come due. Additional financing might include a combination of equity security offerings, debt arrangements or collaborations. However, 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 that our existing cash balance and expected revenue along with the net proceeds from any future equity financing available under our effective Form S-3 filed with SEC in August 2018, will be sufficient to meet our anticipated cash requirements for a period of at least 12 months from the issuance date of our consolidated financial statements.

The following table summarizes our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (2,769)	$ (4,007)	$ (14,307)
Investing activities	(22,579)	(7,929)	(6,105)
Financing activities	(132)	50,268	29,379
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(849)	2	106
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (26,329)	$ 38,334	$ 9,073

Cash Flows from Operating Activities

Net cash used in operating activities consists of our net loss, adjusted for certain non-cash 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, 2019 was $2.8 million. Our net loss of $22.0 million was our primary use of cash in operating activities and included the following noncash items: $22.4 million stock-based compensation expense, $5.5 million of depreciation and amortization expense, $1.6 million non-cash lease expense and other miscellaneous items totaling $0.1 million. Net operating assets and liabilities decreased by $10.4 million.

Net cash used in operating activities for the year ended December 31, 2018 was $4.0 million. Our net loss of $46.8 million was our primary use of cash in operating activities and included the following noncash items: $23.0 million loss on the change in fair value of warrants and derivative liabilities, $7.1 million stock-based compensation expense, $5.8 million loss on debt extinguishment expenses, $4.2 million of depreciation and amortization expense, $2.2 million amortization expense related to the JGB Debt discount, $1.2 million loss related to the revaluation of the contingent consideration, and $0.2 million on amortization of inventory fair market value adjustment. Net operating assets and liabilities decreased by $0.9 million.

Cash Flows from Investing Activities

For the year ended December 31, 2019, net cash used in investing activities was $22.6 million and consisted of $18.2 million for the acquisition of OttrCare and XynManagement, $2.2 million related to additions of capital expenditures, $1.2 million related to the acquisition of intangible assets, and $1.0 million related to our investment in equity securities.

For the year ended December 31, 2018, net cash used in investing activities was $7.9 million and consisted of $5.2 million related to the acquisition of intangible assets per the Illumina License Agreement, $2.0 million for additions of capital expenditures and $0.7 million for the acquisition of the Allenex minority interest.

Cash Flows from Financing Activities

Net cash used by financing activities for the year ended December 31, 2019 was $0.1 million and primarily related to $4.2 million of taxes paid related to the net share settlement of restricted stock units and other miscellaneous payments totaling $0.3 million, offset by $3.6 million cash proceeds from the exercise of stock options, and $0.8 million cash proceeds from issuance of common stock under employee stock purchase plan.

Net cash provided by financing activities for the year ended December 31, 2018 was $50.3 million and primarily related to $52.9 million net proceeds from the 2018 Public Offering, $14.3 million net proceeds from the Perceptive Credit Agreement, $11.0 million proceeds from the exercise of warrants, $1.5 million cash proceeds from the exercise of stock options, and $0.3 million proceeds from issuance of common stock under employee stock purchase plan. Cash received was partially offset by $28.1 million of principal payments of the promissory notes issued to FastPartner AB and Mohammed Al Amoudi, Danske Bank Term Loan, the SSP Primers Loan, and the Perceptive Credit Agreement, $0.7 million of taxes paid related to the net share settlement of restricted stock units, $0.7 million repayment of the Danske Credit Facility, and $0.2 million of acquisition of Conexio.

For a discussion regarding our cash flows for the year ended December 31, 2017, 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, 2018, filed with the SEC on March 6, 2019.

Contractual Obligations

The following table summarizes our significant contractual obligations as of December 31, 2019 and the effect those obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Finance lease obligations	$ 280	$ 209	$ 71	$ —	$ —
Operating lease obligations	6,024	3,416	2,608	—	—
Total	$ 6,304	$ 3,625	$ 2,679	$ —	$ —

We lease operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in South San Francisco, California; Brisbane, California; West Chester, Pennsylvania; Fremantle, Australia; and Stockholm, Sweden. The facility leases expire at various dates through 2022. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

On January 2, 2020, we executed the second amendment to the operating lease agreement for the building located at Brisbane, California. The minimum lease payments in connection with this amendment total $23.9 million starting in March 2021 and up to February 2029.

As of December 31, 2019, we had net unrecognized tax benefits of $3.7 million, which include penalties and interest of $0.2 million. Approximately $0.3 million has been recorded as a noncurrent liability. At this time, we are unable to make a reasonably reliable estimate of the timing of payments in individual years in connection with these tax liabilities. Therefore, such amounts are not included in the above contractual obligation table.

We have also committed to make potential future payments to third parties as part of our collaboration and licensing agreements. Payments under these agreements generally become due and payable only upon achievement of specific project

milestones. Because the achievement of these milestones is generally neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheets and have not been included in the table above.

Off-Balance Sheet Arrangements

As of December 31, 2019, we had no off-balance sheet arrangements as defined under Regulation S-K 303(a)(4) of the Exchange Act, and the instructions thereto.

Foreign Operations

The accompanying consolidated balance sheets contain certain recorded assets in foreign countries, namely Stockholm, Sweden, Vienna, Austria 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 of $38.2 million and $64.6 million at December 31, 2019 and December 31, 2018, respectively, which consisted of bank deposits and money market funds. However, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 50 basis point increase or decrease in interest rates during any of the periods presented would have an approximate impact of less than $0.2 million on our consolidated financial statements.

Foreign Currency Exchange Risk

We have operations in Sweden, Austria, 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. 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, 2019, would have negatively impacted our financial results for the year ended December 31, 2019 by $0.2 million and our product revenue by $1.1 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 stockholders and the Board of Directors of CareDx, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CareDx, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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, 2019, 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, 2020, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases in fiscal year 2019 due to the adoption of Accounting Standards Codification (ASC) Topic 842, *Leases*.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 US 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Valuation of Acquired Intangible Assets — Refer to Note 5 to the consolidated financial statements

Critical Audit Matter Description

On May 7, 2019 the Company completed the acquisition of Ottr Complete Transplant Management ("OttrCare"), which was accounted for as a business combination in accordance with Accounting Standards Codification Topic 805, *Business Combinations*. The determination of the fair value of acquired intangible assets of $6.6 million required management to make estimates related to revenue projections and the discount rate.

We identified the valuation of acquired intangible assets as a critical audit matter because of the significant judgments and assumptions related to revenue projections and the discount rate. Given the fair value determination of intangible assets

required management to make significant estimates and assumptions related to the future projected revenue and the selection of the discount rate, performing audit procedures to evaluate the reasonableness of these estimates and assumptions required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the valuation of acquired intangible assets included the following, among others:

- We tested the effectiveness of controls over the determination of fair value of intangible assets, including those over the future projected revenue and the selection of the discount rate.
- With the assistance of our fair value specialists, we evaluated the selection of the discount rate, including testing the underlying source information and the mathematical accuracy of the calculations by developing a range of independent estimates and comparing those to the rate selected by management.
- We understood and tested the reasonableness of the management revenue growth rate estimate including the following procedures:
  - Compared historical revenues and revenue growth rates with growth rates used in the valuation model and investigated any differences, including the expectations from the market participant perspective.
  - Held discussions with Company management, and management of the acquiree regarding their expectations of revenue growth.
  - Reviewed expected growth in recent industry reports and analyst reports.
  - Reviewed due diligence and internal presentations to the Board and management.

/s/ Deloitte & Touche LLP

San Jose, California
February 27, 2020

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of CareDx, Inc. and subsidiaries (the "Company") as of December 31, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, 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, 2019, of the Company and our report dated February 27, 2020, expressed an unqualified opinion on those financial statements and included an explanatory paragraph related to the Company's change in method of accounting for leases in fiscal year 2019 due to the adoption of Accounting Standards Codification (ASC) Topic 842, *Leases*.

As described in Management's Annual Report on Internal Control over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Ottr Complete Transplant Management and XynManagement, Inc., except for goodwill and intangible assets. Ottr Complete Transplant Management was acquired on May 7, 2019 and XynManagement, Inc. on August 26, 2019, and their financial statements constitute 6% and 3% of the consolidated total assets (excluding goodwill and intangible assets) and revenues, respectively, as of and for the year ended December 31, 2019. Accordingly, our audit did not include the internal control over financial reporting at Ottr Complete Transplant Management and XynManagement, Inc., except for goodwill and intangible assets.

