CareDx, Inc.
Form 10-K
March 06, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

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)

3260 Bayshore Boulevard

Brisbane, California 94005

(Address of Principal Executive Offices, Including Zip Code)

(415) 287-2300

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 30, 2018 as reported by the Nasdaq Global Market on such date was approximately $321,787,874. 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 March 4, 2019 was 41,728,442.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2019 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, 2018.

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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 simi 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 from sales of AlloMap®, AlloSure® and future testing services, if any, and our ability to increase the commercial success of these testing services;
- our ability to obtain, maintain and expand reimbursement coverage from payers for AlloMap, AlloSure and other future testing services, if any;
- our ability to generate revenue from sales of Olerup SSP®, Olerup SBT™, QTYPE®, TruSight® HLA, and future products, if any, and our ability to increase the commercial success of these products;
- our ability to generate revenue from the license and commercialization agreement (the “License Agreement”) with Illumina, Inc. (“Illumina”);
- our plans and ability to develop and commercialize new solutions for the surveillance of heart, kidney, and other solid organ transplant recipients;
- our plans and ability to continue updating our products, services and technology to maintain our leading position in transplantations;
- the outcome or success of our clinical trial collaborations and registry studies;
- the favorable review of our testing services and product offerings, and our future solutions, if any, in peer-reviewed publications;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- anticipated trends and challenges in our business and the markets in which we operate;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- disruptions to our business, including disruptions at our laboratories and manufacturing facilities;
- our ability to retain key members of our management team;
- our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;
- our ability to expand internationally;
- our compliance with federal, state and foreign regulatory requirements;
- our ability to protect and enforce our intellectual property rights, our strategies regarding filing additional patent applications to strengthen our intellectual property rights, and our ability to defend against intellectual property claims that may be brought against us;
- our ability to successfully 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 global transplant diagnostics company with product offerings along the pre- and post-transplant continuum. We focus on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. In diagnostic testing services, we offers AlloMap, which is a gene expression solution for heart transplant patients and AlloSure, which is a donor-derived cell-free DNA (“dd-cfDNA”) solution initially commercialized for kidney transplant patients. We also offer high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs.

Testing Services

AlloMap

Our first commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, 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 solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap, secure positive reimbursement decisions for AlloMap 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, 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 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 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 has been a covered service for Medicare beneficiaries since January 1, 2006. The 2018 reimbursement rate for AlloMap was $3,240, which represents a 14% increase over the 2017 reimbursement rate. AlloMap has also received positive coverage decisions from many of the largest U.S. private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation (HCSC), Humana, Kaiser Foundation Health Plan, Inc., TRICARE, and UnitedHealthcare.

We have also successfully completed a number of landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap on the basis of our Cardiac Transplanted Organ 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 surveillance were equivalent to outcomes in recipients managed with biopsies. The results of our clinical trials have also been presented at major medical society congresses and published in peer-reviewed publications in leading medical journals.

Since the launch of AlloMap in January 2005, we have performed more than 123,000 commercial AlloMap tests, including 16,116 tests during 2018, from our Brisbane, California, laboratory. We estimate that there are approximately 138 centers performing heart transplants in the United States. In 2018, 133 of these centers used AlloMap.

AlloSure

AlloSure, 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. We believe AlloSure may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted organ. We also believe the use of AlloSure, 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 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 became available for commercial testing with Medicare coverage and reimbursement. The Medicare reimbursement rate for AlloSure is $2,841. AlloSure has also received payment from private payers on a case-by-case basis, while our Payer Relations team works to establish positive coverage. However, no positive coverage decisions have been made to the date of this filing.

Prior to the commercialization of AlloSure, we generated a strong body of clinical evidence. In late 2015, we announced the completion of analytical validation of AlloSure. Samples used in the analytical validation included donor recipient pairs with unrelated donors, as well as closely related family members. A report describing the analytical validation of AlloSure including clinical validation 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 were 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 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 plan to analyze and report on additional findings from this dataset in 2019 and into the future.

In January 2018, we initiated the Kidney Allograft Outcomes AlloSure Registry study, or K-OAR, to develop further data on the clinical utility of AlloSure for surveillance of kidney transplant recipients. As of December 31, 2018, 47 centers had been initiated as K-OAR sites and 748 patients had been enrolled.

Throughout 2018, there were 11,634 AlloSure patient test results provided from our Brisbane, California, laboratory. In the fourth quarter of 2018, AlloSure was ordered by 100 kidney transplant centers in the United States.

HeartCare

In September, 2018, we 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 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 – a measure of immune activation, and (ii) AlloSure-Heart – a measure of graft injury. HeartCare provides complementary information about distinct biological processes, such as immune quiescence, active injury, Acute Cellular Rejection ("ACR") and Antibody Mediated Rejection ("AMR") in heart transplant recipients.

Products

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 organs. Olerup SSP is used to type Human Leukocyte Antigen, or HLA alleles based on sequence-specific primer, or SSP, technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles. 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, or PCR, methodology. QTYPE received CE mark certification on April 10, 2018.

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 next generation sequencing 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. 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.

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 most recently changed our name to CareDx, Inc. Our principal executive offices are located at 3260 Bayshore Boulevard, Brisbane, 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. The intellectual property rights of IMX included an exclusive license from 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 98.3% of the outstanding common stock of 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 March 15, 2018, we purchased the remaining 1.7% of outstanding common stock of Allenex.

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 next generation sequencing, or 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. 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.

As of December 31, 2018, 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. We changed our internal organization structure in the third quarter of 2018 and no longer operate in two reportable segments: Post-Transplant and Pre-Transplant. Sales and other financial information by geographic area is provided in Note 16 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 is $1.38 million and for a kidney transplant is $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 patients 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 Services and Products

Testing Services

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

Our first commercialized testing solution, AlloMap, 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. AlloMap is designed to help health care providers and their patients to better manage long-term care, avoid the use of invasive surveillance biopsies and determine the appropriate dosage levels of immumosuppressant medications. AlloMap uses a sample of the patient's blood. AlloMap may be used instead of a surveillance heart biopsy to rule out acute cellular rejection in heart transplant recipients. AlloMap offers rapid, high quality results, and we aim to return AlloMap results to the clinician within three business days after the blood draw.

The test measures the molecular signatures that correlate with biological activity associated with moderate to severe acute cellular rejection. Gene expression may indicate acute cellular rejection well before the evidence of damage is visible from a tissue biopsy sample. AlloMap applies a proprietary mathematical algorithm comprised of the expression of 20 genes, as measured by specific RNA levels. Of the 20 genes, 11 are informative and 9 are for quality control. The algorithm then yields a single AlloMap score. AlloMap may be used for heart transplant recipients 15 years of age or older, starting on day 55 post-transplant.

AlloMap provides a single integer score ranging from 0 to 40 and determines the probability of the absence of moderate to severe acute cellular rejection. A key benefit of the AlloMap score is its negative predictive value, or NPV. The NPV of AlloMap is the likelihood that a heart transplant recipient does not have acute rejection. The NPV for recipients with an AlloMap score below the threshold value can be greater than 99% depending on the actual score.

The clinical utility of AlloMap is well established. AlloMap is the first and only non-invasive method recommended in the International Society for Heart & Lung Transplantation, or ISHLT, patient care guidelines for surveillance of heart transplant recipients for rejection in non-infants. AlloMap has obtained 510(k) clearance from the FDA as an In Vitro Diagnostic Multivariate Index Assay, or IVDMIA. In addition, the clinical utility of AlloMap is supported by numerous clinical trials that we have sponsored, the results of which have been published in leading peer-reviewed medical journals.

When incorporating AlloMap into their practice, clinicians may consider recipient history, a physical exam, graft function and the results of AlloMap at each post-transplant clinic visit. If the recipient's AlloMap score is below an applicable threshold, in the absence of other clinical indicators of rejection, clinicians may elect not to conduct a surveillance biopsy at that time. Where there are signs or indications of rejection, evidence of failure or impaired function or an AlloMap score greater than the applicable threshold, a biopsy may be ordered.

AlloMap Score Variability, or AMV, is a service we offer that we believe provides useful, 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 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 test results within a 24-month period. A low AMV may indicate a lower risk of future events, which suggests that a patient may be a potential candidate for reduced immunosuppression. A high AMV may indicate a higher risk of future events, which suggests a patient may merit more vigilant surveillance. The concept of AMV was developed over the course of several years, beginning as an observation in clinical studies of low score variability among stable patients which suggested that AMV might be a predictor of future clinical events and rejection episodes. The Cardiac Allograft Rejection Gene Expression Observational II, or CARGO II, study included data which demonstrated that AMV may be useful in estimating the probability of future adverse events, such as death, re-transplantation or graft failure in heart transplant recipients who were undergoing surveillance with AlloMap testing more than 315 days following transplantation.

AlloSure, 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. We believe AlloSure may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted organ. We also believe the use of AlloSure, 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 can improve

patient care by helping healthcare providers to reduce the use of invasive biopsies and determine the appropriate dosage levels of immunosuppressants.

HeartCare combines the gene expression profiling technology of AlloMap 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 – 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 ("ACR") and Antibody Mediated Rejection ("AMR") in heart transplant recipients.

Clinical Trials of AlloMap and AlloSure

The clinical validation and utility of AlloMap 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 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 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 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 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 are associated with active rejection of the kidney allograft. The DART study evidence suggests that AlloSure, 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 could help identify patients with new or ongoing organ injury. In the DART study, to investigate the use of AlloSure 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 provides clear stratification of patients for probability of rejection;
- Active rejection patients showed median AlloSure levels at 1.6%;
- Antibody- mediated rejection, or ABMR, patients showed median AlloSure levels at 2.9%;
- Non-rejection patients showed median AlloSure levels of 0.21%; and
- AlloSure 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 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 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 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 plans to enroll greater than 1,000 renal transplant patients who will receive AlloSure long-term surveillance. The clinical outcomes of these patients will be entered into a registry database. The study cohort will include 300 patients at centers that will obtain planned renal surveillance biopsies at 12 months post-transplantation. The other greater than 700 patients will be from centers that do not perform protocol surveillance biopsies. Outcomes in this greater than 700 patient sub-cohort, which represents the majority of the intended use population in the U.S., will be compared to the outcomes of the 300 AlloSure tests from the 12 month surveillance biopsy centers.

A matched control cohort of 300 patients will be retrospectively selected from the subset of centers providing the test cohort patients who have planned surveillance biopsies at 12 months post-transplantation. 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 number of renal allograft biopsies performed during the first year. Outcomes will include patient survival, graft survival, serum creatinine and estimated glomerular filtration rate, evaluated at years 1, 2 and 3 post-transplantation.

Products

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 organs.

Olerup SSP is used to type HLA alleles, based on SSP technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles. 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. TruSight HLA is high resolution solution that uses NGS methodology.

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.

QTYPE was commercially launched at the end of September 2016. 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. QTYPE received CE mark certification on April 10, 2018. QTYPE is validated on a broad range of instruments including the Roche LightCycler® 480 II, QuantStudio 6, 7 and ViiA-7.

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.

Our suite of AlloSeq products are development-stage NGS-based kitted solutions that we acquired as a result of our May 2018 License Agreement with Illumina. These products include: AlloSeq HLA, 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 BMT, a NGS solution for chimerism testing for stem cell transplant recipients. Our AlloSeq products are designed to run on Illumina's NGS instrumentation. We intend to launch our AlloSeq products in 2019.

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. Our ongoing efforts include:

- defining the clinical utility and protocol of AlloSure for kidney transplant patients;
- increased understanding of biological processes of transplant rejection through analysis of genes/metagenes of archived clinical trials, OAR registry and commercial laboratory testing to further improve clinical utility of AlloMap;
- validation and clinical utility studies of AlloSure for other organs such as heart, lung and liver;
- 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;
- developing donor-derived cell-free DNA reagents and software for distribution outside the United States;
- developing solutions for monitoring the success of hematopoietic stem cell transplantation;
- 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;
- 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; and
- integrating real world data to confirm and extend results from other clinical data sets.

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. This is the first report to establish clinical performance characteristics for this emerging 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 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. The Centers for Medicare & Medicaid Services ("CMS"), Medicare Administrative Contractor (MAC), Palmetto GBA (Palmetto"), in October 2017, recommended Medicare coverage for AlloSure which is contingent on this further data development. The K-OAR study commenced in January 2018. K-OAR is a 1, 2 and 3 year post-transplant clinical outcomes study in patients managed with AlloSure surveillance compared to another 300 patients who will serve as a comparative control group managed without AlloSure.

dd-cfDNA for Heart Transplants

We believe that the AlloSure dd-cfDNA-based solution could provide additional value to AlloMap testing for clinicians caring for heart transplant patients, particularly in situations where a recipient's AlloMap 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 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 are offer HeartCare. HeartCare combines the gene expression profiling technology of AlloMap 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 – 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 we have completed initial proof of concept studies. We now offer AlloSure as a laboratory developed test for a limited number of heart transplant centers and physicians as part of our Utility of Donor-Derived Cell-Free DNA in Association with Gene-Expression profiling (AlloMap) in Heart Transplant Recipients, or D-OAR, study.

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 Olerup SSP and QTYPE kits. We have been updating, and intend to continue to update, our HLA typing kits with newly identified alleles. Olerup SSP and QTYPE 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.

Third, our NGS testing platform will be a technology departure from commonly used approaches for HLA typing. This will enable 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 three 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.

Reimbursement

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

Reimbursement for AlloMap comes primarily from Medicare, private third party payers such as insurance companies and managed care organizations, Medicaid and hospitals. A number of payers have adopted coverage policies approving AlloMap for reimbursement. Such policies often approve reimbursement for tests performed from six months or one year post-transplant through five years post-transplant. For 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.

Following the assignment of a Category 1 Current Procedural Terminology, or CPT code, for AlloMap 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 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 testing of Medicare beneficiaries, which represents a 14% increase over the 2017 reimbursement rate. Effective October 9, 2017, AlloSure is reimbursed for kidney transplant patients covered by Medicare. The Medicare reimbursement rate for AlloSure is $2,841.

Medicare coverage and reimbursement was determined by the Molecular Diagnostic Services, or MolDX, Program developed by Palmetto GBA ("Palmetto"). AlloSure began to be reimbursed at a rate of $2,841 for kidney transplants patients covered by Medicare across the United States on October 9, 2017, the effective date of the Palmetto local coverage determination, or LCD. AlloSure has also received payment from private payers on a case-by-case basis, while our Payer Relations team works to establish positive coverage. However, no positive coverage decisions have been made to the date of this filing.

Medicare

We are reimbursed by Medicare for AlloMap and AlloSure tests performed on patients covered by Medicare. Tests performed on patients covered by Medicare represented 46%, 30% and 34% of all tests in 2018, 2017 and 2016, respectively. Approximately 62%, 27% and 44% of all testing services revenue was derived from Medicare for the years ended December 31, 2018, 2017 and 2016, respectively.

Private Payers and Medicaid Payers

We are reimbursed for a substantial portion of the AlloMap tests we perform on patients covered by private payers. Coverage policies approving AlloMap for reimbursement have been adopted by many of the largest private payers, including Aetna, Anthem, Cigna, Health Care Services (HCSC), Humana, Kaiser Foundation Health Plan, Inc., TRICARE, and UnitedHealthcare. Many other payers have positive coverage policies for AlloMap. With private

payers and Medicaid payers that have not yet adopted positive coverage policies for AlloMap, we obtain reimbursement from those payers on a case-by-case basis for a significant portion of claims.

As of yet, no private payers or Medicaid payers have adopted positive coverage policies for AlloSure. As a result, we obtain reimbursement from those payers on a case-by-case basis.

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.