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

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

/s/ Deloitte & Touche LLP

San Jose, California
February 27, 2020

Report of Ernst & Young LLP, Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the year ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated results of its operations and its cash flows for the year ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Ernst & Young LLP

We have served as the Company's auditor from 2009 to 2018.
Redwood City, California
March 22, 2018

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

	As of December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 38,223	$ 64,616
Accounts receivable	24,057	9,760
Inventory	6,014	4,943
Prepaid and other current assets	3,628	1,795
Total current assets	71,922	81,114
Property and equipment, net	4,430	4,134
Operating leases right-of-use assets	4,730	—
Intangible assets, net	45,541	33,252
Goodwill	23,857	12,005
Restricted cash	256	192
Other assets	1,000	—
Total assets	$ 151,736	$ 130,697
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,506	$ 4,711
Accrued compensation	12,484	9,156
Accrued and other liabilities	16,838	5,637
Total current liabilities	34,828	19,504
Deferred tax liability	1,973	2,968
Common stock warrant liability	6,607	10,003
Deferred payments for intangible assets	5,207	—
Other liabilities	4,121	2,294
Total liabilities	52,736	34,769
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at December 31, 2019 and 2018; no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at December 31, 2019 and 2018; 42,498,430 and 41,384,960 shares issued and outstanding at December 31, 2019 and 2018, respectively	42	41
Additional paid-in capital	437,976	412,010
Accumulated other comprehensive loss	(5,205)	(4,278)
Accumulated deficit	(333,813)	(311,845)
Total stockholders' equity	99,000	95,928
Total liabilities and stockholders' equity	$ 151,736	$ 130,697

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,		
	2019	**2018**	**2017**
Revenue:			
Testing services revenue	$ 104,550	$ 60,300	$ 33,106
Product revenue	18,279	15,674	14,634
Digital and other revenue	4,239	595	584
Total revenue	127,068	76,569	48,324
Cost of revenue	45,455	32,987	21,371
Gross profit	81,613	43,582	26,953
Operating expenses:			
Research and development	30,711	14,514	12,388
Sales and marketing	38,894	21,670	12,808
General and administrative	36,540	22,976	20,093
Goodwill impairment	—	—	1,958
Total operating expenses	106,145	59,160	47,247
Loss from operations	(24,532)	(15,578)	(20,294)
Other income (expense):			
Interest income (expense), net	985	(3,701)	(5,863)
Debt extinguishment expenses	—	(5,780)	(459)
Change in estimated fair value of common stock warrant and derivative liabilities	319	(22,978)	(29,622)
Other expense, net	(719)	(178)	(1,031)
Total other income (expense)	585	(32,637)	(36,975)
Loss before income taxes	(23,947)	(48,215)	(57,269)
Income tax benefit	1,979	1,434	1,709
Net loss	(21,968)	(46,781)	(55,560)
Net loss attributable to noncontrolling interest	—	(25)	(91)
Net loss attributable to CareDx, Inc.	$ (21,968)	$ (46,756)	$ (55,469)
Net loss per share attributable to CareDx, Inc. (Note 3):			
Basic	$ (0.52)	$ (1.31)	$ (2.38)
Diluted	$ (0.52)	$ (1.31)	$ (2.38)
Weighted-average shares used to compute net loss per share attributable to CareDx, Inc.:			
Basic	42,151,617	35,638,956	23,332,503
Diluted	42,151,617	35,638,956	23,332,503

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,		
	2019	**2018**	**2017**
Net loss	$ (21,968)	$ (46,781)	$ (55,560)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	(927)	(1,933)	1,306
Net comprehensive loss	(22,895)	(48,714)	(54,254)
Comprehensive loss attributable to noncontrolling interest, net of tax	—	(25)	(99)
Comprehensive loss attributable to CareDx, Inc.	$ (22,895)	$ (48,689)	$ (54,155)

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

CareDx, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' Equity
Balance at December 31, 2016	21,278,373	$ 21	$ 235,673	$ (3,659)	$ (212,553)	$ 279	$ 19,761
Issuance of common stock in connection with public offering	4,992,840	6	18,323	—	—	—	18,329
Issuance of common stock in connection with business acquisition	1,022,544	2	1,144	—	—	—	1,146
Conversion of convertible debt	288,022	—	1,676	—	—	—	1,676
Issuance of common stock under equity incentive plans	166,067	—	94	—	—	—	94
Issuance of common stock for Board of Director services	115,948	—	245	—	—	—	245
Issuance of common stock for cash upon exercise of stock options	70,809	—	262	—	—	—	262
Issuance of common stock for cash upon exercise of warrants	890,416	—	989	—	—	—	989
Issuance of common stock upon exercise of warrants	—	—	4,306	—	—	—	4,306
Employee and non-employee share-based compensation expense	—	—	1,492	—	—	—	1,492
Foreign currency translation adjustment	—	—	—	1,314	—	(8)	1,306
Net loss	—	—	—	—	(55,469)	(91)	(55,560)
Balance at December 31, 2017	28,825,019	$ 29	$ 264,204	$ (2,345)	$ (268,022)	$ 180	$ (5,954)
Adoption of ASC 606	—	—	—	—	2,933	—	2,933
Reclassification of warrants from liability to equity	—	—	6,550	—	—	—	6,550
Issuance of common stock in connection with public offering, net of offering costs of $3.8 million	2,300,000	2	52,547	—	—	—	52,549
Conversion of convertible debt	6,161,331	6	38,846	—	—	—	38,852
Issuance of common stock under ESPP	76,710	—	287	—	—	—	287
RSU settlements, net of shares withheld	178,150	—	(698)	—	—	—	(698)
Issuance of common stock for services	50,509	—	273	—	—	—	273
Issuance of common stock for cash upon exercise of stock options	473,812	1	1,479	—	—	—	1,480
Issuance of common stock for cash upon exercise of warrants	3,091,581	3	38,709	—	—	—	38,712
Employee share-based compensation expense	—	—	5,868	—	—	—	5,868
Non-employee share-based compensation expense	—	—	1,009	—	—	—	1,009
Noncontrolling interests upon acquisition	—	—	(537)	—	—	(155)	(692)
Issuance of common stock for contingent consideration	227,848	—	2,689	—	—	—	2,689
Issuance of warrants in connection with debt	—	—	784	—	—	—	784
Foreign currency translation adjustment	—	—	—	(1,933)	—	—	(1,933)
Net loss	—	—	—	—	(46,756)	(25)	(46,781)
Balance at December 31, 2018	41,384,960	$ 41	$ 412,010	$ (4,278)	$ (311,845)	$ —	$ 95,928
Contingent consideration classified as equity	—	—	222	—	—	—	222
Issuance of common stock under ESPP	51,712	—	759	—	—	—	759
RSU settlements, net of shares withheld	285,963	—	(4,152)	—	—	—	(4,152)
Issuance of common stock for services	7,569	—	209	—	—	—	209
Issuance of common stock for cash upon exercise of stock options	625,685	1	3,552	—	—	—	3,553
Issuance of common stock upon exercise of warrants	142,541	—	3,181	—	—	—	3,181
Employee share-based compensation expense	—	—	22,195	—	—	—	22,195
Foreign currency translation adjustment	—	—	—	(927)	—	—	(927)
Net loss	—	—	—	—	(21,968)	—	(21,968)
Balance at December 31, 2019	42,498,430	$ 42	$ 437,976	$ (5,205)	$ (333,813)	$ —	$ 99,000

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

CareDx, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2019	**2018**	**2017**
Operating activities:			
Net loss	$ (21,968)	$ (46,781)	$ (55,560)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	22,417	7,138	1,744
Amortization of inventory fair market value adjustment	—	234	418
Loss on disposal of property and equipment	160	—	10
Depreciation and amortization	5,523	4,215	3,727
Non-cash lease expense	1,621	—	—
Revaluation of warrants and derivative liabilities to estimated fair value	(319)	22,978	29,622
Revaluation of contingent consideration to estimated fair value	210	1,017	1,180
Amortization of debt discount and noncash interest expense	—	2,232	3,452
Non-cash goodwill impairment	—	—	1,958
Debt extinguishment expenses	—	5,831	274
Changes in operating assets and liabilities:			
Accounts receivable	(12,675)	(3,967)	(109)
Inventory	(1,270)	363	1,025
Prepaid and other current assets	(829)	(502)	(84)
Accounts payable	1,351	(168)	292
Accrued compensation	3,115	4,291	1,065
Accrued and other liabilities	3,029	719	(1,233)
Operating lease liabilities	(1,854)	—	—
Change in deferred taxes	(1,280)	(1,607)	(2,088)
Net cash used in operating activities	(2,769)	(4,007)	(14,307)
Investing activities:			
Additions of capital expenditures, net	(2,201)	(2,035)	(186)
Acquisition of intangible assets	(1,148)	(5,202)	—
Acquisition of business	(18,230)	(692)	(5,919)
Investment in equity securities	(1,000)	—	—
Net cash used in investing activities	(22,579)	(7,929)	(6,105)
Financing activities:			
Proceeds from issuance of common stock, net of issuance costs	—	52,910	18,328
Proceeds from debt, net of issuance costs	—	14,282	24,002
Principal payments on debt and capital lease obligations	(172)	(28,089)	(14,359)
Contingent payments related to acquisition	(225)	(225)	—
Change in short-term credit facility	—	(677)	—
Proceeds from exercise of warrants	105	10,998	989
Proceeds from exercise of stock options	3,553	1,480	262
Proceeds from issuance of common stock under employee stock purchase plan	760	287	94
Taxes paid related to net share settlement of restricted stock units	(4,153)	(698)	—
Change in bank overdraft obligation	—	—	63
Net cash (used in) provided by financing activities	(132)	50,268	29,379
Effect of exchange rate changes on cash and cash equivalents	(849)	2	106
Net increase (decrease) in cash, cash equivalents and restricted cash	(26,329)	38,334	9,073
Cash, cash equivalents, and restricted cash at beginning of period	64,808	26,474	17,401
Cash, cash equivalents, and restricted cash at end of period	$ 38,479	$ 64,808	$ 26,474
Supplemental disclosures of cash information			
Cash paid for interest	$ 22	$ 1,774	$ 3,270
Supplemental disclosures of cash flow information			
Shares issued in lieu of payment	$ 209	$ —	$ 1,145
Deferred purchase consideration	$ —	$ —	$ —
Accrued interest capitalized to debt principal	$ —	$ —	$ 984
Deferred payments for intangible assets	$ 7,207	$ —	$ —
Operating lease right of use assets	$ 6,138	$ —	$ —
Purchased of capital expenditures in accounts payable and accrued liabilities	$ 576	$ —	$ —
Issuance of common stock upon conversion of convertible debt	$ —	$ 38,852	$ —
Offering costs included in accounts payable	$ —	$ 361	$ —
ESPP shares included in accrued compensation	$ 703	$ 341	$ —
Common stock warrants issued upon debt financing	$ —	$ 784	$ —
Contingent consideration	$ 1,442	$ 2,689	$ —
Cash, Cash Equivalents and Restricted Cash as of:			
Cash and cash equivalents	$ 38,223	$ 64,616	$ 16,895
Restricted cash	256	192	9,579
Total cash, cash equivalents, and restricted cash at the end of the period	$ 38,479	$ 64,808	$ 26,474

The accompanying notes are an integral part of these 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 healthcare solutions for transplant patients and caregivers. The Company's headquarters are in South San Francisco, California. The primary operations are in Brisbane, California; Omaha, Nebraska; Fremantle, Australia and Stockholm, Sweden.

The Company's commercially available testing services consist of AlloSure Kidney, which is a donor-derived cell-free DNA ("dd-cfDNA") solution for kidney transplant patients, and AlloMap Heart, which is a gene expression solution for heart transplant patients. 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.

In 2019, the Company began providing digital solutions to transplant centers following the acquisitions of Ottr Complete Transplant Management ("OttrCare") and XynManagement, Inc. ("XynManagement").

Testing Services

In October 2017, the Company commercially launched AlloSure Kidney, its proprietary next generation sequencing-based test that measures dd-cfDNA in kidney transplant recipients. The Medicare reimbursement rate for AlloSure Kidney is currently $2,841. AlloSure Kidney has also received payment from private payers on a case-by-case basis, with the first private payer, BCBS of South Carolina, issuing a positive coverage decision in its October 2019 review.

AlloMap Heart is 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 from many of the largest U.S. private payers.

In January 2018, the Company initiated the Kidney Allograft Outcomes AlloSure Kidney Registry study ("K-OAR"), to develop further 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 plans to enroll greater than 1,500 renal transplant patients who will receive AlloSure Kidney long-term surveillance.

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 KidneyCare iBox developing a multimodality surveillance solution. The Company has not yet made any applications to payers for reimbursement coverage of AlloMap Kidney or KidneyCare iBox.

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 August 2019, AlloSure Heart received a positive draft Local Coverage Determination (dLCD) for Medicare coverage.

In February 2019, AlloSure Lung became available for lung transplant patients through a compassionate use program while the test is undergoing further studies.

Products

TruSight HLA is a next generation sequencing ("NGS")-based high-resolution typing solution that provides NGS-level resolution to HLA typing. The Company's suite of AlloSeq products are commercial NGS-based kitted solutions that the Company acquired as a result of its license agreement with Illumina. 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.

Olerup SSP is used to type Human Leukocyte Antigen ("HLA") alleles, based on the sequence specific primer ("SSP") technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles. QTYPE enables HLA typing at

a low to intermediate resolution for samples that require a fast turnaround time and uses real-time polymerase chain reaction, or PCR methodology.

Digital and Other

Following the acquisitions of both OttrCare and XynManagement, the Company is a leading provider of transplant patient tracking 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 Waitlist Management. XynQAPI simplifies transplant quality tracking and Scientific Registry of Transplant Recipients (“SRTR”) reporting. Waitlist Management includes a team of transplant assistants who maintain regular contact with patients on the waitlist to help prepare for their transplant and maintain eligibility.

The Company's software solutions are currently used in 84 transplant centers in the U.S.

Liquidity and Going Concern

The Company has incurred significant losses and negative cash flows from operations since its inception and had an accumulated deficit of $333.8 million at December 31, 2019. As of December 31, 2019, the Company had cash and cash equivalents of $38.2 million.

The Company may require additional financing in the future to fund working capital and the Company’s future products development. Additional financing might include issuance of equity securities, debt, or cash. There can be no assurance that the Company will be successful in acquiring additional funding at levels sufficient to fund its operations or on terms favorable to the Company. The Company believes its existing cash balance and expected revenues will be sufficient to meet its anticipated cash requirements for the next 12 months.

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.

Changes in Presentation

The presentation of the financial statements for certain prior period amounts has been changed to conform with the current period presentation, including: (i) separate presentation of debt extinguishment expenses from other expense, net, (ii) combined presentation of license and other revenue with digital revenue, (iii) combined presentation of cost of testing services, cost of product, and cost of digital, and (iv) separate presentation of gross profit. These reclassifications had no effect on the reported results of operations.

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; accrued expenses for clinical studies inventory valuation; the fair value of issued common stock warrants; 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; the grant date fair value assumptions used to estimate stock-based compensation expense; income taxes; impairment of long-lived assets and indefinite-lived assets (including goodwill); and legal contingencies. Actual results could differ from those estimates.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash, cash equivalents and 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 and various bank deposit accounts. These financial instruments are held in Company accounts at twelve financial institutions. 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 and AlloMap Heart tests provided for patients located in the U.S. and billed to various third-party payers, from sales of products to distributors, strategic partners and transplant laboratories in Europe, the Middle East, Africa, the U.S., Latin America and other geographic regions, and from sales of 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, 2019, 2018 and 2017, approximately 55%, 48% and 27%, respectively, of total revenue was billed to Medicare. No other payers represented more than 10% of total revenue for the years ended December 31, 2019, 2018 and 2017.

As of December 31, 2019 and 2018, approximately 36% and 27%, respectively, of accounts receivable was due from Medicare. No other payer represented more than 10% of accounts receivable at either December 31, 2019 or 2018.

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 and an agreement with the State of Florida Medicaid, the Company must maintain letters of credit, minimum collateral requirements and a surety bond. These agreements are collateralized by cash. The cash used to support these arrangements of $0.3 million is classified as long-term restricted cash on the accompanying consolidated balance sheets.

Inventory

Inventory is finished goods, work in progress, and raw materials and consists of reagent plates, testing devices, laboratory supplies, reagents and finished goods kits. Inventories are used in connection with tests performed, and kits produced 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 and excluded from the physical inventory. Inventories at the Company's Stockholm, Sweden, and Fremantle, Australia locations are stated at the lower of purchased cost, determined on an average cost basis, or net realizable value. Inventories at the Company's other locations are stated at the lower of actual purchased cost, determined on a first-in, first-out basis, or 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 years for machinery, computer and office 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, consulting services, and direct materials, as well as employee payroll and payroll-related costs. Capitalized internal-use software costs are usually amortized over a period of three to five 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, trademarks, contracts and acquired in-process technology assets acquired as part of a business combination. 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, 2019, the Company performed a qualitative assessment 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 that time. As of December 31, 2019, 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, 2019, 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 such 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.

Common Stock Warrants

Common stock warrants issued with debt, equity or as standalone financing instruments are recorded as either liabilities or equity in accordance with the respective accounting guidance. Warrants recorded as equity are recorded at their relative fair value determined at the issuance date and are not remeasured after that. Warrants recorded as liabilities are recorded at their fair value and remeasured on each reporting date with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the consolidated statements of operations.

The Company utilizes a binomial-lattice pricing model, or the Monte Carlo Simulation Model, that 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 stock prices of peer companies in the diagnostics industry, 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. Increases (decreases) in these assumptions result in a directionally similar impact to the fair value of the common stock warrant liability.

Leases

Effective January 1, 2019, the Company adopted Accounting Standard Codification ("ASC") Topic 842, Leases ("ASC 842"). The Company determines if an arrangement is or contains a lease at contract inception. The Company leases office space and equipment primarily through operating leases with a limited number of finance leases. 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. Short-term leases with an initial term of 12 months or less are not recorded on the balance sheet.

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, 2019, the Company's leases have remaining terms of 0.5 years to 9.17 years, some of which include options to extend the lease term. The Company's lease terms may include renewal options that are reasonably certain to be exercised and termination options that are reasonably certain not to be exercised. Certain finance leases also include bargain purchase options of the leased equipment.

Revenue

The Company recognizes revenue from testing services, products, and digital and other 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 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 and AlloMap Heart 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 CareDx 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 or AlloMap Heart 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, a practical expedient 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.

Digital and other revenue

Digital revenue is mainly derived from perpetual software license agreements entered into with various transplant centers (customers). The main performance obligations in connection with the Company's 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 ("PCS"). 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 digital revenue from software subscriptions. The Company generally bills software subscription fees in advance. Revenue from software subscriptions is deferred and recognized ratably over the subscription term.

Cost of Revenue

Cost of revenue is presented in a single line on the face of the statement of operations. It represents the total combined costs of providing testing services, products and digital solutions to the Company's customers. The Company's cost of revenue associated with each of its revenue sources is as follows:

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 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 digital revenue and other 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, 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 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, volatility using its own historical stock prices and stock prices of peer companies in the diagnostics industry, 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 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 current 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

Effective January 1, 2019, the Company adopted ASC 842 using the optional transition method and applied the standard only to leases that existed at that date. Under the optional transition method, the Company does not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2019 in accordance with ASC Topic 840. The Company has also chosen to apply the package of practical expedients for existing leases, which provides relief from reassessing: (i) whether a contract is or contains a lease, (ii) lease classification, and (iii) whether initial direct costs can be capitalized. The Company has also made some accounting policy elections to: (i) allow the Company not to separate nonlease components from lease components, and instead to account for those as a single lease component, and (ii) elect not to recognize a ROU asset and a lease liability for leases with a term of 12 months or less.

Upon adoption of ASC 842 on January 1, 2019, the Company recorded a ROU asset of approximately $3.0 million and a lease liability of approximately $3.8 million. The lease liability was determined based on the present value of the remaining minimum lease payments. The ROU asset was determined based on the value of the lease liability, adjusted for the deferred rent balances of approximately $0.8 million, which were previously included in accrued and other liabilities as well as deferred rent, net of current portion. See Note 8 for further details.