In 2013, we initiated a commercial agreement with Diaxonhit SA ("Diaxonit"), a leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer. The agreement carries a 10-year term and grants Diaxonhit exclusive rights to promote AlloMap in Europe. Diaxonhit has agreed to commercialize AlloMap in all countries in western and central Europe directly and through sub-partners. Under the terms of our agreement, we provide Diaxonhit with training and a license to perform AlloMap. In Europe, we receive revenue in two ways: first, through our sale of testing materials to Diaxonhit, and second, through royalties on Diaxonhit's net earnings from sales of AlloMap. Diaxonhit pays royalties to us as a percentage of the net earnings from sales, as defined in the agreement, of AlloMap tests, in the mid to high teens. Diaxonhit made an upfront payment to us in cash of approximately €387,500 ($408,000) and Diaxonhit's publicly traded common stock with a value at the time of €387,000 following execution of the agreement. Through Diaxonhit, we have also secured a dedicated laboratory, the Strasbourg University Hospital Central Immunology Laboratory, or HUS, in France.

Testing and Laboratory Operations

Our laboratory operations, where we perform all AlloMap and AlloSure 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 ("CAP"). We believe that our laboratory capacity will be adequate to meet demand for AlloMap and AlloSure for the next few years.

When a clinician orders AlloMap, 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 is tested in triplicate, and the 11 informative genes are combined to produce the AlloMap 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 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 AlloMap and AlloSure 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 QMSx. 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 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 AlloMap and AlloSure, 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. As of December 31, 2018, the sales and marketing team consisted of 20 employees, including sales, marketing, brand managers, and customer service representatives.

Competition

Because of our comprehensive portfolio of HLA typing products and surveillance diagnostic test services, we face many different types of competition.

Testing Services

Our competition principally includes clinical reference labs and hospital labs using existing and routine clinical chemistry tests. 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 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 heart transplant rejection generally involve evaluating biopsy samples to determine the presence or absence of rejection, while existing diagnostic methods for kidney transplant rejection include general, non-specific clinical chemistry tests, though biopsies are also a surveillance diagnostic tool. Both of 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.

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 AlloMap, AlloSure 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.

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 Life Technologies. 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 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 as we launch AlloSeq cfDNA and AlloSeq BMT. 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.

Overall 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.

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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.

Our core patent position for AlloMap 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. Our strategy is to continue to broaden our intellectual property estate for AlloMap through data science discovery and protection of gene expression patterns and their correlation with specific clinical states and outcomes, as well as the algorithms needed for clinical assessment.

As of December 31, 2018, we had 23 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. 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 the area of dd-cfDNA-based transplant diagnostics, we have filed a patent application to cover our research and development work in this field. 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. 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 six issued U.S. patents covering a method of diagnosing or monitoring autoimmune or chronic inflammatory diseases, such as lupus, by detecting specific genes. While we have clinical samples and patents covering lupus diagnostics, we do not intend to actively pursue the lupus test opportunity.

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

AlloMap, AlloSure, AlloSeq, Olerup SSP, Olerup XM-ONE, QTYPE 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 AlloMap and 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 November 2004, we entered into a license agreement with Roche Molecular Systems, Inc., or Roche, as amended from time to time, the Roche License. The Roche License grants us the right to use PCR and q-PCR for use in clinical laboratory services. The Roche License is a non-exclusive license agreement in the United States covering the claims in multiple Roche patents. Under the terms of the Roche License, we were required to report and pay royalties, after adjustment due to a discount for combination services, in the mid-single digits on test revenues from products using

the licensed intellectual property on a quarterly basis until September 30, 2017, pursuant to a Settlement Agreement and Mutual Release, dated September 11, 2014. Effective September 30, 2017, no royalties are incurred by us under the Roche License.

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 an annual license maintenance fee, six milestone payments and royalties in the low single digits on net sales of products incorporating the licensed technology. The license maintenance fee may be offset against earned royalty payments due on net sales in that year.

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.

Regulation

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 ("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 or AlloSure.

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 (the "VALID Act of 2018"). For AlloSure 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 ("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. 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.

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 of 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.

Employees

At December 31, 2018, we had 231 employees, of which 227 were full-time employees. We had 69 employees in manufacturing operations and support, 51 in research and development; 61 in sales and marketing and 50 in general and administrative positions. As of December 31, 2018, 162 employees were located in the United States and 69 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 Olerup 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, 2018, our net loss was $46.8 million. As of December 31, 2018, we had an accumulated deficit of $311.8 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 diagnostic solutions, including additional expenses in connection with our continuing development and commercialization of AlloMap, AlloSure, AlloSeq 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, 2018, we had cash and cash equivalents of $64.6 million and an accumulated deficit of $311.8 million. We may require additional financing in the future to fund working capital and pay our obligations as they come due. 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, 2018, revenue from Medicare for AlloMap and AlloSure represented 62% 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 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 and the new market based rates took effect January 1, 2018. The Centers for Medicare & Medicaid Services ("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, under PAMA, the reimbursement rate for AlloMap is $3,240 for Medicare beneficiaries, which represents a 14% increase over the 2017 reimbursement rate.

On September 26, 2017, we announced that the Molecular Diagnostic Services, or MolDX, Program developed by Palmetto GBA ("Palmetto") has set AlloSure reimbursement at $2,841. AlloSure 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.

However, if an AlloMap or AlloSure reimbursement rate that is significantly lower than the current rate is set bt CMS or MolDx in the future, it could cause us to discontinue AlloMap or AlloSure 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 ("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 or AlloSure 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 AlloMap and AlloSure 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 AlloMap and AlloSure tests, and products for pre-transplant matching, 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. 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;

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- 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 AlloMap, AlloSure, products and our solutions in development outdated. We must continually innovate and expand our test offerings to address unmet needs in monitoring transplant related conditions and in pre-transplant testing. AlloMap, AlloSure, products and our solutions in development could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloMap, AlloSure, products and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our solutions and tests could decline, which would harm our business and financial results.

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

Clinicians and healthcare administrators are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we continue to educate clinicians, administrators and laboratory directors about our testing services and products and, subject to their development, our other solutions, and demonstrate the clinical and diagnostic benefits of these solutions. We believe that clinicians, transplant centers and laboratories may not use our solutions unless they determine, based on published peer-reviewed journal articles, the experience of other

clinicians or laboratory verification, that our solutions provide accurate, reliable and cost-effective information that is useful in pre-transplant matching and monitoring their post-transplant recipients.

We estimate that there are approximately 138 centers managing heart transplant recipients in the United States. In 2018, AlloMap was used in 133 of these centers. However, not all clinicians in these centers are currently using our

test. In order for AlloMap sales to grow, we must continue to market to and educate clinicians and administrators at treatment centers that have used our test to increase the number of clinicians ordering our test, the number of recipients tested and the number of tests per recipient. In addition, we must actively solicit additional treatment centers to establish policies and procedures for ordering our test and to encourage clinicians at those centers to incorporate our test into their standard clinical practice. Some of the challenges that our sales team must overcome include explaining the clinical benefits of AlloMap, which is a highly technical product, and changing a 30-year patient management paradigm of using biopsy as the basis of transplant recipient monitoring.

We estimate that there are approximately 240 centers managing kidney transplant recipients in the United States. In the fourth quarter of 2018, AlloSure was used in 100 of these centers. In order for AlloSure sales to grow, we must continue on our plan to market and educate clinicians and administrators at the treatment centers that have used our test to spread awareness of its effectiveness in creating better long-term care plans for kidney transplant patients.

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 an accuracy, speed and/or cost advantage 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.

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If the use of AlloMap, AlloSure 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.

The results of our studies involving AlloMap and AlloSure have been presented at major medical society congresses and published in peer-reviewed publications in leading medical journals. We need to maintain a continued presence in peer-reviewed publications 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 AlloMap, AlloSure or our other 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 AlloMap, AlloSure 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 solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our diagnostic current and future 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 solutions would suffer and our business would be harmed. While we have had success in generating peer-reviewed publications regarding AlloMap and AlloSure, additional peer-reviewed publications regarding AlloMap, AlloSure and our future 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 solutions or the technology underlying AlloMap, AlloSure or our future 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 and future tests based on donor-derived cell-free DNA (“dd-cfDNA”), we will need to continue our efforts to complete and publicize research and trials, especially the Kidney Allograft Outcomes AlloSure Registry (“K-OAR”) registry study, that provides evidence of the utility of dd-cfDNA and validate AlloSure as a solution.

Transplant centers may not adopt AlloMap, AlloSure 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 cellular rejection in heart transplant recipients by utilizing biopsies. Many clinicians use AlloMap in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloMap as a biopsy alternative, per se, if treatment center administrators view our test as an alternative to a biopsy and 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

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 AlloMap solution for heart transplant recipients competes against existing diagnostic tests utilized by pathologists, which, in the case of heart transplant rejection, 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.

Competition for kidney surveillance diagnostics can also come from biopsies. 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.

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 ("PCR") such as next generation sequencing ("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.

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 have greater brand recognition and 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 AlloMap and AlloSure 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 AlloMap, AlloSure and our future 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 patients. 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 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 become 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 AlloMap and AlloSure depends, in large part, on our ability to perform AlloMap and AlloSure 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 AlloMap, AlloSure 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 testing services revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline.

From 2017 to 2018, our testing services revenue grew from $33.1 million to $60.3 million, which represents annual growth of 82%. 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 products and services;
- the introduction and acceptance of new or enhanced products or services by us or by competitors;
- our ability to maintain reimbursement for AlloMap and AlloSure 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 AlloMap, AlloSure 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 AlloMap, AlloSure, 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 AlloMap, AlloSure 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 AlloMap, AlloSure 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 AlloMap, AlloSure and our products or enhancements to those tests and products;

- 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. 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 and as we attempt to transition to a company with more than one commercialized test. 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.

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 AlloMap, AlloSure 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.

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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 that prove unsuccessful;
- retention of 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 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 AlloMap, AlloSure and our other 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, 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 agent 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 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 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.

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 in Europe with Diaxonhit SA and are distributing AlloMap tests directly in Canada. We also currently distribute products direct in Germany, Austria, Slovenia, Benelux, and in the Nordic countries, 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 in Europe may be negatively affected by the financial instability of, and austerity measures implemented by, several countries in Europe.

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, preferential bidding or import or export licensing requirements;
- political and economic instability, including 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 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.

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 (“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. 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

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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 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, 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. We 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.

The Tax Cuts and Jobs Act of 2017 also implemented global intangible low tax income ("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 ("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 2018. 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

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 ("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 at least annually and more frequently 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.

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

Under the License and Commercialization Agreement (the "License Agreement") with Illumina, Inc. ("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.

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 AlloMap, AlloSure 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 AlloMap and AlloSure 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. Throughout 2017, we did not recognize revenue for test results delivered without a contract for reimbursement, or an established coverage policy and a history of payment. The revenue recognition criteria for cash basis payers changed effective January 1, 2018 under Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606. Revenue for AlloMap and AlloSure tests is estimated based on historical reimbursements received from payers.

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.

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

Reimbursement for AlloMap and AlloSure comes primarily from Medicare, private third party payers such as insurance companies and managed care organizations, Medicaid and hospitals. The reimbursement process can take six months or more to complete depending on the payer. Coverage policies approving AlloMap have been adopted by many of the largest private payers, including Aetna, Anthem, Cigna, Health Care Services Corporation (HCSC), Humana, Kaiser Foundation Health Plan, Inc., TRICARE, 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 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 AlloMap and AlloSure 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.

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Until 2016, AlloMap was billed using an unlisted Current Procedural Terminology ("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 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 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 AlloMap and AlloSure.

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.

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 AlloMap and AlloSure. 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 AlloMap, AlloSure 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 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 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 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 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 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 or AlloSure, 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 ("LDTs") because it believes that laboratories certified as high complexity under 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 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 for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510(k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed intended uses and indications for the device or test.

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

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

If the FDA or the Congress decide to regulate AlloSure and other future solutions under development as medical devices, it could require additional premarket clinical testing subsequent to commercialization in the case of AlloSure and/or 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.

AlloMap, AlloSure and our other solutions, along with the manufacturing processes, packaging, labeling, distribution, import, export, and advertising and promotional activities for such solutions or devices, 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 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 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 AlloMap, 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 advanced diagnostic laboratory tests, or 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 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. Our strategy is to continue to broaden our intellectual

property estate for AlloMap through the discovery and protection of gene expression patterns and their correlation with specific clinical states and outcomes, as well as the algorithms needed for clinical assessment.

As of December 31, 2018, we had 23 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. 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.

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. We have six issued U.S. patents covering a method of diagnosing or monitoring autoimmune or chronic inflammatory disease, such as lupus, by detecting specific genes. While we have clinical samples and patents covering lupus diagnostics, we do not intend to actively pursue the lupus test opportunity.

In the area of dd-cfDNA-based transplant diagnostics, we have submitted a patent application to cover some of our research and development work in this field. There is no guarantee that the U.S. Patent and Trademark Office, or PTO, will approve this application. We do not know what claims, if any, will be granted in our existing and future applications. Our patents and patents that we exclusively license from others address fields that are rapidly evolving, and, particularly with respect to dd-cfDNA-based transplant diagnostics, it is possible that other patents have and will be granted to others that affect our ability to develop and commercialize our current and future solutions. If the reviewers of our patent applications at the PTO refuse our claims, we may not be able to sufficiently protect our intellectual property. Further, recent and future changes in the patent laws and regulations of the United States and other jurisdictions may require us to modify our patent strategy and could restrict our ability to obtain additional patents for our technology.

In connection with our June 2014 acquisition of IMX, 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.

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.

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, AlloSeq, Olerup SSP, Olerup XM-ONE, Olerup SBT, QTYPE 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 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 technology is critical to AlloSure 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.

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 2018 our stock price ranged from $5.18 to $30.02 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 15.6% of our common stock as of December 31, 2018. 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 frequent 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. We are continuing to implement new finance and accounting systems as we grow our business and organization and to satisfy internal control and reporting requirements.

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 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 of the General Corporation Law of the State of Delaware. 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.

We are an “emerging growth company,” and, because we are complying with certain reduced disclosure requirements applicable to emerging growth companies, our common stock could be less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012, and for as long as we continue to be an “emerging growth company,” we may continue to choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will continue to be an “emerging growth company” until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior September 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters are located in Brisbane, California. We lease facilities in North America, Europe, and Australia. The following is a summary of the locations, functions and approximate square footage of those facilities as of December 31, 2018:

Location	Function	Square Footage
United States		
Brisbane, California	Corporate headquarters, research & development and clinical laboratory	46,000
West Chester, Pennsylvania	Sales office and distribution	6,336
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	3,871

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

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 March 4, 2019, there were approximately 111 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.

Stock Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide a performance graph.

Sales of Unregistered Securities

There were no sales of unregistered securities by us during the fourth quarter of 2018.

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

There were no repurchases of equity securities by us during the fourth quarter of 2018.