The standard did not have a material impact on the consolidated statement of cash flows or the consolidated statement of operations.

In February 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-2, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* ("ASU 2018-2"). The amendments in ASU 2018-2 allow a reclassification from accumulated other comprehensive income to retained earnings for certain tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act"). ASU 2018-2 became effective for all interim and annual reporting periods beginning after December 15, 2018 and may be applied retrospectively or as of the beginning of the period of adoption. The Company adopted the standard on January 1, 2019. The adoption of the new standard did not have a material impact on the Company's consolidated financial statements.

In September 2018, the FASB issued ASU No. 2018-7, *Compensation - Stock Compensation (ASC Topic 718): Improvements to Nonemployee Share Based Payment Accounting* ("ASU 2018-7"). ASU 2018-7 is effective for all interim and annual reporting periods beginning on or after December 15, 2018. The Company adopted ASU 2018-7 on January 1, 2019 applying a modified retrospective approach. On transition, the Company only had nonemployee equity-classified awards with an established measurement date. Accordingly, the Company did not record a cumulative-effect adjustment to retained earnings.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal – Use Software (ASC Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"). ASU 2018-15 is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption of ASU 2018-15 is permitted including adoption in any interim period. The Company adopted the standard during the fourth quarter of 2019. The Company expects the new standard will impact its prospective consolidated financial statements after adoption related to implementation costs in a cloud computing arrangement if and when entered by the Company.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (ASC Topic 820), which modifies, removes and adds certain disclosure requirements on fair value measurements based on the FASB Concepts Statement, Conceptual Framework for Financial Reporting—Chapter 8: Notes to Financial Statements. The ASU is effective for the Company's interim and annual reporting periods during the year ending December 31, 2020, and all annual and interim reporting period

thereafter. The amendments on changes in unrealized gains and losses, the range and weighted-average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of ASU 2018-13. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is in the process of assessing the impact that the ASU will have in its consolidated financial statements and disclosures. The Company does not believe adoption of the guidance will have a significant impact on its consolidated financial statements.

In September 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* (ASC Topic 326), which amends the FASB's guidance on the impairment of financial instruments. The ASU adds to U.S. GAAP an impairment model known as the current expected credit loss ("CECL") model, which is based on expected losses rather than incurred losses. Under the new guidance, an entity recognizes as an allowance its estimate of lifetime expected credit losses, which the FASB believes will result in more timely recognition of such losses. The new CECL standard is effective for public companies for annual reporting periods beginning after December 15, 2019, and interim periods therein. ASU 2016-13 has a greater impact on banks. However, nonbank entities that have financial instruments or other assets such as trade receivables, contract assets, lease receivables, financial guarantees, loans and loan commitments, and held-to-maturity debt securities are subject to the CECL model. The Company adopted the standard on January 1, 2020. The adoption of the new standard did not have a material impact on the Company's consolidated financial statements.

3. NET LOSS PER SHARE ATTRIBUTABLE TO CAREDX, INC.

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

For the years ended December 31, 2019, 2018 and 2017, 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,		
	2019	2018	2017
Numerator:			
Net loss attributable to CareDx, Inc. used to compute basic net loss per share	$ (21,968)	$ (46,756)	$ (55,469)
Net loss attributable to CareDx, Inc. used to compute diluted net loss per share	$ (21,968)	$ (46,756)	$ (55,469)
Denominator:			
Weighted-average shares used to compute basic net loss per share attributable to CareDx, Inc.	42,151,617	35,638,956	23,332,503
Weighted-average shares used to compute diluted net loss per share attributable to CareDx, Inc.	42,151,617	35,638,956	23,332,503
Net loss per share attributable to CareDx, Inc.:			
Basic	$ (0.52)	$ (1.31)	$ (2.38)
Diluted	$ (0.52)	$ (1.31)	$ (2.38)

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

	Year Ended December 31,		
	2019	2018	2017
Shares of common stock subject to outstanding options	2,609,848	2,501,057	1,941,472
Shares of common stock subject to outstanding common stock warrants	355,240	656,289	3,678,957
Shares of common stock subject to convertible notes	—	—	6,127,021
Shares of common stock subject to contingent consideration	10	—	227,845
Restricted stock units	1,516,285	968,364	436,176
Total common stock equivalents	4,481,383	4,125,710	12,411,471

On October 10, 2017, the Company completed an underwritten public offering (the "2017 Public Offering"), pursuant to which the Company issued and sold an aggregate of 4,992,840 shares. During 2017 and the three months ended March 31, 2018, 6,415,039 shares of common stock were issued due to the conversion of the JGB Debt. In the three months ended June 30, 2018, the Company achieved the milestone of performing 2,500 commercial AlloSure Kidney tests resulting in the issuance of 227,848 shares of common stock to the former owners of ImmuMetrix, Inc. ("IMX") that was accounted for as contingent consideration.

On November 13, 2018, the Company completed an underwritten public offering (the "2018 Public Offering") pursuant to which the Company issued and sold an aggregate of 2,300,000 shares.

4. FAIR VALUE MEASUREMENTS

The Company records its financial assets and liabilities at fair value except for its debt, which was recorded at amortized cost. 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 fair value of the Company's financial assets and liabilities measured on a recurring basis, as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 29,177	$ —	$ —	$ 29,177
Liabilities				
Common stock warrant liability	$ —	$ —	$ 6,607	$ 6,607

	December 31, 2018			
	Fair Value Measured Using			
	(Level 1)	(Level 2)	(Level 3)	Total Balance
Assets				
Money market funds	$ 59,471	$ —	$ —	$ 59,471
Liabilities				
Common stock warrant liability	$ —	$ —	$ 10,003	$ 10,003

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

	(Level 3)				
	Contingent Consideration Liability	Common Stock Warrant Liability	JGB Debt Derivative Liability	Perceptive Derivative Liability	Total
Balance as December 31, 2017	$ 1,672	$ 18,712	$ 14,600	$ —	$ 34,984
Exercise of warrants	—	(27,714)	—	—	(27,714)
Extinguishment of derivative liabilities	—	—	(12,066)	(202)	(12,268)
Reclassification to equity (Note 2)	—	(6,550)	—	—	(6,550)
Issuance of Perceptive derivative liability	—	—	—	245	245
Issuance of shares of common stock	(2,689)	—	—	—	(2,689)
Change in estimated fair value	1,017	25,555	(2,534)	(43)	23,995
Balance as December 31, 2018	$ —	$ 10,003	$ —	$ —	$ 10,003
Exercise of warrants	—	(3,077)	—	—	(3,077)
Change in estimated fair value	—	(319)	—	—	(319)
Balance as December 31, 2019	$ —	$ 6,607	$ —	$ —	$ 6,607

As of December 31, 2019, the Company had one investment in convertible preferred shares carried at cost. See Note 6, "Goodwill and Intangible Assets". In the event the Company had to fair value this investment, it would be based on Level 3 inputs. This investment is not considered material to the Company's consolidated financial statements.

The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers between Level 1, Level 2 and Level 3 categories during the periods presented.

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. At December 31, 2019 and 2018, money market funds were included as cash and cash equivalents in the consolidated balance sheets.
- *Common stock warrant liability*—The Company utilizes a binomial-lattice pricing model (the "Monte Carlo Simulation Model") that 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 stock prices of peer companies in the diagnostics industry, 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. Increases (decreases) in the assumptions discussed above result in a directionally similar impact to the fair value of the common stock warrant liability.

Common Stock Warrant and Derivative Liability Valuation Assumptions:

	December 31,	
	2019	2018
Private Placement Common Stock Warrant Liability		
Stock Price	$ 21.57	$ 25.14
Exercise Price	$ 1.12	$ 1.12
Remaining term (in years)	3.29	4.29
Volatility	81.00 %	79.00 %
Risk-free interest rate	1.62 %	2.46 %

Warrants liabilities exercised during 2019 were remeasured at the exercise date. Their fair value approximate their intrinsic value, which was recorded to additional paid in capital in the consolidated statements of stockholders' equity.

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. BUSINESS COMBINATIONS

Business Combinations

OttrCare

On May 7, 2019, the Company acquired 100% of the outstanding common stock of OttrCare for total consideration of $16.1 million. OttrCare was formed in 1993 and is a leading provider of organ transplant patient tracking software. The Ottr software provides comprehensive solutions for transplant patient management and enables integration with EMR systems providing patient surveillance management tools and outcomes data to transplant centers.

The Company accounted for the transaction as a business combination using the acquisition method of accounting. Results of operations of OttrCare have been included with the Company's results since the date of the acquisition. 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 $10.2 million arising from the acquisition primarily consists of synergies from integrating the Ottr software with transplant center EMR systems and the current testing solutions offered by the Company. Goodwill synergies also arise from acquired workforce know-how of transplant centers workflow. 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 consideration paid for OttrCare 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	$	16,037
Accrued purchase consideration		111
Total consideration	$	16,148
Recognized amounts of identifiable assets acquired and liabilities assumed		
Current assets	$	1,525
Fixed assets		35
Identifiable intangible assets		6,600
Current liabilities		(2,210)
Total identifiable net assets acquired		5,950
Goodwill		10,198
Total consideration	$	16,148

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.

The fair value of the acquired current liabilities as of June 30, 2019 included a preliminary deferred revenue balance of $2.3 million. During the three months ended September 30, 2019, the Company recorded an adjustment of $0.5 million to the initial valuation amount of deferred revenue, decreasing its balance to $1.8 million as of the acquisition date. This change is a result of updated assumptions and methodologies for acquired software maintenance contracts. As part of this adjustment, goodwill decreased by approximately $0.6 million.

At the acquisition date, the Company estimated net deferred tax assets of approximately $0.2 million arising from temporary differences related to assets acquired and liabilities assumed. The Company estimated that OttrCare had net operating losses ("NOLs") carryforward of approximately $6.9 million, $4.3 million of which will begin to expire in 2033, and the remaining $2.6 million will be carried forward indefinitely. A full valuation allowance of $0.2 million was recognized as of the acquisition date resulting in no impact from deferred taxes to OttrCare's opening balance. An Internal Revenue Code Section 382 study for NOLs was finalized during the third quarter of 2019 and deferred taxes acquired were finalized as of December 31, 2019.

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	$ 4,200	15
Developed technology	2,300	10
Trademark	100	2
Total	$ 6,600	

Customer relationships acquired by the Company represent the fair value of future projected revenue that is expected to be derived from sales of OttrCare'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 OttrCare's proprietary software. The trademark acquired consists primarily of the OttrCare 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 15.0% and 1.0% were used to estimate the fair value of the developed technology and the trademark, respectively.

The Company utilized a discount rate of 14.5% in estimating the fair value of these three intangible assets. As of December 31, 2019, OttrCare's digital revenue of $3.4 million was included in the Company's consolidated statement of operations from the acquisition date of May 7, 2019. Unaudited supplemental pro forma information is not disclosed because it is considered immaterial.

XynManagement

On August 26, 2019, the Company acquired 100% of the outstanding common stock of XynManagement for total cash consideration of $2.0 million. As a result of the acquisition, the Company recognized contingent consideration of $1.4 million, including liability and equity components, goodwill of $1.7 million and intangible assets of $2.1 million. Goodwill synergies arise from acquired workforce know-how of transplant centers workflow. The goodwill for this acquisition is not deductible for income tax purposes. Contingent consideration relates to potential future cash payments upon reaching specified revenue and non-financial targets. The fair value of contingent consideration was determined using the Monte Carlo simulation model.

6. 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, 2019. The following table presents details of the Company's goodwill for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Balance as of January 1,	$ 12,005	$ 12,005
Goodwill acquired	11,852	—
Balance as of December 31,	$ 23,857	$ 12,005

On December 1, 2019, 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, 2019, no impairment of goodwill has been identified.

Intangible Assets

The following tables present details of the Company's intangible assets as of December 31, 2019 (in thousands):

	December 31, 2019				
	Acquisition Cost	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
Intangible assets with finite lives:					
Acquired and developed technology	$ 29,106	$ (6,473)	$ (1,852)	$ 20,781	8.2
Customer relationships	18,168	(3,397)	(1,498)	13,273	10.1
Commercialization rights	8,079	(231)	—	7,848	9.7
Trademarks and tradenames	2,360	(618)	(206)	1,536	9.1
Total intangible assets with finite lives	57,713	(10,719)	(3,556)	43,438	
Acquired in-process technology	2,103	—	—	2,103	
Total intangible assets	$ 59,816	$ (10,719)	$ (3,556)	$ 45,541	

Acquisition of intangible assets

Illumina License and Commercialization Agreement

On May 4, 2018, the Company entered into the License Agreement with Illumina, which provides the Company with certain worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in the field of bone marrow and solid organ transplantation diagnostic testing (the "Field"). As a result, from June 1, 2018, the Company is the exclusive worldwide distributor of Illumina's TruSight HLA product line. In addition, the Company was also granted the exclusive right to develop and commercialize other NGS product lines for use in the Field.

The License Agreement required the Company to make a $5.0 million initial cash payment to Illumina and further requires the Company to pay royalties in the mid-single to low-double digits on sales of future commercialized products. Pursuant to the License Agreement, the Company is obligated to complete timely development and commercialization of other NGS product lines for use in the Field, and has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

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

Costs relating to the assets acquired were $5.2 million, comprising of the cash consideration of $5.0 million and associated transaction costs of $0.2 million. A deferred tax balance was not required to be established on the License Agreement date as the book and tax basis of the intangible assets was equivalent to the amount paid.

The allocation of the purchase price to identified intangible assets acquired was based on the Company's best estimate of the fair value of such assets as of the acquisition date. Significant assumptions utilized in the valuation of identified intangible assets were based on company-specific information and projections, which are not observable in the market and are thus considered Level 3 measurements as defined by U.S. GAAP. The Company determined the estimated fair values using Level 3

inputs after review and consideration of relevant information, including discounted cash flows, quoted market prices and estimates made by management.

Customer relationships represent the fair value of future projected revenue that is expected to be derived from sales of TruSight HLA products to existing customers of Illumina. The customer contracts and related relationships value has been estimated utilizing a multi-period excess earnings method under 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 life of the products, assuming that the existing customers will remain with the Company until the products become obsolete. The Company utilized a discount rate of 18% in estimating the fair value of the customer relationships.

The acquired in-process technology represents the fair value of products in development that have not reached commercial production at the date of acquisition. The fair value of the products was also determined using the multi-period excess earnings method under income approach. A discount rate of 40% for the AlloSeq HCT acquired in-process technology was utilized to discount the cash flows to the present value. The acquired in-process technology will not be amortized until completion of the related products, which is determined to occur when the products commence commercial production. Upon completion, each acquired in-process technology product will be amortized over its estimated useful life.

In November 2019, the acquired in-process technology intangible for AlloSeq Tx commenced commercial production. As of December 31, 2019; such acquired in-process technology has been classified as an intangible assets with finite live, and is being amortized over a useful life of 14 years.

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

	Estimated Fair Value	Estimated Useful Life (Years)
Customer relationships: TruSight HLA	$ 380	2.6
Acquired in-process technology: AlloSeq HCT	2,103	—
Total	$ 2,483	

Cibiltech License and Commercialization Agreement

Effective April 30, 2019, the Company entered into a license and commercialization agreement (the "Cibiltech Agreement") with Cibiltech SAS ("Cibiltech"). Cibiltech is a French company engaged in the development and support of predictive medicine and artificial intelligence software, services and technology, with an emphasis on personalized patient care and clinical research, including its proprietary software and service offering known as KidneyCare iBox in the U.S. for the predictive analysis of post-transplantation kidney allograft loss. The Cibiltech Agreement provides the Company with an irrevocable, non-transferable right to commercialize Cibiltech's proprietary software in the field of transplantation in the U.S. for a period of ten years. The Company estimated the fair value of the acquired commercialization rights intangible asset based on expected contractual payments discounted to present value using a discount rate of 6%. In September 2019, the Company initiated the OKRA clinical study, which incorporates KidneyCare iBox. On such date, the Company commenced amortization of the acquired commercialization intangible asset.

On July 26, 2019, pursuant to the Cibiltech Agreement, the Company purchased $1.0 million of convertible preferred shares of Cibiltech, which is recorded in other assets. The Company does not have a significant influence on Cibiltech's operations.

The following tables present details of the Company's intangible assets as of December 31, 2018 (in thousands):

	December 31, 2018				
	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	$ 22,937	$ (4,399)	$ (1,411)	$ 17,127	8.4
Customer relationships	13,058	(2,290)	(1,131)	9,637	11.6
Trademarks and tradenames	2,260	(454)	(140)	1,666	12.0
Total intangible assets with finite lives	38,255	(7,143)	(2,682)	28,430	
Acquired in-process technology	4,822	—	—	4,822	
Total intangible assets	$ 43,077	$ (7,143)	$ (2,682)	$ 33,252	

The net carrying amount of intangible assets and the related amortization expense of intangible assets may change due to the effects of foreign currency fluctuations as a result of acquiring an entity with a functional currency other than the U.S. dollar.

Amortization expense was $3.6 million for the year ended December 31, 2019, of which $2.3 million, and $1.3 million were amortized to cost of revenue and sales and marketing expenses, respectively. Amortization expense was $2.4 million for the year ended December 31, 2018, of which $1.4 million and $1.0 million were amortized to cost of revenue and sales and marketing expenses, respectively. Amortization expense was $2.6 million for the year ended December 31, 2017, of which $1.6 million, and $1.0 million were amortized to cost of revenue and sales and marketing expenses, respectively.

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

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2019 (in thousands):

Years Ending December 31,	Cost of Product	Sales and Marketing	Total
2020	$ 3,217	$ 1,459	$ 4,676
2021	3,170	1,269	4,439
2022	3,170	1,252	4,422
2023	3,170	1,252	4,422
2024	3,170	1,252	4,422
Thereafter	12,731	8,326	21,057
Total future amortization expense	$ 28,628	$ 14,810	$ 43,438

7. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2019	2018
Finished goods	$ 1,236	$ 2,506
Work in progress	1,189	651
Raw materials	3,589	1,786
Total inventory	$ 6,014	$ 4,943

Property and Equipment, Net

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

	December 31,	
	2019	2018
Leasehold improvements	$ 5,458	$ 5,187
Furniture and fixtures	683	720
Computer and office equipment	4,996	4,488
Machinery and equipment	7,546	6,961
Construction in progress	840	878
	$ 19,523	$ 18,234
Less: Accumulated depreciation and amortization	(15,093)	(14,100)
Property and equipment, net	$ 4,430	$ 4,134

Depreciation expense was $1.6 million in the year ended December 31, 2019, and $1.2 million in each of the years ended December 31, 2018 and 2017.