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, 2018 and 2017 and the selected statements of operations data for each of the years ended December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements that are included elsewhere 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,				
	2018	2017	2016	2015	2014
	(In thousands, except share and per share data)				
Revenue:					
Testing revenue (1)	$60,300	$33,106	$29,680	$27,881	$25,842
Product revenue	15,674	14,634	10,715	—	—
License and other revenue	595	584	236	263	1,464
Total revenue	76,569	48,324	40,631	28,144	27,306
Operating expenses:					
Cost of testing	21,456	12,345	10,882	10,273	8,541
Cost of product	11,531	9,026	10,240	—	—
Research and development	14,514	12,388	12,385	9,333	3,846
Sales and marketing	21,670	12,808	11,166	8,349	6,472
General and administrative	21,959	18,913	20,725	12,247	8,436
Goodwill impairment	—	1,958	13,021	—	—
Change in estimated fair value of contingent consideration	1,017	1,180	(456)	(126)	(1,239)
Total operating expenses	92,147	68,618	77,963	40,076	26,056
Income (loss) from operations	(15,578)	(20,294)	(37,332)	(11,932)	1,250
Interest expense, net	(3,701)	(5,863)	(1,860)	(1,587)	(2,116)
Debt extinguishment expenses	(5,780)	(459)	—	—	—
Other expense, net	(178)	(1,031)	(1,920)	(188)	(78)
Change in estimated fair value of common stock warrant and derivative liabilities	(22,978)	(29,622)	(250)	—	225
Loss before income taxes	(48,215)	(57,269)	(41,362)	(13,707)	(719)
Income tax benefit	1,434	1,709	1,606	—	1,500
Net income (loss)	(46,781)	(55,560)	(39,756)	(13,707)	781
Net loss attributable to noncontrolling interest	(25)	(91)	(287)	—	—
Net income (loss) attributable to CareDx, Inc.	$(46,756)	$(55,469)	$(39,469)	$(13,707)	$781
Net (loss) income per share:					
Basic	$(1.31)	$(2.38)	$(2.39)	$(1.16)	$0.13
Diluted	$(1.31)	$(2.38)	$(2.39)	$(1.16)	$0.10
Shares used to compute net (loss) income per share:					
Basic	35,638,956	23,332,503	16,496,911	11,860,885	5,815,928
Diluted	35,638,956	23,332,503	16,496,911	11,860,885	9,283,001

(1) On January 1, 2018, we adopted the new revenue accounting standard – ASC 606, using the modified retrospective method. The impact of adopting ASC 606 is disclosed in Note 2 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Balance Sheet Data:

	As of December 31,	
	2018	2017
	(In thousands)	
Cash and cash equivalents	$64,616	$16,895
Working capital	61,610	(16,139)
Total assets	130,697	83,565
Total debt	—	34,059
Accumulated deficit	(311,845)	(268,022)
Total CareDx, Inc. stockholders' (deficit) equity	95,928	(6,134)

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 global transplant diagnostics company with product and service offerings along the pre- and post-transplant continuum. We focus on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients.

Testing Services

AlloMap

Our first commercialized testing solution, the AlloMap heart transplant molecular test, or AlloMap, 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 solution through ongoing studies to substantiate the clinical utility and actionability of AlloMap, secure positive reimbursement decisions for AlloMap 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, 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 can improve patient care by helping healthcare providers avoid the use of unnecessary, invasive surveillance biopsies and determine the appropriate dosage levels of immunosuppressants. In 2008, AlloMap 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 has received positive coverage decisions for reimbursement from Medicare. The 2018 reimbursement rate for AlloMap was $3,240, which represented a 14% increase over the 2017 reimbursement rate. AlloMap 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., TRICARE and UnitedHealthcare.

We have also successfully completed a number of landmark clinical trials in the transplant field demonstrating the clinical utility of AlloMap for surveillance of heart transplant recipients. We initially established the analytical and clinical validity of AlloMap 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 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.

Since the launch of AlloMap in January 2005, we have performed more than 123,000 commercial AlloMap tests, including 16,116 tests during 2018. During the year ended December 31, 2018, AlloMap was used in 133 of the approximately 138 heart transplant centers in the United States.

AlloSure

AlloSure, 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 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, 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 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 became available for commercial testing with Medicare coverage and reimbursement. The Medicare reimbursement rate for AlloSure is $2,841. AlloSure has also received payment from private payers on a case-by-case basis, but no positive coverage decisions have been made to the date of this filing.

Prior to the commercialization of AlloSure, we generated a strong body of clinical evidence. In late 2015, we announced the completion of analytical validation of AlloSure. A report describing the analytical validation of AlloSure 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 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 2019. We plan to analyze and report on additional findings from this dataset in 2019 and into the future.

In 2018, we initiated the Kidney Allograft Outcomes AlloSure Registry, or K-OAR study, to develop further data on the clinical utility of AlloSure for surveillance of kidney transplant recipients. As of December 31, 2018, 47 centers have been initiated as K-OAR study sites.

During the year 2018, there were 11,634 AlloSure patient test results provided. In the fourth quarter of 2018, AlloSure was ordered by 100 kidney transplant centers in the United States.

HeartCare

In September, 2018, we 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 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 – 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 (“ACR”) and Antibody Mediated Rejection (“AMR”) in heart transplant recipients.

Products

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 organs. We also help clinicians manage transplant patients after the transplant has occurred.

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 Human Leukocyte Antigen, or 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 a 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 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.

Fourth Quarter 2018 Highlights

- Continued the acceleration of AlloSure penetration
  - In the fourth quarter of 2018, 100 U.S. transplant centers provided 4,575 AlloSure tests to approximately 3,400 patients
  - Continued progress in AlloSure Registry (K-OAR) enrollment, with 47 centers initiated and 748 patients enrolled as of December 31, 2018
- Achieved total revenue of $23.5 million for the fourth quarter of 2018, increasing 88% year-over-year
  - Testing services revenue of $18.9 million, with 4,575 AlloSure and 4,057 AlloMap patient results provided
  - Product revenue of $4.6 million
- Generated a net loss of $3.8 million, positive adjusted EBITDA of $0.8 million and positive net cash from operations of $2.0 million in the fourth quarter of 2018
- Strengthened balance sheet through public equity offering and repayment of all outstanding debt
  - Cash and cash equivalents of $64.6 million at December 31, 2018

Financial Operations Overview

Revenue

We derive our revenue from testing services, products sales and license and other revenues. On January 1, 2018, we adopted the new revenue accounting standard Revenue from Contracts with Customers (Topic 606), or ASC 606, using the modified retrospective method. Under the new accounting standard, 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. The adoption of ASC 606 resulted in a one-time adjustment of $2.9 million to accounts receivable and accumulated deficit. This adjustment reflected the estimated payments to be received for tests where the result had been delivered at December 31, 2017, but the associated revenue had not been recognized by December 31, 2017, because payments had not been received. As of December 31, 2018, we had received payments of $3.4 million for these tests and recorded a change in estimate of $0.5 million as additional testing services revenue during 2018 year. Adoption of ASC 606 did not have any impact on product and license revenue recognized in prior periods.

Testing Services Revenue

Our testing services revenue is derived from AlloMap and AlloSure tests, which represented 79%, 69% and 73% of our total revenues for the years ended December 31, 2018, 2017 and 2016, 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.

During 2018 we performed 16,116 commercial AlloMap tests that are included in our estimated testing revenue. We also recognized additional $0.5 million in revenue related to tests performed in prior period due to the change in estimated transaction price in accordance with new revenue recognition standard ASC 606.

Since October 2017, when we launched AlloSure, we performed 282 commercial AlloSure tests as of December 31, 2017. During 2018 we performed 11,634 commercial AlloSure tests. All tests were performed from our Brisbane, California laboratory.

Product Revenue

Our product revenue is derived primarily from sales of Olerup SSP, QTYPE, Olerup SBT and TruSight products. Product revenue represented 20%, 30% and 26% of total revenue for the years ended December 31, 2018, 2017 and 2016, 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.

License and Other Revenue

License agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Our performance obligations under the collaboration and license agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration partners. We make judgments that affect the periods over which we recognize revenue. We review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated revenues.

Segment Reporting

We changed our segment reporting from two reportable segments: Post-Transplant and Pre-Transplant to one reportable segment. In the third quarter of 2018, we completed a business reorganization to support our strategy to become a global transplant care leader. The position of the head of the former Pre-Transplant segment was eliminated, and global functional leaders were identified to manage sales and marketing, research and development, manufacturing and quality and other global functions. These changes resulted in changes to the presentation of financial information provided to our chief operating decision maker (the "CODM"), who is our chief executive officer, for resource allocation and management performance assessment. The CODM continues to review revenue and cost of

sales by testing services and products, as reported in the consolidated statements of operations. Earnings before interests, tax, depreciation and amortization, and operating results are reviewed at the consolidated level only. Effective September 30, 2018, we report a single operating segment.

Goodwill Impairment

We test goodwill and indefinite-lived intangibles for impairment at least annually and more frequently if impairment indicators are present. We recorded goodwill impairment charges related to our former Pre-Transplant reporting unit

of $13.0 million and $2.0 million as of December 31, 2016 and March 31, 2017, respectively. Goodwill allocated to our former Pre-Transplant reporting unit was fully impaired at March 31, 2017. The remaining goodwill of $12.0 million relates to our former Post-Transplant reporting unit and it was not impaired. No impairment charges were recorded in 2018.

Change in Estimated Fair Value of Contingent Consideration

We revalued our contingent consideration obligation liability in connection with our acquisition of IMX in 2014 at the end of each reporting period through the settlement date. Changes in the fair value of our contingent consideration obligation were recognized as a component of operating expense within our consolidated statements of operations. We achieved the contingent consideration obligation milestone of 2,500 commercial AlloSure tests and issued 227,848 shares of our common stock in the three month period ended June 30, 2018. We recorded $1.0 million expense related to changes in fair value of contingent consideration from January 1, 2018 to the date of the shares issuance. There is no contingent consideration obligation outstanding as of December 31, 2018.

Debt Extinguishment Expenses

In connection with the repayment and conversion to shares of common stock of all outstanding debt obligations during 2018, we recorded $2.8 million loss on the conversion of the convertible debt financing with JGB (the “JGB Debt”) 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. During the same period we also recorded a $3.0 million loss on debt extinguishment of the credit agreement with Perceptive Credit Holdings II, LP, or Perceptive, or the Perceptive Credit Agreement.

Other Expense, Net

Other expense includes gains and losses on foreign currency transactions and other miscellaneous expenses. During the year ended December 31, 2018, the other expense charge of $0.2 million primarily consisted franchise taxes paid.

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

We recorded $23.0 related to changes in fair value of common stock warrants and derivative liabilities, as these financial instruments are classified in liabilities during the year ended December 31, 2018. Common stock warrants issued in connection with our debt and equity financings are considered freestanding financial instruments and are analyzed as to whether they meet equity or liability classification in accordance with United States generally accepted accounting principles, or US GAAP. Warrants that meet liability classification are remeasured at each period end with changes in fair value recorded in our consolidated statements of operations until these warrants are exercised or expire. On January 1, 2018, we adopted Accounting Standards Update No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception, and this resulted in the liability balance for our warrants issued to JGB being reclassified to equity on the date of adoption.

The JGB Debt included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The embedded derivative was remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liability in the consolidated statements of operations. As of March 27, 2018, the JGB Debt was fully converted to shares of our common stock and the derivative was extinguished.

On April 17, 2018, we entered into the Perceptive Credit Agreement for an initial term loan of $15.0 million, which included an embedded derivative that required bifurcation related to early repayment provision. We recorded changes in the fair value of the derivative liabilities in the change in estimated value of common stock warrant liability and derivative liability in our consolidated statements of operations. All amounts owing under the Perceptive Credit Agreement were fully paid off on November 20, 2018 and the derivative was extinguished.

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 license 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 are performed 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.

During 2018, we recognized $0.5 million additional revenue related to the change in estimate of reimbursement of testing services as we collected more than we estimated for tests performed in prior year.

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.

License and Other Revenue

We generate revenue from license agreements. License agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. Our performance obligations under the agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees. We make judgments to determine if performance obligations are distinct or should be combined and the transaction price allocated to each performance obligation, which affect the periods over which revenue is recognized. We periodically review our estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis. We constrain variable consideration, such as milestones, if it is probable that a significant portion of revenue would be reversed. Our deferred revenue relates to one performance obligation, which should be recognized over time.

We did not recognize any revenue connected with milestones during the twelve months ended December 31, 2018 or 2017.

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 operating expenses.

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

Acquired Intangible Assets

Amortizable intangible assets 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. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

Impairment of Goodwill, Intangible Assets and Long-lived Assets

Goodwill

Goodwill recorded in a business combination is not subject to amortization. Instead, it is tested for impairment on an annual basis and whenever events or changes in circumstances indicate its carrying amount may not be recoverable.

Our annual impairment test date is December 1st. A qualitative assessment is initially made to determine whether it is necessary to perform a quantitative assessment. A qualitative assessment includes, among others, consideration of: (i) past, current and projected future earnings; (ii) recent trends and market conditions; and (iii) valuation metrics involving similar companies that are publicly-traded and acquisitions of similar companies, if available. If this qualitative assessment indicates that it is more likely than not that an impairment exists, or if we decides to bypass this option, it proceeds to 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 the third quarter of 2018, we changed our segments and reporting units. During that period, we determined that we operate in one reportable segment. Prior to September 30, 2018 we had two reporting units – Post and Pre-transplant. We recorded goodwill impairment charges of $13.0 million and $2.0 million for the periods ended December 31, 2016 and December 31, 2017, respectively. The impairment charges resulted in full impairment of goodwill related to our former Pre-transplant reporting unit as of March 31, 2017. No goodwill impairment related to former Post-transplant reporting unit was recorded in prior periods. See Note 6 for additional discussion regarding the impairment charge recorded.

In connection with our annual goodwill assessment on December 1, 2018, 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, 2018, 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. 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 (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 the 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.

Derivative Liability

The JGB Debt included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The combined embedded derivative liability was remeasured on a quarterly basis 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 Monte Carlo simulation model to estimate the fair value of our embedded derivative liability. The Monte Carlo simulation model uses multiple input assumptions to simulate the likelihood that market conditions will be achieved through 100,000 random trials. These assumptions included the expected term of the embedded derivative, the volatility of our stock prices and our peers' stock prices over such expected term, likelihood, timing, and amount of future equity financing rounds, the likelihood of any prepayment or default events, the likelihood of monthly redemptions by the JGB Debt holders and the likelihood and ability of JGB to convert the debt into equity. In each iteration of the simulations, these assumptions were used to simulate our stock price drawing from a risk neutral distribution, the occurrence of a conversion event, the occurrence of a prepayment event, the occurrence of a default event, and any resulting payoff from such event. The average present value over all iterations of the simulation was then calculated. The assumptions used in this simulation model were reviewed on a quarterly basis and adjusted, as needed.

As of March 27, 2018, the JGB Debt was fully converted to shares of our common stock. The change in the fair market value of the derivative liability through March 27, 2018 of $2.5 million was recorded in change in estimated fair value of common stock warrant liability and derivative liability in the consolidated statements of operations.

In April, 2018, we entered into the Perceptive Credit Agreement, which included an embedded derivative related to early repayment provisions that required bifurcation. This embedded derivative of $0.2 million was extinguished in November 2018, when the outstanding debt was fully paid off.

Recently Issued Accounting Standards

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

operations, financial position and cash flows.

Factors Affecting Our Performance

The Number of AlloMap and AlloSure Tests We Receive and Report

The growth of our testing services business is tied to the number of AlloMap and AlloSure patient samples we receive and patient results we report. Historically, less than two percent of AlloMap patient samples received are not

reported due to improper sampling, damage in transit or other causes. 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 and TruSight HLA 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 14 countries. We also use distributors to sell products in approximately 60 countries.

Continued Adoption of and Reimbursement for AlloMap

AlloMap test volume and the corresponding reimbursement revenue has generally increased over time since the launch of AlloMap, as Medicare provided reimbursement and payers adopt coverage policies and fewer payers consider AlloMap 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 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 testing of Medicare beneficiaries, and increase from the 2017 reimbursement rate of $2,840. AlloMap 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., TRICARE and UnitedHealthcare.

Reimbursement for AlloSure

On September 26, 2017 we received notice that the Molecular Diagnostics Services, or MolDX, Program developed by Palmetto had set AlloSure reimbursement at $2,841. Effective October 9, 2017, AlloSure was made available for commercial testing with Medicare coverage and reimbursement. We believe the use of AlloSure, 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 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 organs. Olerup SSP is used to type Human Leukocyte Antigen, or HLA, alleles based on sequence-specific primer, or SSP, technology. Olerup SBT is a complete product range for sequence-based typing of HLA alleles. 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.

In May 2018, we entered into a License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's next generation sequencing ("NGS") product line for use in transplantation diagnostic testing. As a result, from June 1, 2018, we are the exclusive worldwide distributor of Illumina's TruSight HLA v1 and v2 product line. In addition, we were also granted the exclusive right to develop and commercialize other NGS product lines for use in the Field, as defined in the agreement.