Assets purchased under finance leases, included above in machinery and equipment, and computer and office equipment, were $0.6 million at each of December 31, 2019 and 2018. Accumulated depreciation was $0.4 million and $0.2 million at December 31, 2019 and 2018, respectively. Related amortization expense, included in depreciation and amortization expense, was $0.2 million, $0.2 million and $0.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Accrued and Other Liabilities

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

	December 31,	
	2019	2018
Deferred revenue	$ 3,686	$ 39
Clinical studies	3,068	1,815
Short-term lease liability	3,017	—
Deferred payments for intangible assets	2,098	—
Test sample processing fees	835	657
Contingent consideration	810	—
Professional fees	766	822
Accrued royalty	547	285
Other accrued expenses	2,011	2,019
Total accrued and other liabilities	$ 16,838	$ 5,637

8. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in South San Francisco, California; Brisbane, California; West Chester, Pennsylvania; Fremantle, Australia; and Stockholm, Sweden. The Company also leases equipment under finance lease agreements. The lease for the Company's facility in Vienna, Austria is on a month-to-month basis. The facility leases expire at various dates through 2022. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

The following table summarizes the lease cost for the year ended December 31, 2019 (in thousands):

	Twelve Months Ended December 31,
	2019
Operating lease cost	$ 1,993
Finance lease cost	218
Total lease cost	$ 2,211

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

Other information:	
Weighted-average remaining lease term - Operating leases (in years)	2.21
Weighted-average remaining lease term - Finance leases (in years)	1.31
Weighted-average discount rate - Operating leases (%)	10.5 %
Weighted-average discount rate - Finance leases (%)	6.6 %

Rent expense under the non-cancelable operating leases was $2.3 million, $2.0 million and $1.7 million in 2019, 2018 and 2017, respectively. Future minimum lease commitments under these operating and finance leases on December 31, 2019, are as follows (in thousands):

Years ending December 31,	Finance Leases	Operating leases
2020	$ 209	$ 3,416
2021	71	1,350
2022	—	1,258
Total minimum lease payments	$ 280	$ 6,024

On January 2, 2020, the Company executed the second amendment to the operating lease agreement for the building located at Brisbane, California. The total minimum lease payments in connection with this amendment total $23.9 million starting in March 2021 and up to February 2029. Refer to Note 16 for additional details.

The current portion of obligations under finance leases is included in accrued and other liabilities on the balance sheets. The long-term portion is included in other liabilities on the balance sheets.

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. Royalties incurred for the year ended December 31, 2019 were not material.

Illumina

On May 4, 2018, the Company entered into the License Agreement with Illumina. The License Agreement requires the Company to pay royalties in the mid-single to low-double digits on sales of future commercialized products. In the year ended December 31, 2019, the Company paid no royalties to Illumina.

Cibiltech Commitments

Pursuant to the Cibiltech Agreement, the Company will share an agreed-upon percentage of revenue with Cibiltech, if and when revenues are generated from KidneyCare iBox.

Other Commitments

Pursuant to the License Agreement with Illumina, the Company is obligated to complete timely development and commercialization of other NGS product lines for use in the Field, and has agreed to minimum purchase commitments of finished products and raw materials from Illumina through 2023.

Litigation and Indemnification Obligations

In response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against the Company on February 18, 2020, in the U.S. District Court for the District of Delaware alleging CareDx made false and misleading claims about the performance capabilities of AlloSure. 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 13th, 2020, in the U.S. District Court for the District of Delaware alleging, among other things, that AlloSure infringes Natera's U.S. Patent 10,526,658. The suit seeks a judgment that the Company has infringed Natera's patent, an order preliminarily and permanently enjoining the Company from any further infringement of such patent and unspecified damages. The Company intends to defend both of these matters vigorously, and believe 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.

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. The Company is not involved in any material litigation as of December 31, 2019.

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations. The Company also has indemnification obligations to its directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at the Company's request in such capacities. There have been no claims to date and the Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recorded any liabilities for these agreements as of December 31, 2019 and as of December 31, 2018.

9. DEBT

The Company did not have any outstanding debt as of December 31, 2019.

Perceptive Credit Agreement

On April 17, 2018, the Company entered into a credit agreement with Perceptive Credit Holdings II, LP (the "Perceptive Credit Agreement") for an initial term loan of $15.0 million. On November 20, 2018, the Company paid off all obligations owing under, and terminated, the Perceptive Credit Agreement. The Perceptive Credit Agreement debt extinguishment resulted in a $3.0 million loss that was included in debt extinguishment expenses, in the consolidated statements of operations.

JGB Debt

In February and March 31, 2018, JGB Collateral LLC and certain of its affiliates ("JGB") converted the remaining $26.7 million of principal and accrued interest of the Company's convertible debt (the "JGB Debt") into an aggregate of 6,161,331 shares of the Company's common stock. In connection with these conversions, the Company recognized $6,000 to common stock and $38.8 million to additional paid in capital; the unamortized debt discount of $2.7 million was extinguished; and the compound derivative liability of $12.1 million was also extinguished. The JGB Debt conversion resulted in a $2.8 million loss on debt extinguishment that was included in debt extinguishment expenses in the consolidated statements of operations for the year ended December 31, 2018.

10. STOCKHOLDERS' EQUITY

2017 Public Offering

On October 10, 2017, the Company sold in the 2017 Public Offering (the "2017 Public Offering") an aggregate of 4,992,840 shares of its common stock, including 651,240 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares to cover over-allotments, at a public offering price of $4.00 per share.

Net proceeds from the 2017 Public Offering were $18.3 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

JGB Debt

On October 5, 2017, JGB converted $1.3 million of outstanding principal under the Debentures into shares of common stock. Accordingly, the Company issued 288,022 shares of common stock to JGB at a price per share of $4.34. In 2018, JGB converted the remaining $26.7 million of outstanding principal and accrued interest for a total issuance of 6,161,331 shares of the Company's common stock at a price per share of $4.33.

Contingent Consideration Liability

The Company had a contingent obligation to issue 227,845 shares of the Company's common stock to the former owners of IMX, in conjunction with its acquisition of IMX in June 2014. The shares were issuable upon the Company completing 2,500 commercial tests involving the measurement of dd-cfDNA in organ transplant recipients in the United States by June 10, 2020. The Company achieved the contingent consideration milestone of 2,500 commercial tests and issued the 227,848 shares in May 2018.

2018 Public Offering

On November 16, 2018, the Company sold in the 2018 Public Offering an aggregate of 2,300,000 shares of its common stock, including 300,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares at a public offering price of $24.50 per share. Total net proceeds received were $52.9 million net of underwriter's fees and issuance costs.

The Company did not issued preferred stock during the years ended December 31, 2019, 2018 and 2017.

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. Employee contributions are voluntary and are determined on an individual basis subject to the maximum allowable under federal tax regulations. On January 1, 2018, the Company began to make contributions to the employee plan. The Company incurred expenses related to contributions to the plan of $0.6 million and $0.3 million for the year ended December 31, 2019 and 2018, respectively.

12. WARRANTS

The Company issues common stock warrants in connection with debt or equity financings to a lender, a placement agent or 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 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.

In the year ended December 31, 2019, warrants to purchase approximately 94,000 shares of common stock were exercised for cash payments of $0.1 million. During the year ended December 31, 2019, approximately 207,400 warrants were exercised on a cashless basis and approximately 49,000 shares were issued pursuant to the exercises.

In the year ended December 31, 2018, warrants to purchase approximately 2,998,000 shares of common stock were exercised for cash payments of $11.0 million

As of December 31, 2019, outstanding warrants to purchase common stock were:

	Classified as	Original Term	Exercise Price	Number of Shares Underlying Warrants
Original issue date:				
January 2015	Equity	5 years	$ 6.96	34,483
April 2016	Liability	7 years	$ 1.12	320,757
				355,240

13. STOCK INCENTIVE PLANS

2014 Equity Incentive Plan

The Company grants stock based awards under 2014 Equity Inceptive 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 394,063 shares of common stock reserved for future issuance under the 2014 Plan as of December 31, 2019.

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. The terms in the 2016 Plan are substantially similar to the 2014 Plan. There were 50,511 shares of common stock reserved for future issuance under the 2016 Plan as of December 31, 2019.

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 Equity Incentive Plan

The Company grants stock based awards under 2019 Equity Inceptive 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 60,200 shares of common stock reserved for future issuance under the 2019 Plan as of December 31, 2019.

Stock Options and RSUs

The following table summarizes options and RSUs activity under the Company's 2014, 2016 and 2019 Plans 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, 2018	322,178	2,501,057	$ 9.10	968,364	$ 11.49
Additional options authorized	1,855,398	—	—	—	—
Common stock awards for services	(7,569)	—	—	—	—
RSUs granted	(1,260,088)	—	—	1,260,088	27.27
RSUs vested	—	—	—	(524,938)	15.09
Options granted	(991,130)	991,130	27.88	—	—
Options exercised	—	(625,685)	5.70	—	—
Repurchases of common stock under employee incentive plans	142,103	—	—	—	—
RSUs forfeited	187,229	—	—	(187,229)	21.88
Options forfeited	241,533	(241,533)	15.37	—	—
Options expired	15,121	(15,121)	6.45	—	—
Balance—December 31, 2019	504,775	2,609,848	$ 16.47	1,516,285	$ 22.51

The total intrinsic value of options exercised was $15.1 million, $6.8 million and less than $0.2 million in the years ended December 31, 2019, 2018 and 2017, respectively.

The total fair value of RSUs vested during 2019 was $7.9 million. As of December 31, 2019, the total intrinsic value of outstanding RSUs was approximately $32.7 million and there were $22.9 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 3.08 years.

Options outstanding that have vested and are expected to vest at December 31, 2019 are as follows:

	Number of Shares Issued	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (In thousands)
Vested	1,017,549	$ 8.57	6.45	$ 13,795
Expected to Vest	1,488,440	21.52	8.89	6,055
Total	2,505,989			$ 19,850

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, 2019 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, 2019, 2018 and 2017 using the Black-Scholes Model was $17.74, $9.05 and $1.60, respectively.