Development of Additional Products

We rely on sales of AlloMap, AlloSure, 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 also expend funds to secure clinical samples that can be used in discovery, product development, clinical validation, utility and outcome studies. The timing of these research and development activities is difficult to predict. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses will affect our financial results. 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, 2018 and 2017

(In thousands)

	Year Ended December 31,		
	2018	2017	Change
Revenue:			
Testing revenue	$60,300	$33,106	$27,194
Product revenue	15,674	14,634	1,040
License and other revenue	595	584	11
Total revenue	76,569	48,324	28,245
Operating expenses:			
Cost of testing	21,456	12,345	9,111
Cost of product	11,531	9,026	2,505
Research and development	14,514	12,388	2,126
Sales and marketing	21,670	12,808	8,862
General and administrative	21,959	18,913	3,046
Goodwill impairment charge	—	1,958	(1,958)
Change in estimated fair value of contingent consideration	1,017	1,180	(163)
Total operating expenses	92,147	68,618	23,529
Loss from operations	(15,578)	(20,294)	4,716
Interest expense, net	(3,701)	(5,863)	2,162
Debt extinguishment expenses	(5,780)	(459)	(5,321)
Other expense, net	(178)	(1,031)	853

Change in estimated fair value of common stock warrant and derivative liabilities	(22,978)	(29,622)	6,644
Income tax benefit	1,434	1,709	(275)
Net loss	(46,781)	(55,560)	8,779
Net loss attributable to noncontrolling interest	(25)	(91)	66
Net loss attributable to CareDx, Inc.	$(46,756)	$(55,469)	$8,713

Testing Services Revenue

Testing services revenue increased by $27.2 million, or 82%, for the year ended December 31, 2018, compared to the same period in 2017. This increase is mainly due to the 11,634 AlloSure test results provided in the year ended December 31, 2018, compared to 282 AlloSure tests provided in the year ended December 31, 2017 following the commercial launch of AlloSure in October 2017. Additionally, AlloMap test results increased to 16,116 in the year ended December 31, 2018, compared to 15,312 in the same period in 2017, and the Medicare reimbursement rate for AlloMap increased from $2,841 to $3,240 on January 1, 2018. Furthermore, in the year ended December 31, 2018, we recognized $0.5 million testing services revenue related to payments received in excess of the $2.9 million accounts receivable adjustment recorded on January 1, 2018 upon adoption of the new revenue recognition standard, ASC 606.

Furthermore, the adoption of the new revenue standard had a $1.6 million favorable impact on our Testing Revenue, as compared to the revenue that would have been recognized under the prior guidance for the year ended December 31, 2018.

Product Revenue

Product revenue increased by $1.0 million, or 7%, for the year ended December 31, 2018, compared to the same period in 2017. The increase was due to sales of the TruSight HLA products related to the License Agreement with Illumina, which was signed in May 2018, and increased sales of QTYPE, partially offset by a decrease in sales of Olerup SSP and Olerup SBT products.

License and Other Revenue

License and other revenue increased by less than $0.1 million for the year ended December 31, 2018.

Cost of Testing Services

Cost of testing increased by approximately $9.1 million, or 74%, for the year ended December 31, 2018, compared to the same period in 2017, primarily due to the increase in test results provided for AlloSure, which was launched in October 2017, and AlloMap.

Cost of Product

Cost of product increased by $2.5 million, or 28%, for the year ended December 31, 2018, compared to the same period in 2017. The increase in revenue, a change in the mix of products, and the addition of sales of TruSight HLA products, which were purchased directly from Illumina, led to an increase of $2.1 million. Furthermore, in the year ended December 31, 2018 there was an increase in scrap and obsolescence provision of $0.4 million.

Research and Development

Research and development expenses increased by $2.1 million, or 17%, for the year ended December 31, 2018, compared to the same period in 2017. This increase is primarily due to an increase of $0.9 million in stock-based compensation expense, an increase of $0.6 million in clinical trial costs, an increase of $0.5 million in personnel costs, and an increase of $0.1 million in consulting and professional fees.

Sales and Marketing

Sales and marketing expenses increased by approximately $8.9 million, or 69%, for year ended December 31, 2018, compared to the same period in 2017, primarily due to an increase in personnel related expenses of $4.3 million, higher conference fees and travel costs of $2.0 million associated with several key transplant industry events, increased stock-based compensation expenses of $0.8 million, higher consulting and professional fees of $0.7 million, and higher marketing related costs of $0.4 million.

General and Administrative

General and administrative expenses increased by $3.0 million, or 16%, for the year ended December 31, 2018, compared to the same period in 2017. This primarily reflects an increase of $2.7 million in stock-based compensation expense, an increase of $1.8 million in personnel related expenses, higher travel expenses of $0.2

million, and higher facilities and software related costs of $0.2 million, partially offset by a decrease in consulting and professional fees of $1.6 million, and a decrease in audit fees of $0.8 million.

Goodwill Impairment

In the three months ended March 31, 2017, we determined that the decrease in our market capitalization constituted an indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. We recorded a goodwill impairment charge of $2.0 million and wrote off the remaining goodwill in the former Pre-Transplant reporting unit as of March 31, 2017. No impairment was identified in the year ended December 31, 2018.

Change in Estimated Fair Value of Contingent Consideration

In accordance with the IMX acquisition agreement, we estimated the contingent consideration liability fair value at each period end based on our common stock price at the end of the period and a probability of meeting the contractual milestone related to the number of commercial tests performed by June 2020. The contingent consideration liability was settled in the six months ended June 30, 2018, with the achievement of the contractual milestone of 2,500 commercial AlloSure tests. Changes in fair value of the contingent liability were $1.0 million expense and $1.2 million expense for the years ended December 31, 2018 and 2017 respectively. The $1.0 million expense reflected an increase in our share price from January 1, 2018 to the date of the issuance of the 227,848 shares and settlement of the liability. The $1.2 million expense reflected an increase in our share price in the year ended December 31, 2017 and an increase in our estimate of the probability of meeting the milestone under our business combination agreement with IMX.

Interest Expense, Net

Interest expense decreased by $2.2 million for the year ended December 31, 2018, compared to the same period in 2017.

The interest expense of $3.7 million in the year ended December 31, 2018, consisted of $2.5 million of interest expense and debt discount amortization related to 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 the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan. These interest expense amounts were partially offset by interest income of $0.2 million earned on cash and cash equivalent balances.

The interest expense of $5.9 million in the year ended December 31, 2017, consisted of $4.2 million of interest expense and debt discount amortization related to the JGB Debt, $0.6 million of interest expense recorded in relation to deferred purchase consideration owed to the former shareholders of Allenex, $0.9 million in interest expense recorded on the Allenex Notes, the Danske Bank Term Loan and the SSP Primers Loan and $0.2 million of interest expense recorded on the East West Bank Debt.

The JGB Debt was entered into on March 15, 2017 and during the three months ended March 31, 2018 was converted into shares of our common stock. The deferred purchase consideration was related to the acquisition of Allenex and was settled in November 2017. The SSP Primers Loan was repaid in February 2018 and the Allenex Notes and Danske Bank Term Loan were repaid in April 2018. The outstanding indebtedness under the East West Bank Debt was repaid in March 2017. On April 17, 2018, we entered into the Perceptive Credit Agreement for an initial term loan of $15.0 million. The obligations under the Perceptive Credit Agreement were fully repaid on November 20, 2018.

Debt Extinguishment Expenses

Debt extinguishment expenses increased by $5.3 million in the year ended December 31, 2018 compared to the same period in 2017. In the year ended December 31, 2018, debt extinguishment expenses of $5.8 million consisted of a loss of $2.8 million on the conversion of the JGB Debt in the three months ended March 31, 2018 and a $3.0 million loss on the debt extinguishment of the Perceptive Credit Agreement. In the year ended December 31, 2017,

debt extinguishment expenses of $0.5 million consisted of a $0.3 million loss on a $1.2 million conversion of JGB debt and $0.2 million of debt extinguishment fees on East West Bank debt.

Other Expense, Net

Other expense decreased by $0.8 million in the year ended December 31, 2018, compared to the same period in 2017. In the year ended December 31, 2018, the other expense charge of $0.2 million primarily consisted franchise taxes paid. In the year ended December 31, 2017, the other expense charge of $1.0 million consisted mainly of a foreign exchange loss of $0.6 million, $0.2 million for franchise taxes and $0.2 million in JGB Debt issuance costs.

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

The change in estimated fair value of common stock warrant liability and derivative liability was $23.0 million expense in the year ended December 31, 2018 and $29.6 million expense in 2017.

The $23.0 million expense in the year ended December 31, 2018, consisted of a remeasurement charge of $25.6 million related to the changes in fair value of 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 debt conversion date of March 27, 2018.

The $25.6 million remeasurement charge in the year ended December 31, 2018 reflects changes in the fair value of our common stock warrant liability and also a charge for warrants exercised during the period. In the year ended December 31, 2018, we recorded a revaluation charge of $7.3 million on the 0.4 million common stock warrants outstanding at December 31, 2018, which had an average fair value of $24.14 compared to $6.49 at December 31, 2017. In the year ended December 31, 2018, approximately 1.7 million warrants with an average exercise price of $2.86 per share and a December 31, 2017 fair value of $5.70 per share were exercised. The average market price of our common stock on the days of exercise was $19.54 per share, resulting in a charge of $18.3 million.

In the year ended December 31, 2017, the $29.6 million charge consisted of changes in fair value of common stock warrant liability expenses of $16.9 million and changes in fair value of the JGB Debt embedded derivative liability of $12.7 million of expense.

The $16.9 million expense related to our common stock warrant liability was due to:

- Changes in the valuation of warrants due to the change in the share price of our common stock during the year. The price of our common stock increased from $2.70 on December 30, 2016 to $7.34 on December 29, 2017;
- The adjustment in the exercise price of the Private Placement and Placement Agent warrants from $4.00 and $3.99 per share, respectively, to $1.12 per share, effective July 3, 2017, as a result of the issuance of 1,022,544 shares at a price of $1.12 pursuant to amendments to the Conditional Share Purchase Agreements (as discussed below);
- In connection with the issuance of the JGB Debt, on March 15, 2017, we issued warrants to JGB to purchase up to an aggregate of 1,250,000 shares of our common stock; and
- Adjustments to the quantity and exercise price of the JGB warrants as a result of the issuance of 1,022,544 shares at a price of $1.12 pursuant to the Conditional Share Purchase Agreements. The shares issuable upon the exercise of the warrants increased from 1,250,000 shares to 1,296,679 shares and the exercise price of the warrants decreased from $5.00 to $4.82 per share, effective July 3, 2017. In addition, as a result of the 2017 Public Offering, the shares issuable upon exercise of the warrants increased to 1,338,326 shares and the exercise price decreased to $4.67 per share, effective October 10, 2017.

The JGB Debt included certain embedded derivatives that require bifurcation, including settlement and penalty provisions. The $12.7 million expense related to the JGB debt embedded derivative reflects the change in the fair

value of the derivative liability from the JGB Debt issuance date of March 15, 2017 to December 31, 2017. We utilized the Monte Carlo simulation model to estimate the fair value of the embedded derivative liability for the measurement at issuance and subsequent remeasurement at December 31, 2017.

The $12.7 million increase in the fair value of the derivative liability mainly reflects the increase in the price of our common stock from $2.15 on March 15, 2017 to $7.34 on December 31, 2017 and the increase in the derivative liability related to the conversion of the JGB Debt into shares of our common stock during the term of the debt.

As of January 1, 2018, we adopted the new accounting standard and reclassified the outstanding common stock warrants issued in connection with the JGB Debt to equity. The JGB Warrants were not remeasured through earnings after January 1, 2018. This common stock warrant issued in connection with the JGB Debt were exercised in August 2018. Warrants issued in connection with the Private Placement Warrants continue to be classified as liability and will be remeasured at the end of each reporting period until expired or exercised. Changes in the common stock fair value, estimated volatility and expected contractual term will significantly impact the fair value of the warrant liability.

Income Tax Benefit

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. For the year ended December 31, 2017, we recorded an income tax benefit of $1.7 million on a loss before income taxes of $57.3 million. For both the 2018 and 2017 years, the income tax benefit is a result of the tax impact of the losses related to our foreign operations. The effective tax rate for the year ended December 31, 2018 defers from the federal statutory tax rate. This is a result of the full valuation allowance against U.S. deferred tax assets due to the lack of future source of taxable income and tax benefit as a result of losses in our foreign operations in the current year.

Comparison of the Years Ended December 31, 2017 and 2016

(In thousands)

	Year Ended December 31,		
	2017	2016	Change
Revenue:			
Testing revenue	$33,106	$29,680	$3,426
Product revenue	14,634	10,715	3,919
Collaboration and license revenue	584	236	348
Total revenue	48,324	40,631	7,693
Operating expenses:			
Cost of testing	12,345	10,882	1,463
Cost of product	9,026	10,240	(1,214)
Research and development	12,388	12,385	3
Sales and marketing	12,808	11,166	1,642
General and administrative	18,913	20,725	(1,812)
Goodwill impairment charge	1,958	13,021	(11,063)
Change in estimated fair value of contingent consideration	1,180	(456)	1,636
Total operating expenses	68,618	77,963	(9,345)
Loss from operations	(20,294)	(37,332)	17,038
Interest expense, net	(5,863)	(1,860)	(4,003)

Debt extinguishment expenses	(459)	—	(459)
Other expense, net	(1,031)	(1,920)	889
Change in estimated fair value of common stock warrant and derivative liabilities	(29,622)	(250)	(29,372)
Income tax benefit	1,709	1,606	103
Net loss	(55,560)	(39,756)	(15,804)
Net loss attributable to noncontrolling interest	(91)	(287)	196
Net loss attributable to CareDx, Inc.	$(55,469)	$(39,469)	$(16,000)

Testing Services Revenue

Testing services revenue increased by $3.4 million, or 12%, in 2017 compared to the same period in 2016 mainly due to the increase in AlloMap test volume representing $1.8 million, as well as increased AlloMap cash collections of $1.1 million. AlloMap tests results delivered increased by 1,164, or 8%, in 2017 compared to 2016.

AlloSure was launched in October 2017 and contributed $0.5 million of testing services revenue.

Product Revenue

Product revenue increased by $3.9 million, or 37%, in 2017, compared to 2016. The increase in product revenue mainly reflects product revenue not being comparatively included in the year ended December 31, 2016, as the Allenex acquisition occurred on April 14, 2016.

License and Other Revenue

License and other revenue increased by $0.3 million in 2017, compared to 2016, reflecting additional royalty payments received under our services agreement with CardioDx, Inc.

Cost of Testing Services

Cost of testing services increased by approximately $1.5 million, or 13%, in 2017 compared to 2016 primarily due to higher headcount related expenses of $1.1 million and laboratory material costs of $0.6 million. These increases were partially offset by a decrease in royalty payments to Roche of $0.2 million, as from September 30, 2017, no further royalties were due.

Cost of Product

Cost of product decreased $1.2 million or 12%, in 2017 compared to 2016. The decrease primarily relates to a net $3.6 million decrease in the charge recorded for the amortization of acquisition-related mark-up in the value of inventory. In 2016, a charge of $4.0 million was recorded related to inventory purchased in the Allenex acquisition. In 2017, a charge of $0.4 million was recorded related to the inventory purchased in the Conexio asset acquisition.

This decrease was partially offset by the effect of the cost of product not being comparatively included. The cost of product related to the Allenex and Conexio acquisitions are not comparatively included because the Allenex acquisition occurred on April 14, 2016 and the Conexio acquisition occurred on January 20, 2017.

Research and Development

Research and development expenses increased less than $0.1 million, or 1%, in 2017 compared to 2016. This increase is primarily due to a $1.0 million increase for product related development costs, which are not comparatively included in the twelve months ended December 31, 2016, as the Allenex acquisition occurred on April 14, 2016, partially offset by a decrease of $0.9 million of AlloSure development expenditures.

Sales and Marketing

Sales and marketing expenses increased by approximately $1.6 million, or 15%, in 2017 compared to 2016. The increase primarily reflects an increase of $0.9 million in the product sales and marketing payroll related expenses, due mainly to product related results not being comparatively included in the twelve months ended December 31, 2016.

We incurred an additional $0.6 million related to headcount increases for customer service and sales operations personnel.

General and Administrative

General and administrative expenses decreased by approximately $1.8 million, or 9%, in 2017 compared to 2016. The decrease primarily reflects a reduction in audit, tax and other professional and consulting fees incurred in 2016, primarily in connection with our acquisition of Allenex.

Goodwill impairment

On January 1, 2017, we adopted ASU 2017-04, which eliminated the Step 2 requirement of the goodwill impairment test. Instead, the goodwill impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. In the three months ended March 31, 2017, we determined that the decrease in our market capitalization constituted an indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. The goodwill impairment test determined that the fair value of the former Pre-Transplant reporting unit was $3.5 million, which was lower than its carrying value. Accordingly, we recorded a goodwill impairment charge of $2.0 million for the three months ended March 31, 2017, which represented the remaining goodwill balance in the former Pre-Transplant reporting unit. No additional goodwill impairment was recorded in the year ended December 31, 2017. During the year ended December 31, 2016, we recorded goodwill impairment charges related to our former Pre-Transplant reporting unit of $13.0 million. The impairment test performed in December 2016 indicated a reduction in our forecasted revenue and operating results for the former Pre-transplant reporting unit. This was the primary cause of the reduction in fair value of the former Pre-Transplant reporting unit, which triggered the impairment charge recorded in 2016.

Change in Fair Value of Contingent Consideration

We revalued the contingent consideration liability for the years ended December 31, 2017 and 2016 and recognized a non-cash loss of $1.2 million and a non-cash gain of $0.5 million, respectively, as a result of management's estimate of the probability meeting the milestone under our business combination agreement with ImmuMetrix, Inc. increasing to 100% at December 31, 2017, and our common stock price increasing by $4.67 and decreasing by $3.70 for the years ended December 31, 2017 and 2016, respectively.

Interest Expense, Net

Interest expense increased by $4.0 million for the year ended December 31, 2017 compared to the same period in 2016. The increase primarily consists of:

- $1.6 million of interest expense due to the higher principal balance and interest rate of the JGB Debt, which was outstanding from March 15, 2017 to December 31, 2017 as compared to the East West Bank Debt which was outstanding for all of 2016 and from January 1, 2017 to March 15, 2017;
- $1.8 million in increased debt discount amortization due to the higher debt discount applicable to the JGB Debt as compared to the debt discount applicable to the East West Bank Debt;
- $0.4 million in increased interest expense on Danske Bank debt and the Allenex Promissory Notes recorded in 2017, but not comparatively included in 2016 due to the acquisition of Allenex that occurred on April 14, 2016; and
- $0.2 million in increased interest expense due to the commencement of interest accruing from January 1, 2017 on the deferred purchase consideration payable related to the Allenex acquisition.

Debt Extinguishment Expenses

In the year ended December 31, 2017, debt extinguishment expenses of $0.5 million consisted of a $0.3 million loss on a $1.2 million conversion of JGB debt and $0.2 million of debt extinguishment fees on East West Bank debt. In the year ended December 31, 2016 no debt extinguishment expenses were recorded.

Other Expense, Net

Other expense decreased by $0.9 million in the year ended December 31, 2017, compared to the same period in 2016. In the year ended December 31, 2017, the other expense charge of $1.0 million consisted mainly of a foreign exchange loss of $0.6 million, $0.2 million for franchise taxes and $0.2 million in JGB Debt issuance costs. In the

year ended December 31, 2016, the other expense charge of $1.9 million consisted mainly of a $2.1 million charge in 2016 to expense financing costs associated with a proposed six-month bridge loan that did not materialize.

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

The change in the estimated fair value of common stock warrant and derivative liabilities was due to a $29.6 million expense in 2017 compared to a $0.3 million expense in 2016.

For the twelve months ended December 31, 2017, the $29.6 million charge comprised common stock warrant liability expenses of $16.9 million and $12.7 million of expense related to the JGB Debt embedded derivative liability.

The $16.9 million expense related to our common stock warrant liability was due to:

- Changes in the valuation of warrants due to the change in the share price of our common stock during the year. The price of our common stock increased from $2.70 on December 30, 2016 to $7.34 on December 29, 2017;
- The adjustment in the exercise price of the Private Placement Warrants and Placement Agent Warrants from $4.00 and $3.99 per share, respectively, to $1.12 per share, effective July 3, 2017, as a result of the issuance of 1,022,544 shares at a price of $1.12 pursuant to amendments to the Conditional Share Purchase Agreements (as discussed below);
- In connection with the issuance of the JGB Debt, on March 15, 2017, we issued warrants to JGB to purchase up to an aggregate of 1,250,000 shares of our common stock; and
- Adjustments to the quantity and exercise price of the JGB warrants as a result of the issuance of 1,022,544 shares at a price of $1.12 pursuant to the Conditional Share Purchase Agreements. The shares issuable upon the exercise of the JGB Warrants increased from 1,250,000 shares to 1,296,679 shares and the exercise price of the JGB Warrants decreased from $5.00 to $4.82 per share, effective July 3, 2017. In addition, as a result of the 2017 Public Offering, the shares issuable upon exercise of the warrants increased to 1,338,326 shares and the exercise price decreased to $4.67 per share, effective October 10, 2017.

The JGB Debt includes certain embedded derivatives that require bifurcation, including settlement and penalty provisions. The $12.7 million expense related to the JGB Debt embedded derivative reflects the change in the fair value of the derivative liability from the JGB Debt issuance date of March 15, 2017 to December 31, 2017. We utilized the Monte Carlo simulation model to estimate the fair value of the embedded derivative liability for the measurement at issuance and subsequent remeasurement at December 31, 2017.

The $12.7 million increase in the fair value of the derivative liability mainly reflects the increase in the price of our common stock from $2.15 on March 15, 2017 to $7.34 on December 31, 2017 and the increase in the derivative liability related to the conversion of the JGB Debt into shares of our common stock during the term of the debt.

Income Tax Benefit

For the year ended December 31, 2017, we recorded an income tax benefit of $1.7 million on a loss before income taxes of $57.3 million. The effective tax rate for the twelve months ended December 31, 2017 differs from the federal statutory tax rate as a result of the income tax expense and benefit related to the warrant revaluation expense and remeasurement of the deferred tax asset, partially offset by valuation allowance.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $311.8 million at December 31, 2018. As of December 31, 2018, we had cash and cash equivalents of $64.6 million, and no debt outstanding.

JGB Debt

On March 1, 2018, we notified JGB of our intent to prepay on April 13, 2018, in full the outstanding principal and interest under the JGB Debt. During the three months ended, March 31, 2018, JGB converted all outstanding $26.7 million of principal and accrued interest of the JGB Debt into an aggregate of 6,161,331 shares of our common stock. Restricted cash of $9.4 million was released from any restrictions after the conversion and included in our cash and cash equivalent balance as of March 31, 2018.

Perceptive Credit Agreement

On April 17, 2018, we entered into the Perceptive Credit Agreement for a term loan of $15.0 million and repaid the outstanding indebtedness under the Allenex Notes, the Danske Bank Term Loan and the Danske Credit Facility. On November 20, 2018, we paid off all obligations owing under, and terminated, the Perceptive Credit Agreement.

Allenex Notes, Danske Bank Term Loan and Danske Credit Facility

All outstanding amounts under the Allenex Notes of $4.4 million and Danske Bank Term Loan and Danske Credit Facility of $6.7 million were repaid on April 17, 2018.

Going Concern

As of December 31, 2018, we had cash and cash equivalents of $64.6 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, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$(4,007)	$(14,307)	$(16,523)
Investing activities	(7,929)	(6,105)	(21,121)
Financing activities	50,268	29,379	24,927
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2	106	83
Net increase (decrease) in cash, cash equivalents and restricted cash	$38,334	$9,073	$(12,634)

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, 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, $4.2 million of depreciation and amortization expense, $5.8 million loss on debt extinguishment expenses, $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.

Net cash used in operating activities for the year ended December 31, 2017 was $14.3 million. Our net loss of $55.5 million was our primary use of cash in operating activities and included a number of noncash items. Our noncash items included $29.6 million loss on the revaluation of warrants and derivative liabilities to estimated fair value, $3.8 million of depreciation and amortization, $3.5 million amortization of debt discount and noncash interest

expense, $2.0 million of goodwill impairment, and $1.2 million loss related to the revaluation of the contingent consideration. Net operating assets and liabilities decreased by $1.1 million.

Net cash used in operating activities for the year ended December 31, 2016 was $16.5 million. Our net loss of $39.8 million was our primary use of cash in operating activities. Our net loss also included a number of noncash items including $13.0 million of goodwill impairment related to our purchase of Allenex, $4.2 million of amortization of inventory fair market value adjustment, $2.9 million of depreciation and amortization, $2.0 million of stock based compensation expense, and $0.5 million on a revaluation gain on a contingent consideration liability related to our acquisition of IMX in June 2014.

Cash Flows from Investing Activities

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 purchases of property and equipment and $0.7 million for the acquisition of the Allenex minority interest.

For the year ended December 31, 2017, net cash used in investing activities was $6.1 million, which was primarily due to the $5.4 million repayment of the deferred purchase obligation related to the Allenex acquisition and $0.5 million related to the acquisition of the assets of Conexio.

For the year ended December 31, 2016, net cash used in investing activities was $21.1 million, which was mainly the cash paid to acquire Allenex of $20.6 million, net of cash acquired of $0.6 million.

Cash Flows from Financing Activities

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, cash proceeds of $11.0 million 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.

Net cash provided by financing activities for the year ended December 31, 2017 was $29.4 million, which primarily reflected the proceeds from the 2017 Public Offering of $18.3 million, the JGB Debt proceeds of $24.0 million, $1.0 million related to the exercise of warrants and $0.3 million of proceeds from exercise of stock options. These amounts were offset by $12.8 million of East West Bank Debt extinguishments, $1.5 million principal payments on Danske debt, and $0.1 million of capital lease obligations.

Net cash provided by financing activities for the year ended December 31, 2016 of $24.9 million consisted primarily of $20.6 million from the issuance of equity securities in private financing transactions, $7.9 million in proceeds received from the Public Offering an underwritten public offering completed on September 26, 2016, net of issuance costs, and $0.3 million from the issuance of common stock under the employee stock purchase plan and the exercise of stock options, partly offset by $3.9 million of principal payments on debt and capital lease obligations.

Contractual Obligations

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

Off-Balance Sheet Arrangements

As of December 31, 2018, we had no off-balance sheet arrangements as defined under Regulation S-K 303(a)(4) of the Exchange Act, and the instructions thereto.

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 $64.6 million and $16.9 million at December 31, 2018 and December 31, 2017, respectively, which consisted of bank deposits and money market funds. Additionally, we had no outstanding debt and $34.1 million as of December 31, 2018 and December 31, 2017, respectively. Such variable interest-bearing instruments carry a degree of risk. 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 $0.3 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, 2018, would have negatively impacted our financial results for the year ended December 31, 2018 by $0.3 million and our product revenue by $0.9 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 Deloitte & Touche 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 accompanying consolidated balance sheet of CareDx, Inc. and its subsidiaries (the "Company") as of December 31, 2018, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principles

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for revenue in fiscal year 2018 due to the adoption of ASC Topic 606, Revenue from Contracts with Customers.

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 audit. 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 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 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 audit we are required to obtain an understanding of internal control over financial reporting but not for expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Jose, CA

March 6, 2019

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

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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 accompanying consolidated balance sheet of CareDx, Inc. (the Company) as of December 31, 2017, 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, 2017, 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 consolidated financial position of the Company at December 31, 2017, and the consolidated results of its operations and its cash flows for each of the two years in the period 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

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CareDx, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	As of December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$64,616	$16,895
Accounts receivable	9,760	2,991
Inventory	4,943	5,529
Prepaid and other assets	1,795	1,352
Total current assets	81,114	26,767
Property and equipment, net	4,134	2,075
Intangible assets, net	33,252	33,139
Goodwill	12,005	12,005
Restricted cash	192	9,579
Total assets	$130,697	$83,565
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$4,711	$3,391
Accrued compensation	9,156	5,013
Accrued and other liabilities	5,408	3,735
Deferred revenue	39	39
Deferred purchase consideration	190	407
Derivative liability	—	14,600
Current portion of long-term debt	—	15,721
Total current liabilities	19,504	42,906
Deferred rent, net of current portion	470	913
Deferred revenue, net of current portion	691	730
Deferred tax liability	2,968	4,933
Long-term debt, net of current portion	—	18,338
Contingent consideration	—	1,672
Common stock warrant liability	10,003	18,712
Other liabilities	1,133	1,315
Total liabilities	34,769	89,519
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at December 31, 2018 and 2017; no shares issued and outstanding at December 31, 2018 and 2017	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at December 31, 2018 and 2017; 41,384,960 and 28,825,019 shares issued and outstanding	41	29

at December 31, 2018 and 2017, respectively		
Additional paid-in capital	412,010	264,204
Accumulated other comprehensive loss	(4,278)	(2,345)
Accumulated deficit	(311,845)	(268,022)
Total CareDx, Inc. stockholders' equity (deficit)	95,928	(6,134)
Noncontrolling interest	—	180
Total stockholders' equity (deficit)	95,928	(5,954)
Total liabilities and stockholders' equity (deficit)	$130,697	$83,565

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,		
	2018	2017	2016
Revenue:			
Testing revenue	$60,300	$33,106	$29,680
Product revenue	15,674	14,634	10,715
License and other revenue	595	584	236
Total revenue	76,569	48,324	40,631
Operating expenses:			
Cost of testing services	21,456	12,345	10,882
Cost of product	11,531	9,026	10,240
Research and development	14,514	12,388	12,385
Sales and marketing	21,670	12,808	11,166
General and administrative	21,959	18,913	20,725
Goodwill impairment	—	1,958	13,021
Change in estimated fair value of contingent consideration	1,017	1,180	(456)
Total operating expenses	92,147	68,618	77,963
Loss from operations	(15,578)	(20,294)	(37,332)
Interest expense, net	(3,701)	(5,863)	(1,860)
Debt extinguishment expenses	(5,780)	(459)	—
Other expense, net	(178)	(1,031)	(1,920)
Change in estimated fair value of common stock warrant and derivative liabilities	(22,978)	(29,622)	(250)
Loss before income taxes	(48,215)	(57,269)	(41,362)
Income tax benefit	1,434	1,709	1,606
Net loss	(46,781)	(55,560)	(39,756)
Net loss attributable to noncontrolling interest	(25)	(91)	(287)
Net loss attributable to CareDx, Inc.	$(46,756)	$(55,469)	$(39,469)
Net loss per share attributable to CareDx, Inc. (Note 3):			
Basic	$(1.31)	$(2.38)	$(2.39)
Diluted	$(1.31)	$(2.38)	$(2.39)
Weighted-average shares used to compute net loss per share attributable to CareDx, Inc.:			
Basic	35,638,956	23,332,503	16,496,911
Diluted	35,638,956	23,332,503	16,496,911

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

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CareDx, Inc.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year ended December 31,		
	2018	2017	2016
Net loss	$(46,781)	$(55,560)	$(39,756)
Other comprehensive loss:			
Foreign currency translation adjustments, net of tax	(1,933)	1,306	(3,727)
Net Comprehensive loss	(48,714)	(54,254)	(43,483)
Comprehensive loss attributable to noncontrolling interest, net of tax	(25)	(99)	(355)
Comprehensive loss attributable to CareDx, Inc.	$(48,689)	$(54,155)	$(43,128)