The total fair value of options that vested during 2019 was $4.0 million. As of December 31, 2019, there were approximately $17.7 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 3.05 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 2019 that ended on June 30, 2019, 20,528 shares were purchased for aggregate proceeds of $0.4 million from the issuance of shares, which occurred on July 1, 2019. The Company issued 51,712 shares and 76,710 shares of common stock during the years ended December 31, 2019 and December 31, 2018, respectively, pursuant to the ESPP. The Company received proceeds of $0.8 million and $0.3 million from the purchases of shares during the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the Company had 488,932 shares available for issuance under the ESPP.

Board of Directors Stock Awards Granted for Services

For the years ended December 31, 2019, 2018 and 2017, 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, 2019, there were a total of 253,967 shares issued to the Company's directors, for a total fair value of $1.3 million. Stock-based compensation expense associated with the awards was $0.2 million, $0.3 million and $0.2 million for the years ended December 31, 2019, 2018 and 2017, respectively, which was included in general and administrative expense in the consolidated statements of operations.

Valuation Assumptions

The estimated fair value of employee stock options and ESPP shares was estimated using the Black-Scholes Model based on the following weighted average assumptions.

	Year Ended December 31,		
	2019	2018	2017
Employee Stock Options			
Expected term (in years)	5.97	5.9	5.9
Expected volatility	70.78 %	69.69 %	57.34 %
Risk-free interest rate	2.32 %	2.77 %	2.01 %
Expected dividend yield	— %	— %	— %
Employee Stock Purchase Plan			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	70.80-76.66 %	59.94 – 105.32%	62.27 – 98.58%
Risk-free interest rate	2.10-2.51%	1.61 – 2.14%	0.65 – 1.13%
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 and those comparable public companies that were deemed to be representative of future stock price trends.

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, 2019, 2018 and 2017, included in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cost of revenue	$ 2,183	$ 821	$ 188
Research and development	4,422	1,631	405
Sales and marketing	4,008	986	157
General and administrative	11,804	3,700	994
	$ 22,417	$ 7,138	$ 1,744

No tax benefit was recognized related to share-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 share-based compensation costs were capitalized for the periods presented.

14. INCOME TAXES

Loss before income taxes for the years ended December 31, 2019, 2018 and 2017 is summarized as follows (in thousands):

	As of December 31,		
	2019	2018	2017
United States	$ (19,386)	$ (41,109)	$ (50,132)
Foreign	(4,561)	(7,106)	(7,137)
	$ (23,947)	$ (48,215)	$ (57,269)

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

	As of December 31,		
	2019	2018	2017
Current			
Federal	$ (571)	$ 24	$ 74
State	1	—	(4)
Foreign	83	139	68
Total current income tax expense (income tax benefit)	(487)	163	138
Deferred			
Federal	(558)	13	42
State	(47)	4	1
Foreign	(887)	(1,614)	(1,890)
Total deferred income tax expense (income tax benefit)	(1,492)	(1,597)	(1,847)
Income tax benefit	$ (1,979)	$ (1,434)	$ (1,709)

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 2019 and 2018 and 34% in the year ended 2017, to loss before income taxes as a result of the following:

	Year Ended December 31,		
	2019	2018	2017
Federal tax rate	21.0 %	21.0%	34.0%
Stock-based compensation	9.9 %	1.3%	(0.2)%
Change in valuation allowance	(16.6)%	(9.4)%	38.0 %
Foreign rate differential	0.3 %	2.4%	(1.1)%
Warrant revaluation	0.3 %	(10.0)%	(17.5)%
Interest expense	(0.2)%	(1.7)%	(1.8)%
Goodwill impairment	— %	—%	(1.2)%
Impact of 2017 Tax Cuts and Jobs Act on change in deferred tax assets	— %	—%	(46.5)%
Non-deductible executive compensation	(7.6)%	(0.7)%	— %
Other	1.2%	0.1 %	(0.7)%
Effective income tax rate	8.3 %	3.0 %	3.0 %

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

	As of December 31, 2019	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 56,735	$ 52,135
Tax credit carryforwards	7,239	6,235
Accruals	2,649	3,068
Property and equipment	1,078	1,571
Lease liability	1,015	—
Other	2,224	812
Gross deferred tax assets	70,940	63,821
Valuation allowance	(64,412)	(60,327)
Total deferred tax assets	6,528	3,494
Deferred tax liabilities:		
Purchased intangibles	(7,589)	(6,429)
Operating leases right-of-use assets	(878)	—
Other	(34)	(33)
Total deferred tax liabilities	(8,501)	(6,462)
Net deferred tax liabilities	$(1,973)	$(2,968)

The Company assesses the realizability of its net deferred tax assets by evaluating all available evidence, both positive and negative, including (1) cumulative results of operations in recent years, (2) sources of recent losses, (3) estimates of future taxable income and (4)the length of net operating loss carryforward periods. The Company believes that based on the history of its U.S. losses and other factors, the weight of available evidence indicates that it is more likely than not that it will not be able to realize its U.S. net deferred tax assets. The Company has also placed a valuation allowance on the net deferred tax assets of its 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 $4.1 million and decreased by $5.4 million during the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the Company had domestic federal net operating loss carryforwards of $220.3 million, domestic state net operating loss carryforwards of $89.7 million, and foreign net operating loss carryforwards of $10.5 million that can reduce

future taxable income. The domestic federal and state net operating loss carryforwards will begin to expire in 2020 and 2029, respectively. The foreign net operating loss carryforwards can be carried forward indefinitely.

As of December 31, 2019, the Company had credit carryforwards of approximately $5.7 million and $6.6 million available to reduce future taxable income, if any, for domestic federal and California state income tax purposes, respectively. The domestic federal credit carryforwards begin to expire in 2021. California credits have no expiration date.

Utilization of the Company's net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. Based on a preliminary review of the Company's equity transactions since inception, the Company believes a portion of its net operating loss carryforwards and credit carryforwards may be limited due to equity financings which occurred in 2000, 2004, 2007, 2014 and through the current period.

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

	Year Ended December 31,		
	2019	2018	2017
Balance at the beginning of the year	$ 3,449	$ 3,164	$ 5,252
Additions based on tax positions related to the current year	667	285	186
Additions (decreases) based on tax positions related to prior years	(466)	—	(2,274)
Balance at the end of the year	$ 3,650	$ 3,449	$ 3,164

Approximately $0.1 million of the $3.7 million of net unrecognized tax benefit as of December 31, 2019, if recognized, would impact the Company's effective tax rate. During the year ended December 31, 2019, 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, 2019 and December 31, 2018, the Company had $0.2 million and $0.3 million, respectively, 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 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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, the Tax Act, was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2018. The Company calculated the impact of the Tax Act in its year end income tax provision in accordance with its understanding of the Tax Act and guidance available as of the date of this filing which did not result in any additional income tax expense in the fourth quarter of 2017. The enactment of the Tax Act also requires companies to recognize the effects of changes in tax laws and rates on deferred tax assets and liabilities and the retroactive effects of changes in tax laws in the period in which the new legislation is enacted. Consequently, the Company accounted for a provisional estimated reduction of the U.S. deferred tax assets from $72.5 million to approximately $45.9 million with a corresponding decrease of $27.0 million to the Company’s valuation allowance. The Company completed its analysis of the impacts of the 2017 Tax Act in the fourth quarter of 2018 with no net change to its provisional estimates due to the valuation allowance.

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 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 CEO 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. Both the OttrCare and XynManagement acquisitions have been integrated into the Company’s 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,		
	2019	2018	2017
Testing services revenue			
United States	$ 104,056	$ 59,683	$ 32,598
Rest of World	494	617	508
	$ 104,550	$ 60,300	$ 33,106
Product revenue			
United States	$ 8,078	$ 5,881	$ 4,189
Europe	7,690	7,506	7,980
Rest of World	2,511	2,287	2,465
	$ 18,279	$ 15,674	$ 14,634
Digital and other revenue			
United States	$ 4,062	$ 499	$ 498
Europe	100	96	86
Rest of World	77	—	—
	$ 4,239	$ 595	$ 584
Total United States	$ 116,196	$ 66,063	$ 37,285
Total Europe	$ 7,790	$ 7,602	$ 8,066
Total Rest of World	$ 3,082	$ 2,904	$ 2,973
Total	$ 127,068	$ 76,569	$ 48,324

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

	December 31, 2019	December 31, 2018
Long-lived assets:		
United States	$ 3,346	$ 3,235
Europe	509	625
Rest of World	575	274
Total	$ 4,430	$ 4,134

16. SUBSEQUENT EVENTS

On January 2, 2020, the Company executed the second amendment to the operating lease agreement for the building located at Brisbane, California. The building is mainly utilized for laboratory operations and research and development. The lease will be extended for a period of eight years and two months starting on January 1, 2021. The Company has determined that the amendment constitutes a lease modification effective January 1, 2020. The Company estimates that the lease liability and the ROU asset will increase by approximately $14.1 million and $13.2 million, respectively, on the effective modification date.

17. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table presents selected unaudited consolidated financial data for each of the eight quarters in the two-year period ended December 31, 2019. The Company believes this information reflects all recurring adjustments necessary to fairly present this information when read in conjunction with the Company's consolidated financial statements and the related notes. Net loss per share attributable to CareDx, Inc., basic and diluted, for the four quarters of each fiscal year may not sum to the total for the fiscal year because of the different number of shares outstanding during each period. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future period.