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

CareDx, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Interest	(Deficit)
Balance at December 31, 2015	—	—	11,902,363	12	202,566	—	(173,084)	—	29,494
Issuance of common stock in connection with business acquisition	—	—	1,375,029	1	7,204	—	—	—	7,205
Issuance of preferred stock through private placement and subsequent financing	4,630,145	5	—	—	13,064	—	—	—	13,064
Conversion of convertible private placement and subsequent financing preferred stock to common stock	(4,630,145)	(5)	4,630,145	5	—	—	—	—	5
Issuance of common stock through private placement and subsequent financing	—	—	926,029	1	2,595	—	—	—	2,596
Issuance of common stock through public offering	—	—	2,283,392	2	7,923	—	—	—	7,925
Issuance of common stock under equity	—	—	93,806	—	304	—	—	—	304

incentive plans									
Issuance of common stock for Board of Director services	—	—	61,921	—	304	—	—	—	304
Issuance of common stock for cash upon exercise of stock options	—	—	5,688	—	19	—	—	—	19
Employee and non-employee share-based compensation expense	—	—	—	—	1,694	—	—	—	1,694
Noncontrolling interest upon acquisition	—	—	—	—	—	—	—	634	634
Foreign currency translation adjustment	—	—	—	—	—	(3,659)	—	(68)	(3,727)
Net loss	—	—	—	—	—	—	(39,469)	(287)	(39,756)
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 to common stock	—	—	288,022	—	1,676	—	—	—	1,676
Issuance of common stock under employee benefit 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 (Note 2)	—	—	—	—	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	—	—	76,710	—	287	—	—	—	287

under ESPP									
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 interest upon acquisition	—	—	—	—	(537)	—	—	(155)	(692)
Issuance of common stock for contingent consideration	—	—	227,848	—	2,689	—	—	—	2,689
Issuance of warrants in connection with Perceptive 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

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

CareDx, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2018	2017	2016
Operating activities:			
Net loss	$(46,781)	$(55,560)	$(39,756)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,215	3,759	2,920
Amortization of inventory fair market value adjustment	234	418	4,175
Loss on disposal of property and equipment	—	10	—
Stock-based compensation expense	7,138	1,744	1,998
Amortization of deferred revenue	—	(32)	(45)
Revaluation of warrants and derivative liabilities to estimated fair value	22,978	29,622	250
Revaluation of contingent consideration to estimated fair value	1,017	1,180	(456)
Amortization of debt discount and noncash interest expense	2,232	3,452	(101)
Non-cash goodwill impairment	—	1,958	13,021
Debt extinguishment expenses	5,831	274	—
Changes in operating assets and liabilities:			
Accounts receivable	(3,967)	(109)	1,047
Inventory	363	1,025	492
Prepaid and other assets	(502)	(84)	999
Accounts payable	(168)	292	(620)
Accrued compensation	4,291	1,065	977
Accrued royalties	—	(263)	21
Accrued and other liabilities	758	(970)	(105)
Change in deferred revenue	(39)	—	—
Change in deferred taxes	(1,607)	(2,088)	(1,340)
Net cash used in operating activities	(4,007)	(14,307)	(16,523)
Investing activities:			
Purchase of property and equipment	(2,035)	(186)	(549)
Acquisition of intangible assets	(5,202)	—	—
Acquisition of Allenex AB and noncontrolling interests, net of cash acquired	(692)	(5,404)	(20,572)
Acquisition of assets of Conexio Genomics Pty Ltd.	—	(515)	—
Net cash used in investing activities	(7,929)	(6,105)	(21,121)
Financing activities:			
Proceeds from issuance of common stock, net of issuance costs	52,910	18,328	7,926
Proceeds from debt, net of issuance costs	14,282	24,002	—
Principal payments on debt and capital lease obligations	(28,089)	(14,359)	(3,944)
Contingent payments related to the acquisition of Conexio Genomics Pty Ltd.	(225)	—	—
Change in short-term credit facility	(677)	—	—
Proceeds from private placement and subsequent financing, net of issuance costs	—	—	20,622
Proceeds from exercise of warrants	10,998	989	—
Proceeds from exercise of stock options	1,480	262	19
Proceeds from issuance of common stock under employee stock purchase plan	287	94	304
Taxes paid related to net share settlement of restricted stock units	(698)	—	—
Change in bank overdraft obligation	—	63	—
Net cash provided by financing activities	50,268	29,379	24,927

Effect of exchange rate changes on cash and cash equivalents	2	106	83
Net increase (decrease) in cash, cash equivalents and restricted cash	38,334	9,073	(12,634)
Cash, cash equivalents, and restricted cash at beginning of period	26,474	17,401	30,035
Cash, cash equivalents, and restricted cash at end of period	$64,808	$26,474	$17,401
Supplemental disclosures of cash information			
Cash paid for interest	$1,774	$3,270	$867
Supplemental disclosures of cash flow information			
Shares issued in lieu of cash payment	$—	$1,145	$—
Deferred purchase consideration	$—	$—	$5,700
Accrued interest capitalized to debt principal	$—	$984	$—
Common stock issued for acquisition	$—	$—	$7,205
Debt assumed as part of acquisition	$—	$—	$13,421
Conversion of convertible private placement and subsequent financing preferred stock to common stock	$—	$—	$13,064
Issuance of common stock upon conversion of convertible debt	$38,852	$—	$—
Offering costs included in accounts payable	$361	$—	$—
ESPP shares included in accrued compensation	$341	$—	$—
Common stock warrants issued upon debt financing	$784	$—	$—
Common stock shares issued for contingent consideration	$2,689	$—	$—
Cash, Cash Equivalents and Restricted Cash as of:			
Cash and cash equivalents	$64,616	$16,895	$17,258
Restricted cash	192	9,579	143
Total cash, cash equivalents, and restricted cash at the end of the period	$64,808	$26,474	$17,401

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

CareDx, Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

CareDx, Inc. ("CareDx" or the "Company") together with its subsidiaries, is a global transplant diagnostics company with product offerings along the pre- and post-transplant continuum. The Company focuses on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. In diagnostic testing services, the Company offers AlloMap, which is a gene expression solution for heart transplant patients and AlloSure, which is a donor-derived cell-free DNA ("dd-cfDNA") solution initially used for kidney 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.

Testing Services

AlloMap is a covered service for Medicare beneficiaries since January 1, 2006. The 2018 the reimbursement rate for AlloMap was $3,240, which represents a 14% increase over the 2017 reimbursement rate. AlloMap has also received positive coverage decisions from many of the largest U.S. private payers.

In October 2017, the Company commercially launched AlloSure, its proprietary next generation sequencing-based test that measures dd-cfDNA after transplantation. The Medicare reimbursement rate for AlloSure is $2,841. AlloSure has also received payments from private payers on a case-by-case basis, however, no positive coverage decisions have been made for AlloSure in 2018.

Products

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 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. The Company received CE mark certification for QTYPE on April of 2018.

In May 2018, the Company entered into a License and Commercialization Agreement (the "License Agreement") with Illumina, Inc. ("Illumina"), which provides the Company with worldwide distribution, development and commercialization rights to Illumina's next generation sequencing ("NGS") product line for use in transplantation diagnostic testing. Refer to Note 5 for additional details.

In the third quarter of 2018, the Company changed its internal organizational structure and no longer operates in two reportable segments: Post-Transplant and Pre-Transplant. The Company's Chief Operating Decision Maker ("CODM") did not change as a result of this reorganization and continues to be the Chief Executive Officer ("CEO") of the Company. This change is reflective of the Company's CODM's review of the operating performance and allocation of resources at the consolidated level. Refer to Note 16 for additional details.

The Company's headquarters are in Brisbane, California. The primary operations are in Brisbane, U.S., Stockholm, Sweden and Fremantle, Australia.

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 $311.8 million at December 31, 2018. As of December 31, 2018, the Company had cash and cash equivalents of $64.6 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. In April 2016, the Company acquired 98.3% of the controlling interest of CareDx International AB, formerly Allenex AB ("Allenex") and recorded noncontrolling interest of 1.7%. On March 15, 2018, the Company acquired the remaining noncontrolling interest in Allenex and has not reported any noncontrolling interest balances since that date.

The Company recorded debt extinguishment expenses on the conversion of debt in other expense, net in its consolidated statements of operations in its Annual Report on Form 10-K for the year ended December 31, 2017 and in its Quarterly Reports on Form 10-Q in 2018. These extinguishments expenses on the conversion of debt have been reclassified from other expense, net to debt extinguishment expenses for all periods presented in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

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 and embedded derivatives; the fair value of assets and liabilities acquired in a business combination or an assets acquisition (including identifiable intangible assets acquired); the fair value of contingent consideration recorded in connection with a business combination; 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 eight 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 AlloMap and AlloSure tests provided for patients located in the U.S. and billed to various third-party payers, and 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. The Company has not experienced any significant credit losses and does not require collateral on receivables. For the years ended December 31, 2018, 2017 and 2016, approximately

48%, 27% and 44%, respectively, of total revenue was billed to Medicare. No other payers represented more than 10% of total revenue for the years ended December 31, 2018, 2017 and 2016.

As of December 31, 2018 and 2017, approximately 27% and 16%, respectively, of accounts receivable was due from Medicare. No other payer represented more than 10% of accounts receivable at either December 31, 2018 or 2017.

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 $0.2 million is classified as long-term restricted cash on the accompanying consolidated balance sheets.

A restricted cash balance of $9.4 million related to the debt obligation with JGB (the "JGB Debt") was released upon the full conversion of the JGB Debt to common stock during the three months ended March 31, 2018, and is no longer classified as restricted cash.

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.

Assets held under capital leases are recorded at the lower of the net present value of the minimum lease payments or the fair market value of the leased asset at the inception of the lease. Amortization expense is computed using the straight-line method over the shorter of the estimated useful lives of the assets or the period of the related lease.

The Company capitalizes certain costs incurred for software developed or obtained for internal use. 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 depreciated over three years.

Business Combinations

The Company determines and allocates 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, which either arise from a contractual or legal right or 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.

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.

The Company tests amortizable intangible assets for impairment on an annual basis and in between annual tests if it becomes aware of events or changes that would indicate that it is more likely than not that the fair value of the assets is below their carrying amounts. The amortizable intangible assets annual impairment test is performed as of December 1 of each fiscal year. If the fair value exceeds the carrying value, then there is no impairment. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of an asset to its carrying value, without consideration of any recoverability test. The Company has not identified any such impairment losses to date.

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 the third quarter of 2018, the Company changed its reportable segments and reporting units. During that period, the Company determined that it operates in one reportable segment and one reporting unit. Prior to September 30, 2018 the Company had two reporting units – Post and Pre-transplant. The Company recorded goodwill impairment charges

of $13.0 million and $2.0 million for the periods ended December 31, 2016 and December 31, 2017, respectively. The impairment charges resulted in full impairment of goodwill related to the Company's former Pre-transplant reporting unit as of March 31, 2017. No goodwill impairment related to former Post-transplant reporting unit was recorded in prior periods. See Note 6 for additional discussion regarding the impairment charge recorded.

In connection with the Company's annual goodwill assessment on December 1, 2018, 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, 2018, 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, 2018, 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 Warrant Liability and Derivative Liabilities

Common Stock Warrant Liability

On January 1, 2018, the Company adopted Accounting Standard Update ("ASU") No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. The Company determined that the common stock warrants issued to JGB (the "JGB Warrants") meet equity

classification criteria under the new standard and reclassified $6.6 million (the fair value of the JGB Warrants as of January 1, 2018) from warrant liability to equity (additional paid in capital). As of September 30, 2018, the JGB Warrants were fully exercised.

The warrant issued to Perceptive Credit Holdings II, LP (“Perceptive” and such warrant the “Perceptive Tranche A Warrant”), on April 17, 2018, also met the equity classification as noted in Note 13.

The new standard did not impact the classification of the other warrants included in the warrant liability balance as these financial instruments have other than down-round anti-dilution adjustments features. Outstanding warrants

liabilities are remeasured each reporting period with changes in fair value recorded in change in estimated fair value of common stock warrant liability and derivative liability in the consolidated statement of operations. Refer to Note 4 for valuation methodology and assumptions used to estimate the warrant liability's fair value.

Derivative Liability

The JGB Debt included certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The combined embedded derivative was remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liabilities in the consolidated statements of operations. As of March 27, 2018, the JGB Debt was fully converted to shares of the Company's common stock. The change in the fair market value of the derivative liability through March 27, 2018 was recorded in change in estimated fair value of common stock warrant liability and derivative liabilities in the consolidated statements of operations.

On April 17, 2018, the Company entered into the Perceptive Credit Agreement, which included an embedded derivative that required bifurcation related to early repayment provisions. This embedded derivative fair value of $0.2 million was recorded as debt issuance discount. Refer to Note 10 for additional details. The derivative was remeasured at the end of each reporting period with changes recorded in change in estimated fair value of common stock warrant liability and derivative liabilities in the consolidated statements of operations. The embedded derivative liability of $0.2 million was extinguished on November 20, 2018, when the Company paid off all obligations under the Perceptive Credit Agreement.

Revenue

The Company recognizes revenue from testing services, products, and license 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

AlloMap and AlloSure 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 a 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 of 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 AlloMap or AlloSure 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. 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. The Company estimates 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 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. As of December 31, 2018, the Company had received payments of $0.5 million more than estimated as of December 31, 2017, related to tests performed in prior periods. This change in estimate was included in testing services revenue in the year ended December 31, 2018, when cash was collected.

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. 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.

License and Other Revenue

The Company generates revenue from license agreements. License agreements may include non-refundable upfront payments, partial or complete reimbursement of research and development costs, contingent payments based on the occurrence of specified events under the agreements, license fees and royalties on sales of products or product candidates if they are successfully commercialized. The Company's performance obligations under the agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees. The Company makes judgments to determine if performance obligations are distinct or should be combined and the transaction price allocated to each performance obligation, which affect the periods over which revenue is recognized. The Company periodically reviews its estimated periods of performance based on the progress under each arrangement and accounts for the impact of any change in estimated periods of performance on a prospective basis. The Company constrains variable consideration, such as milestones, if it is probable that a significant portion of revenue would be reversed. The Company's deferred revenue relates to one performance obligation, which should be recognized over time. The Company did not recognize any revenue connected with milestones during the years ended December 31, 2018, 2017 or 2016.

Cost of Testing Services

Cost of testing services reflects the aggregate costs incurred in delivering the Company's testing services. The components of cost of testing services are materials and service costs, direct labor costs, stock-based compensation, equipment and infrastructure expenses associated with testing samples, shipping, logistics and specimen processing charges to collect and transport samples, and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Prior to adoption of the new revenue guidance, the Company recorded costs of testing associated with performing tests (except royalties) in the period when tests were performed without consideration of whether revenue was recognized in the same period. With the adoption of the new revenue standard on January 1, 2018, revenue and cost of testing services for tests performed are recognized in the same period. Royalties for licensed technology, calculated as a percentage of testing services revenues, are recorded as license fees in cost of testing services at the time the testing services revenues are recognized.

Cost of Product

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

impaired, slow moving or obsolete inventory.

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 product and 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 record 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 (deficit) 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

On January 1, 2018, the Company adopted the new revenue accounting standard Revenue from Contracts with Customers (Topic 606) ("ASC 606") using the modified retrospective method. The adoption of ASC 606 resulted in a one-time adjustment of $2.9 million to accounts receivable and accumulated deficit on January 1, 2018. The adjustment reflects the estimated payments to be received for tests where the result had been delivered at December 31, 2017, but associated revenue had not been recognized by December 31, 2017, because payment had not been received. As of December 31, 2018, the Company had received payments of $3.4 million for these tests and recorded additional testing revenue of $0.5 million as a change in estimate. The new standard did not impact the Company's product revenue or license and other revenue, nor did it impact contract assets or contract liabilities.

The following table summarizes the impact of the ASC 606 adoption on accounts receivable as of December 31, 2018 (in thousands):

	Balance as Reported	Balance without the adoption of ASC 606	Impact of Adoption of ASC 606
Balance Sheets			
Accounts Receivable	$ 9,760	$ 5,424	$ 4,336

The following table summarizes the impact to the consolidated statements of operations in accordance with the new revenue standard requirements for the year ended December 31, 2018 (in thousands):

	Year Ended December 31, 2018		
	Balance As Reported	Balance without the adoption of ASC 606	Revenue Impact of adoption of ASC 606
Statements of Operations			
Testing revenue	$60,300	$58,661	$ 1,639
Product revenue	15,674	15,674	—
License and other revenue	595	595	—
	$76,569	$74,930	$ 1,639

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases (Topic 842) ("ASC 842"), which, for operating leases, requires the lessee to recognize a right-of-use ("ROU") asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The guidance also requires a lessee to recognize single lease costs, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases. Additionally, the FASB issued ASU, No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers a practical expedient for transitioning at the adoption date. These ASUs will be effective for the Company on January 1, 2019 and the Company has chosen to use this practical expedient and recognize a cumulative-effect adjustment to the opening balance of the accumulated deficit. 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 (IDCs) 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 ("short-term leases").

The Company has substantially completed an evaluation of the impact of adopting this guidance will have on its consolidated financial statements and disclosures. The Company believes the most significant changes to the consolidated financial statements will be the recognition of ROU assets and offsetting lease liabilities related to

operating leases in the consolidated balance sheet. Upon adoption of ASC 842 on January 1, 2019, the Company anticipates that it will record a ROU asset of approximately $3.0 million and a lease liability of approximately $4.0 million.

The Company does not expect the standard to have a material impact on the consolidated statement of cash flows or the consolidated statement of operations. The Company is currently working to complete the implementation of new processes and information technology tools to assist in its ongoing lease data collection and analysis, and updating its accounting policies and internal controls in connection with the adoption of the new standard.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force) ("ASU 2016-15"), to reduce the diversity in practice with respect to the presentation of certain cash flows. The ASU is effective for interim and annual periods beginning after December 15, 2017. The Company adopted ASU 2016-15 on January 1, 2018 on a retrospective basis. The adoption of ASU 2016-15 did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (a consensus of the FASB Emerging Issues Task Force) ("ASU 2016-18"). This guidance requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2016-18 on January 1, 2018 on a retrospective basis and included restricted cash together with cash and cash equivalents in its consolidated statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"). The amendments provide guidance about how to account for changes to terms or conditions of a share-based payment award required under modification accounting. ASU 2017-09 is effective for all interim and annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2017-09 on January 1, 2018 on a prospective basis and the adoption of ASU 2017-09 did not have a material impact to the consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral of Mandatorily Redeemable Financial Instruments of Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 is effective for all interim and annual reporting periods beginning on or after December 15, 2018 with early adoption permitted. The Company adopted ASU 2017-11 on January 1, 2018, and the adoption resulted in the JGB common stock warrant liability balance being reclassified to additional paid in capital (Refer to Note 13).

In February 2018, the FASB issued ASU No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income ("ASU 2018-02"). The amendments in ASU 2018-02 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 2018-02 will become 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 does not expect that the adoption of the new standard will have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 is effective for all interim and annual reporting periods beginning on or after December 15, 2018. The Company will adopt ASU 2018-07 on January 1, 2019. The Company is in the process of assessing the impact that the ASU will have in its consolidated financial statements and disclosures.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other – Internal – Use Software (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 plans to adopt the standard during 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.

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, 2018, 2017 and 2016, 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,		
	2018	2017	2016
Numerator:			
Net loss attributable to CareDx, Inc. used to compute basic net loss per share	$(46,756)	$(55,469)	$(39,469)
Net loss attributable to CareDx, Inc. used to compute diluted net loss per share	$(46,756)	$(55,469)	$(39,469)
Denominator:			
Weighted-average shares used to compute basic net loss per share attributable to CareDx, Inc.	35,638,956	23,332,503	16,496,911
Weighted-average shares used to compute diluted net loss per share attributable to CareDx, Inc.	35,638,956	23,332,503	16,496,911
Net loss per share attributable to CareDx, Inc.:			
Basic	$(1.31)	$(2.38)	$(2.39)
Diluted	$(1.31)	$(2.38)	$(2.39)

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

	Year Ended December 31,

	2018	2017	2016
Shares of common stock subject to outstanding options	2,501,057	1,941,472	1,757,309
Shares of common stock subject to outstanding common stock warrants	656,289	3,678,957	3,259,926
Shares of common stock subject to convertible notes	—	6,127,021	—
Shares of common stock subject to contingent consideration	—	227,845	227,845
Restricted stock units	968,364	436,176	306,245
Total common stock equivalents	4,125,710	12,411,471	5,551,325

The Company issued 4,630,145 shares of preferred stock pursuant to the Private Placement and Subsequent Financing (as described in Note 11), which were completed on April 14, 2016 and June 15, 2016, respectively. All of the preferred stock was converted to common stock upon receipt of the approval of the Private Placement by the Company's stockholders (the "Requisite Stockholder Approval") on June 16, 2016. As of December 31, 2016, there was no preferred stock outstanding. On September 26, 2016, the Company completed the Public Offering (the

"2016 Public Offering"), pursuant to which the Company issued and sold an aggregate of 2,250,000 shares of common stock.

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 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, 2018 and 2017 (in thousands):

	December 31, 2018 Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Money market funds	$59,471	$ —	$ —	$59,471

Liabilities				
Common stock warrant liability	—	—	$ 10,003	$ 10,003

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	December 31, 2017 Fair Value Measured Using			Total
	(Level 1)	(Level 2)	(Level 3)	Balance
Assets				
Money market funds	$13,097	$ —	$ —	$13,097
Liabilities				
Contingent consideration	$—	$ —	$1,672	$1,672
Common stock warrant liability	—	—	18,712	$18,712
Derivative Liability	—	—	14,600	14,600
Total liabilities	$—	$ —	$34,984	$34,984

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 of December 31, 2016	$492	$5,208	$—	$ —	$5,700
Issuance of JGB Debt and warrants	—	900	2,290	—	3,190
Exercise of warrants	—	(4,306)	—	—	(4,306)
Conversion of JGB Debt	—	—	(402)	—	(402)
Change in estimated fair value	1,180	16,910	12,712	—	30,802
Balance as of 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 of December 31, 2018	$—	$10,003	$—	$ —	$10,003

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, 2018 and 2017, money market funds were included as cash and cash equivalents in the consolidated balance sheets.
- Contingent consideration liability— As of December 31, 2017, 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 fair value of the contingent consideration was estimated using the closing market price of the common stock multiplied by management's estimate of the probability of achievement of the contingency condition disclosed above, as of each period end. The probability of achievement of a contingency condition was a significant input in the Level 3

measurement and was 100% in presented periods. Increases (decreases) in the estimation of the probability percentage resulted in a directionally similar impact to the fair value of the contingent consideration liability. The Company achieved the contingent consideration milestone of 2,500 commercial tests and issued the 227,848 shares on May 22, 2018. There is no contingent consideration outstanding at December 31, 2018.

- 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.
- JGB Debt derivative liability— The Company utilized the Monte Carlo Simulation Model to estimate the fair value of the compound derivative liability recorded in connection with the JGB Debt. The Monte Carlo Simulation Model used multiple input assumptions to simulate the likelihood that market conditions will be achieved through 100,000 random trials. These assumptions included the expected term of the embedded derivative, the volatility of the Company's stock prices and its peers' stock prices over such expected term, likelihood, timing, and amount of future equity financing rounds, the likelihood of any prepayment or default events, the likelihood of monthly redemptions by the JGB Debt holders, and the likelihood and ability of JGB to convert the debt into equity. In each iteration of the simulations these assumptions were used to simulate the Company's stock price drawing from a risk neutral distribution, the occurrence of a conversion event, the occurrence of a prepayment event, the occurrence of a default event, and any resulting payoff from such event. The average present value over all iterations of the simulation was then calculated. Increases (decreases) in the assumptions discussed above resulted in a directionally similar impact to the fair value of the derivative liability. The assumptions used in this simulation model were reviewed on a quarterly basis and adjusted, as needed. For the year ended December 31, 2017 and from January 1, 2018 to March 27, 2018, the Company recorded the changes in fair value of the derivative liability of $12.7 million income and of $2.5 million income, respectively, in the change in estimated value of common stock warrant liability and derivative liability in its consolidated statements of operations. The derivative liability was remeasured and fully extinguished upon the final JGB Debt conversion on March 27, 2018 (see Note 10).
- Perceptive Credit Agreement derivative liability – The Company used a net present value analysis to estimate the fair value of the embedded derivative liability recorded in connection with the Perceptive Credit Agreement. The assumptions used in the analysis were the discount rate, the probability of early repayment during the term of the Perceptive Credit Agreement and the expected term of the derivative. An increase in the discount rate will result in a decrease in liability and an increase in the probability of early repayment will result in an increase in liability. The assumptions used in this analysis were reviewed on a quarterly basis and adjusted, as needed. The derivative liability was remeasured and fully extinguished upon the repayment of the Perceptive Credit Agreement on November 20, 2018 (see Note 10).

Common Stock Warrant and Derivative Liability Valuation Assumptions:

	December 31, 2018		December 31, 2017	
Private Placement Common Stock Warrant Liability				
Stock Price	$ 25.14		$ 7.34	
Exercise Price	$ 1.12		$ 1.12	
Remaining term (in years)	4.29		5.29	
Volatility	79.00	%	66.00	%
Risk-free interest rate	2.46	%	2.21	%
Subsequent Financing Common Stock Warrant Liability				
Stock Price	$ —		$ 7.34	
Exercise Price	$ —		$ 4.00	
Remaining term (in years)	—		5.46	
Volatility	—	%	65.00	%
Risk-free interest rate	—	%	2.21	%
Placement Agent Common Stock Warrant Liability				
Stock Price	$ 25.14		$ 7.34	
Exercise Price	$ 1.12		$ 1.12	
Remaining term (in years)	2.29		3.29	
Volatility	86.00	%	82.00	%
Risk-free interest rate	2.44	%	1.99	%
JGB Common Stock Warrant Liability				
Stock Price	$ —		$ 7.34	
Exercise Price	$ —		$ 4.67	
Remaining term (in years)	—		4.71	
Volatility	—	%	30.00	%
Risk-free interest rate	—	%	1.89	%
JGB Derivative Liability				
Stock Price	$ —		$ 7.34	
Remaining term (in years)	—		2.16	
Volatility	—	%	69.00	%
Risk-free interest rate	—	%	2.14	%

Warrants liabilities exercised during 2018 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 (deficit).

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 AND ASSET ACQUISITIONS

Business Combinations

Allenex

On April 14, 2016, the Company acquired 98.3% of the outstanding common stock of Allenex, a transplant diagnostic company based in Stockholm, Sweden that developed, manufactured and sold products that help match donor organs with potential recipients prior to transplantation. Allenex had a presence and direct distribution channels in the United States and Europe, with additional third party distributors in Europe and other markets around the world. Under the terms of the Conditional Share Purchase Agreements entered into on December 16,

2015, as amended, and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the aggregate purchase consideration paid by the Company was approximately $34.1 million and consisted of (i) $26.9 million of cash, of which $5.7 million (which represents SEK 50,620,000 as of the acquisition date) was the fair value of deferred purchase consideration originally payable to Midroc Invest AB, FastPartner AB ("Fast Partner") and Xenella Holding AB, the former majority shareholders of Allenex (the "Former Majority Shareholders") by no later than March 31, 2017, subject to certain contingencies being met, and (ii) the issuance of 1,375,029 shares of the Company's common stock valued at $7.2 million.

Of the total cash consideration, $8.0 million of cash payable to the Former Majority Shareholders was deposited into an escrow account by the Company and subsequently invested in the Company by the Former Majority Shareholders through a purchase of the Company's equity securities in a private placement. Upon the completion of such private placement, certain contingencies in the Conditional Share Purchase Agreements were waived. On June 8, 2016, the Company delisted Allenex's common stock from Nasdaq Stockholm.

The date by which the deferred purchase consideration was due to the Former Majority Shareholders was subsequently extended to July 1, 2017. In addition, interest began accruing on the Company's obligations to the Former Majority Shareholders (the "Deferred Obligation") at a rate of 10.0% per year commencing on January 1, 2017. On July 1, 2017, the Deferred Obligation totaled $6.3 million. On July 1, 2017, the Conditional Share Purchase Agreements were amended in order to, among other things: (i) convert approximately $1.1 million of the Deferred Obligation into 1,022,544 shares of the Company's common stock at a per share price equal to $1.12; (ii) require that the Company make an immediate cash payment of $0.5 million thereby reducing the Deferred Obligation by $0.5 million; (iii) extend the maturity date of a portion of the obligations, totaling approximately $2.9 million, under the Conditional Share Purchase Agreements to March 31, 2019; and (iv) provide that approximately $2.1 million of the Deferred Obligation would become payable on December 31, 2017 unless converted into shares of the Company's common stock prior to that date, which issuance of shares was subject to approval by the Company's stockholders. Interest began to accrue on the Deferred Obligation at a rate of 10% per annum commencing on July 1, 2017. On November 14, 2017, the Company further amended the Conditional Share Purchase Agreements with the Former Majority Shareholders, and, as a result, the Company paid the total remaining deferred purchase consideration of $4.7 million, plus accrued interest.

The Company has accounted for the Allenex transaction as a business combination in exchange for total consideration of approximately $34.1 million. Under business combination accounting, the total purchase price was allocated to Allenex's net tangible and identifiable intangible assets based on their estimated fair values as of April 14, 2016.

The fair value of the remaining 1.7% of noncontrolling interest in Allenex was purchased on March 15, 2018. The fair value of the noncontrolling interest was determined based on the number of outstanding shares comprising the noncontrolling interest and Allenex's stock price of SEK 2.48 per share as of the acquisition date (April 14, 2016). The noncontrolling interest was presented as a component of stockholders' equity on the Company's consolidated balance sheets at December 31, 2017.

Conexio

On January 20, 2017, the Company acquired the business assets of Conexio Genomics Pty. Ltd ("Conexio"). Prior to the acquisition, the Company was the exclusive distributor of the Conexio SBT™ product line for all countries excluding Australia. The Company purchased rights to many of the assets, such as machinery, facilities leases, know-how and the opportunity to retain key Conexio employees to continue producing and selling SBT products. The Company paid $0.4 million in cash and makes quarterly payments of 20% of the gross revenue from the sale of SBT products up to an aggregate total of $0.7 million. During the year ended December 31, 2018, the Company paid an aggregate of $0.2 million, representing the December 2017 quarterly payment and the March, June and September

2018 quarterly payments. The Company also assumed all obligations under the lease of the Conexio facilities, and any liabilities for product warranty claims up to $35,000. The Company accounted for this transaction as a business combination.

As of December 31, 2018, the estimated fair value of remaining obligations to Conexio of $0.2 million is recorded in deferred purchase consideration in the Company's consolidated balance sheet.

The following table summarizes the fair values of the assets acquired and liabilities assumed as of the acquisition date (in thousands):

	Total
Inventory	$1,040
Property, plant and equipment	97
Intangible assets	155
Goodwill	85
Assumed liabilities	(82)
Total acquisition consideration	$1,295

The following table presents details of the identified intangible assets acquired at the acquisition date (in thousands):

	Estimated Fair Value	Estimated Useful Life (Years)
Completed technology	$ 127	4
Customer relationships	28	4
Total	$ 155	

Goodwill recorded from the acquisition of the Conexio business assets is primarily related to expected synergies. The goodwill resulting from the acquisition is not deductible for tax purposes. The post-acquisition results of operations of the Conexio business assets for the period from January 20, 2017 through December 31, 2018 are included in the Company's consolidated statements of operations.

Pro Forma Impact of the Acquisition of Allenex (unaudited)

The following table presents pro forma results of operations and gives effect to the Allenex transaction as if the transaction had been consummated on January 1, 2016. The unaudited pro forma results of operations have been prepared for comparative purposes only and are not necessarily indicative of what would have occurred had the business combination been completed at the beginning of the period or of the results that may occur in the future. Furthermore, the pro forma financial information does not reflect the impact of any reorganization or operating efficiencies resulting from combining the two companies (in thousands) as of December 31, 2016.