Quarter Ended:	March 31	June 30	September 30	December 31
	(In thousands, except share and per share data)			
2019				
Consolidated Statements of Operations Data:				
Total revenue	$ 25,982	$ 31,454	$ 33,811	$ 35,821
Net loss attributable to CareDx, Inc. used to compute basic net loss per share	$ (7,531)	$ (7,847)	$ (1,813)	$ (4,777)
Net loss per common share attributable to CareDx, Inc., basic	$ (0.18)	$ (0.19)	$ (0.04)	$ (0.11)
Net loss per common share attributable to CareDx, Inc., diluted	$ (0.18)	$ (0.19)	$ (0.04)	$ (0.11)
Shares used in calculation of net loss per share attributable to CareDx, Inc., basic	41,611,399	42,132,396	42,393,550	42,457,171
Shares used in calculation of net income loss per share attributable to CareDx, Inc., diluted	41,611,399	42,132,396	42,393,550	42,457,171
2018				
Consolidated Statements of Operations Data:				
Total revenue	$ 14,053	$ 17,823	$ 21,184	$ 23,509
Net loss attributable to CareDx, Inc. used to compute basic net loss per share	$ (8,969)	$ (14,062)	$ (19,970)	$ (3,755)
Net loss per common share attributable to CareDx, Inc., basic	$ (0.30)	$ (0.40)	$ (0.54)	$ (0.09)
Net loss per common share attributable to CareDx, Inc., diluted	$ (0.30)	$ (0.40)	$ (0.54)	$ (0.09)
Shares used in calculation of net loss per share attributable to CareDx, Inc., basic	29,615,441	35,549,837	37,154,293	40,104,341
Shares used in calculation of net income loss per share attributable to CareDx, Inc., diluted	29,615,441	35,549,837	37,154,293	40,104,341

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 its disclosure controls and procedures, as such terms are defined in Rules 13a-15(b) and 15d-15(e) promulgated under the Exchange Act, as of December 31, 2019. 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, the Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level and are 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 to our management and board of directors regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States.

During 2019, we completed the acquisitions of OttrCare and XynManagement. For further discussion of these acquisitions, refer to Note 5 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The Securities and Exchange Commission permits companies to exclude acquisitions from their assessment of internal control over financial reporting during the first year of an acquisition, and our management has elected to exclude OttrCare and XynManagement from our assessment as of December 31, 2019, except for goodwill and intangible assets. OttrCare and XynManagement constitute 6% and 3% of our consolidated total assets (excluding goodwill and intangible assets) and revenues as of and for the year ended December 31, 2019, respectively.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2019. 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 the Company maintained effective internal control over financial reporting as of December 31, 2019.

Attestation Report of the Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

Changes in Internal Control over Financial Reporting

None.

ITEM 9B. OTHER INFORMATION

None.

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, 2019 in connection with the Annual Meeting of Stockholders to be held in 2020, or the 2020 Proxy Statement. To the extent that we do not file the 2020 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.

We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees (including our principal executive officer, principal financial officer, principal accounting officer or controller and other employees who perform financial or accounting functions), agents and representatives, including our independent directors and consultants, who are not employees of ours, with regard to their CareDx-related activities. Our Company's Code of Business Conduct and Ethics is available on its website at www.caredx.com under the heading "Compliance" under the section titled "Company". We will post on this section of our website any amendment to our Code of Business Conduct and Ethics, as well as any waivers of our Code of Business Conduct and Ethics that are required to be disclosed by the rules of the SEC or The Nasdaq Stock Market LLC.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2020 Proxy Statement. The 2020 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file our 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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 2020 Proxy Statement. The 2020 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019. To the extent that we do not file the 2020 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	Amended and Restated Bylaws of the Registrant.	10-Q	001-36536	3.4	8/28/2014
4.1	Form of Registrant's common stock certificate.	10-K	001-36536	4.1	3/31/2015
4.2#	2014 Equity Incentive Plan and forms of agreements, as amended.	8-K	001-36536	10.1	6/26/2018
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

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
4.5#	2016 Inducement Equity Incentive Plan.	S-8	333-211538	4.1	5/23/2016
4.6	Form of Warrant.	8-K	001-36536	10.3	4/14/2016
4.7	Form of Common Stock Purchase Warrant issued to the Purchasers on March 15, 2017.	8-K	001-36536	4.2	3/15/2017
4.8#	2019 Inducement Equity Incentive Plan.	8-K	001-36536	10.1	9/4/2019
4.9*	Description of Securities of CareDx, Inc.				
10.1#	Chief Executive Employment Agreement, dated September 19, 2012, by and between the Registrant and Peter Maag.	S-1	333-196494	10.6	6/3/2014
10.2#	Offer Letter, dated October 18, 2011, by and between the Registrant and Michael D. Goldberg.	10-K	001-36536	10.15	3/31/2015
10.3#	Offer Letter, dated April 8, 2014, by and between the Registrant and George Bickerstaff, III.	10-K	001-36536	10.14	3/31/2015
10.4#	Offer Letter, between the Registrant and Michael Bell, dated as of April 21, 2017.	10-K	001-36536	10.43	4/21/2017
10.5#	Offer Letter, between the Registrant and Sasha King, dated October 20, 2017.	10-K	001-36536	10.6	3/22/2018
10.6#	Offer Letter, dated November 13, 2018, between the Registrant and Reginald Seeto, MBBS.	8-K	001-36536	10.1	11/26/2018
10.7#	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
10.8#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-196494	10.1	6/3/2014
10.9#	Executive Incentive Compensation Plan.	10-K	001-36536	10.19	3/31/2015
10.10*#	Outside Director Compensation Policy.				
10.11	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
10.14†	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.	S-1/A	333-196494	10.17	7/15/2014
10.16†	Business Sale Agreement, between CareDx Pty Ltd and Conexio Genomics Pty Ltd., dated as of January 12, 2017.	10-Q	011-36536	—	6/9/2017
10.17	Sales Agreement, dated August 31, 2018 by and between the Registrant and Jeffries LLC.	S-3	333-227168	1.2	8/31/2018
10.18†	License and Commercialization Agreement, dated May 4, 2018, between the Registrant and Illumina, Inc.	10-Q/A	001-36536	10.3	10/9/2018
21.1*	Subsidiaries of the Registrant.				
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.				
23.2*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (see page 115 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*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase				
101.LAB*	XBRL Taxonomy Extension Label Linkbase				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase				

† Confidential treatment has been granted with respect to certain portions of this Exhibit. Omitted portions have been filed separately with 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/ PETER MAAG
Peter Maag
Chairman and Chief Executive Officer

Date: February 27, 2020

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Maag and Michael Bell, 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/ PETER MAAG Peter Maag	Chairman and Chief Executive Officer *(Principal Executive Officer)*	February 27, 2020
/s/ MICHAEL BELL Michael Bell	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 27, 2020
/s/ GEORGE W. BICKERSTAFF, III George W. Bickerstaff, III	Director	February 27, 2020
/s/ FRED E. COHEN Fred E. Cohen	Director	February 27, 2020
/s/ GRACE COLÓN Grace Colón	Director	February 27, 2020
/s/ CHRISTINE M. COURNOYER Christine M. Cournoyer	Director	February 27, 2020
/s/ MICHAEL D. GOLDBERG Michael D. Goldberg	Director	February 27, 2020
/s/ RALPH SNYDERMAN Ralph Snyderman	Director	February 27, 2020
/s/ WILLIAM HAGSTROM William Hagstrom	Director	February 27, 2020

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CORPORATE INFORMATION

Board of Directors

Peter Maag, PhD
Chairman of the Board
CareDx, Inc.
Chief Executive Officer
CareDx, Inc.

Michael D. Goldberg, MBA
Audit Committee
Compensation Committee,
Nominating/Corporate Governance

Fred E. Cohen, MD, DPhil
Senior Managing Director
Vida Ventures Compensation
Committee*,
Science and Technology Committee

Grace Colón, PhD
President & CEO Incarda Therapeutics, Inc.
Compensation Committee,
Science and Technology Committee*

Chris M. Cournoyer
Chairperson and Chief Executive Officer for N-of-One
Audit Committee,
Science and Technology Committee

Ralph Snyderman, MD
Chancellor Emeritus & James B. Duke Professor of Medicine
Duke University
Nominating/Corporate Governance Committee*,
Science and Technology Committee

George W. Bickerstaff, III
Managing Director
MM Dillon & Co.
Audit Committee*

William Hagstrom CEO,
Octave BioscienceAudit
Committee,
Compensation Committee

*Indicates Chairperson of the Committee

Executive Team

Peter Maag, PhD
Chief Executive Officer

Reginald Seeto, MD, BS
President and Chief Business Officer

Michael Bell
Chief Financial Officer

Sasha King
Chief Marketing Officer

Annual Stockholders Meeting

June 17, 2020 at 10AM PST
1 Tower Place, 9 th Floor,
South San Francisco, CA 94080

Exchange

Nasdaq Global Market
Ticker Symbol CDNA

Transfer Agent

Computershare Trust Company, N.A.
PO Box 30170
College Station, TX 77842

Legal Counsel

Paul Hastings LLP
1117 S. California Avenue
Palo Alto, CA 94034

Independent Registered Public Accounting Firm

Deloitte
225 West Santa Clara Street, Suite 600
San Jose, CA 95113

Investor Relations

Gilmartin Group
1628 Tiburon Blvd
Belvedere Tiburon, CA 94920

Note on Forward-Looking Statements

This annual report contains forward-looking statements within the meaning of the federal securities laws. Results could differ materially. Further information on factors that could affect results is included in the 2019 Form 10-K included in this annual report.

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2019 Annual Report

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