	Total 2016
Revenue:	
Testing revenue	$29,680
Product revenue	15,101
Other revenue	407
Total revenue	$45,188
Net loss	$(32,319)

The unaudited pro forma financial information for the years ended December 31, 2016 is prepared using the acquisition method of accounting and has been adjusted to give effect to the pro forma events that are: (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) expected to have a continuing impact on the combined results. The pro forma adjustments directly attributable to the acquisition exclude acquisition-related expenses of $4.3 million and $2.1 million of expenses related to a potential financing that did not eventuate.

The total revenue of Allenex for the period from April 14, 2016 through December 31, 2016 was $10.7 million and the net loss for this period was $17.9 million, of which $13.0 million was a goodwill impairment charge.

Asset Acquisition

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 v1 and v2 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's specific information and projections, which are not observable in the market and are thus considered Level 3 measurements as defined by U.S. GAAP.

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 becomes 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 technological feasibility at the date of acquisition. The fair value of the products was also determined using the multi-period excess earnings method under income approach. The rate of 30% and 40% for the AlloSeq HLA acquired in-process technology and the AlloSeq BMT acquired in-process technology, respectively, was utilized to discount the cash flows to the present value. The acquired in-process technology will not be amortized until completion of development of the related products. Upon completion, each acquired in-process technology product will be amortized over its estimated useful life.

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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 HLA	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—
Total	$ 5,202	

6. GOODWILL AND INTANGIBLE ASSETS

Goodwill

Goodwill is recorded when the purchase consideration of an acquired business exceeds the fair value of the net assets acquired.

The following table presents details of the Company's goodwill for the year ended December 31, 2017 (in thousands):

	Former Post-Transplant	Former Pre-Transplant	Total
Balance as of December 31, 2016	$ 12,005	$ 1,834	$13,839
Goodwill acquired	—	85	85
Goodwill impairment	—	(1,958)	(1,958)
Foreign currency translation adjustments	—	39	39
Balance as of December 31, 2017	$ 12,005	$ —	$12,005

As of December 31, 2018, the Company's goodwill carrying amount of $12 million remains the same.

The Company tested its goodwill for impairments as of December 1, 2016 and estimated the fair value of the former Pre-Transplant reporting unit was $1.7 million, which was lower than its carrying value. Based on the analysis, the implied fair value of the goodwill was lower than the carrying value of the former Pre-Transplant reporting unit, resulting in a goodwill impairment charge of $13.0 million for the period ended December 31, 2016. The significant assumptions utilized in the 2016 discounted cash flow analysis for the former Pre-Transplant reporting unit were a discount rate of 16.8%, a terminal growth rate of 3.2%, and a capitalization multiple of 7.37.

On January 1, 2017, the Company adopted ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which eliminated the Step 2 requirement of the goodwill impairment test. Instead, the goodwill impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. The Company determined that the decrease in its market capitalization in the first quarter of 2017 constituted an indicator of impairment and therefore a goodwill impairment test was completed as of March 31, 2017. The goodwill impairment test determined that the fair value of the former Pre-Transplant reporting unit was $3.5 million, which was lower than its carrying value. Accordingly, the Company recorded a goodwill impairment charge of $2.0 million as of March 31, 2017, which represented the remaining goodwill balance in the former Pre-Transplant reporting unit. The significant assumptions utilized in the March 31, 2017 discounted cash flow analysis for the former Pre-Transplant reporting unit were a discount rate of 16.6%, a terminal growth rate of 3.2% and a

capitalization multiple of 7.48.

As of December 31, 2017, the remaining goodwill amount of $12.0 million was related to the former Post-Transplant reportable segment only. Management performed a goodwill impairment analysis and concluded that goodwill was not impaired.

On December 1, 2018, with consideration to the change to one reporting unit (see Note 16) 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, 2018, no impairment of goodwill has been identified.

Intangible Assets

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

	December 31, 2018				
	Acquisition Cost	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Weighted Average Remaining Useful Life (In Years)
Intangible assets with finite lives:					
Customer relationships: Allenex	$12,650	$ (2,198)	$ (1,129)	$9,323	12.0
Customer relationships: Conexio	28	(6)	(2)	20	2.0
Customer relationships: TruSight HLA	380	(86)	—	294	2.0
Developed technology: Olerup SSP	11,650	(3,065)	(998)	7,587	7.0
Acquired technology: QTYPE	4,510	(671)	(407)	3,432	12.0
Acquired technology: Olerup SBT	127	(28)	(6)	93	2.0
Acquired technology dd-cfDNA	6,650	(635)	—	6,015	11.8
Trademarks	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: AlloSeq HLA	2,719	—	—	2,719	—
Acquired in-process technology: AlloSeq BMT	2,103	—	—	2,103	—
Total intangible assets	$43,077	$ (7,143)	$ (2,682)	$33,252	

The following tables present details of the Company's intangible assets as of December 31, 2017 (in thousands):

	December 31, 2017				
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation	Net Carrying Amount	Remaining Useful Life (In Years)
Customer relationships: Allenex	$12,650	$ (1,394)	$ (250)	$ 11,006	13.0
Customer relationships: Conexio	28	(3)	1	26	8.1
Developed technology: Olerup SSP	11,650	(1,942)	(258)	9,450	8.0
Acquired technology: QTYPE	4,510	(376)	(84)	4,050	13.0

Acquired technology: Olerup SBT	127	(14)	5	118	8.1
Acquired technology: dd-cfDNA	6,650	(127)	—	6,523	12.9
Trademarks	2,260	(310)	16	1,966	13.0
Total intangible assets	$37,875	$ (4,166)	$ (570)	$ 33,139	

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 $2.4 million for the year ended December 31, 2018, of which $1.4 million, and $1.0 million were amortized to cost of product and sales and marketing expenses, respectively. Amortization expense was $2.6 million for the year ended December 31, 2017, of which $1.5 million, $1.0 million and $0.1 million were amortized to cost of product, sales and marketing and cost of testing services, respectively. Amortization expense was $1.7 million for the year ended December 31, 2016, of which $1.0 million and $0.7 million were amortized to cost of product 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 acquired in process technology of $6.7 million achieved technological feasibility in the fourth quarter of 2017, with the launch of AlloSure.

The following table summarizes the Company's estimated future amortization expense of intangible assets with finite lives as of December 31, 2018 (in thousands):

Years Ending December 31,	Cost of Product	Sales and Marketing	Total
2019	$1,925	$ 1,073	$2,998
2020	1,925	1,073	2,998
2021	1,878	916	2,794
2022	1,878	916	2,794
2023	1,878	916	2,794
Thereafter	7,643	6,409	14,052
Total future amortization expense	$17,127	$ 11,303	$28,430

7. BALANCE SHEET COMPONENTS

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2018	2017
Finished goods	$2,506	$2,569
Work in progress	651	1,471
Raw materials	1,786	1,489
Total inventory	$4,943	$5,529

Property and Equipment, Net

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

	December 31,	
	2018	2017
Leasehold improvements	$5,187	$5,194
Furniture and fixtures	720	825
Computer and office equipment	4,488	4,734
Machinery and equipment	6,961	6,806
Construction in progress	878	—
	$18,234	$17,559
Less: Accumulated depreciation and amortization	(14,100)	(15,484)
Property and equipment, net	$4,134	$2,075

Depreciation expense was $1.2 million in each of the years ended December 31, 2018, 2017 and 2016. In the year ended December 31, 2018, the Company recorded a write-off of $2.4 million of property and equipment cost and accumulated depreciation. The assets written-off mainly consisted of laboratory equipment that were fully depreciated and not in use.

Assets purchased under capital leases, included above in machinery and equipment, and computer and office equipment, were $0.6 million and $1.4 million at December 31, 2018 and 2017, respectively. Accumulated amortization was $0.2 million and $1.3 million at December 31, 2018 and 2017, respectively. Related amortization expense, included in depreciation and amortization expense, was $153,047, $135,000 and $204,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

Accrued and Other Liabilities

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

	December 31,	
	2018	2017
Clinical studies	$1,815	$1,115
Professional fees	822	475
Test sample processing fees	657	633
Deferred rent – current portion	432	419
Accrued royalty	285	—
Customer overpayments and refunds due	184	270
Capital leases – current portion	172	13
Software implementation costs	58	94
Uninvoiced receipts	—	253
Accrued interest payable	—	81
Other accrued expenses	983	382
Total accrued and other liabilities	$5,408	$3,735

8. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its operating and office facilities for various terms under long-term, non-cancelable operating lease agreements in Brisbane, California; West Chester, Pennsylvania; Fremantle, Australia; and Stockholm, Sweden. 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 2020. In the normal course of business, it is expected that these leases will be renewed or replaced by leases on other properties.

Rent expense under the non-cancelable operating leases was $2.0 million, $1.7 million and $1.5 million in 2018, 2017 and 2016, respectively. Future minimum lease commitments under these operating and capital leases on December 31, 2018, are as follows (in thousands):

Years ending December 31,	Capital Leases	Operating leases
2019	$ 193	$ 2,161
2020	193	2,045
2021	67	10
2022 and thereafter	—	7
Total minimum lease payments	$ 453	$ 4,223
Less: amounts representing interest	(32)	
Present value of minimum lease payments	421	
Less: current portion of obligations under capital leases	(172)	
Long-term portion of obligations under capital leases	$ 249	

The current portion of obligations under capital 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.

See Note 10 for the aggregate annual payment schedule for the Company's outstanding debt.

Royalty Commitments

Roche Molecular Systems, Inc. ("Roche")

In November 2004, the Company entered into a license agreement with Roche pursuant to which Roche granted the Company the right to use certain Roche technology relating to PCR and quantitative real-time PCR in clinical laboratory services, including in connection with AlloMap. This is a non-exclusive license agreement in the United States covering claims in multiple Roche patents.

Under the license agreement, the Company incurred royalty expenses as a percentage of AlloMap revenue and classifies those expenses as a component of cost of testing services in the consolidated statements of operations. Royalty expenses in connection with the Roche agreement were $0.9 million and $1.1 million for the years ended December 31, 2017 and 2016, respectively. Effective September 30, 2017, no future royalties are payable by the Company under the Roche agreement.

The Board of Trustees of the Leland Stanford Junior University ("Stanford")

In June 2014, the Company entered into a license agreement with Stanford, or 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 payment amounts and royalties in the low single digits of net sales of products incorporating the licensed technology. The license maintenance fee may be offset against earned royalty payments due on net sales in that year.

In 2017, the Company paid Stanford $0.1 million in aggregate for license maintenance fees and for the completion of the Company's first commercial sale. Commercial sales of AlloSure, which incorporates the licensed technology from Stanford, began in October 2017. The Company incurred royalties of $0.7 million in the year ended December 30, 2018.

Conexio

On January 20, 2017, the Company acquired the business assets of Conexio, which included machinery, facilities leases, know-how and the opportunity to retain key Conexio employees to continue producing and selling the SBT line of products. The Company makes quarterly payments to Conexio of 20% of the gross revenue from the sale of the SBT products using the purchased assets up to an aggregate total of $0.7 million. During the years ended December 31, 2018 and 2017, the Company paid $0.2 million and $0.4 million, respectively.

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, 2018, the Company paid no royalties to Illumina.

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. The Company expects to meet these purchase commitments and did not record any contingent losses related to these future products' purchases.

Litigation and Indemnification Obligations

From time to time, the Company may become involved in litigation and other legal actions. The Company estimates the range of liability related to any pending litigation where the amount and range of loss can be estimated. The

Company records its best estimate of a loss when the loss is considered probable. Where a liability is probable and there is a range of estimated loss with no best estimate in the range, the Company records a charge equal to at least the minimum estimated liability for a loss contingency when both of the following conditions are met: (i) information available prior to issuance of the consolidated financial statements indicates that it is probable that a liability had been incurred at the date of the consolidated financial statements and (ii) the range of loss can be reasonably estimated. The Company is not involved in any litigations as of December 31, 2018.

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, 2018 and as of December 31, 2017.

9. LICENSING AND OTHER REVENUE

Diaxonhit

In June 2013, the Company entered into an exclusive Distribution and Licensing Agreement with Diaxonhit, SA ("Diaxonhit"), a French public company, whereby Diaxonhit agreed to have the AlloMap test performed in a European laboratory and commercialize the test in the European Economic Area ("EEA"). The agreement will expire at the later of the last-to-expire patent in the EEA or ten years from the first commercial sale of the test in the EEA, which occurred in 2014.

Consideration under the agreement included an upfront cash payment of approximately €387,500 ($408,000) that is designated to offset royalties earned by the Company. The Company is entitled to receive royalties from Diaxonhit as a percent of net sales, as defined in the agreement, of AlloMap tests in the mid to high teens. Approximately, €250,000 ($263,000) of the upfront payments is refundable under certain circumstances. Upon confirmation that the CE mark was in place, the Company also received an equity payment of Diaxonhit common stock with a value of €387,500 ($408,000). The Company sold the shares of common stock in July 2013 for total consideration of $467,000. The CE mark is a mandatory conformity marking for certain products sold within the EEA.

Other performance obligations for which the Company may recognize revenue includes agreed-upon per unit pricing for the supply of AlloMap products, and additional royalties that are payable upon the achievement of various sales milestones by Diaxonhit. Commercial sales of the AlloMap test began in the EEA in June 2014. Total revenue recognized from this arrangement for the years ended December 31, 2018, 2017 and 2016 was $39,000, $39,000 and $2,000, respectively.

CardioDx, Inc.

In 2005, the Company entered into a services agreement with what at the time was a related party, CardioDx, Inc. ("CDX"), whereby the Company provided CDX with biological samples and related data and performed laboratory services on behalf of CDX. Each company granted the other a worldwide license under certain of its intellectual property rights. Pursuant to this agreement, CDX pays royalties to the Company in an amount equal to a low single-digit percentage of the cash collected from sales of CDX licensed products. The royalty obligation to the Company continues until 2019. The Company recognizes royalty revenues when payments are received as it was assessed that collection was not able to be estimated. Royalty revenues were $0.3 million, $0.5 million and $0.2 million for the years ended December 31, 2018, 2017 and 2016, respectively, and are included in license and other revenue on the consolidated statements of operations. The Company had no receivable balances from CDX at December 31, 2018 and 2017, and does not expect to record future revenue from CDX.

10. DEBT

The Company did not have any outstanding debt as of December 31, 2018.

Debt consisted of the following (in thousands):

	December 31, 2017
JGB Debt	$ 7,743
Danske Bank Term Loan & Credit Facility	6,763
SSP Primers Loan	1,215
Current portion of long-term debt	$ 15,721
JGB Debt	$ 14,168
FastPartner Subordinated Promissory Notes	2,400
Al Amoudi Subordinated Promissory Notes	1,770
Long-term debt, net of current portion	$ 18,338

Unamortized debt discount and issuance costs as of December 31, 2017 were $4.6 million. Total interest accrued on debt as of December 31, 2017was $0.3 million. The long-term accrued interest balance of $0.2 million as of December 31, 2017, was recorded in accrued and other liabilities and in other liabilities long-term in the consolidated balance sheet.

Perceptive Credit Agreement

On April 17, 2018, the Company entered into a the Perceptive Credit Agreement for an initial term loan of $15.0 million (“Tranche A Term Loan”) with a second tranche of $10.0 million that would have been available at the Company’s option, subject to the satisfaction of customary conditions (the “Tranche B Term Loan” and, together with the “Tranche A Term Loan”, the “Term Loam”). Approximately $11.1 million of the proceeds of the Tranche A Term Loan were used to fully repay the Company’s outstanding indebtedness, including accrued interest, with FastPartner AB, Mohammed Al Amoudi and Danske Bank A/S (“Danske”) on April 17, 2018.

The Term Loan was secured by substantially all of the Company’s assets and a pledge of 65% of the equity interests of CareDx International AB. The Term Loan accrued interest per annum at 9.00% (the “Applicable Margin”) plus the greater of the one-month LIBOR or 1.5%.

The Company paid a fee of $0.3 million to Perceptive in its capacity as the administrative agent under the Security Agreement. In addition, on April 17, 2018, the Company issued to Perceptive the Perceptive Tranche A Warrant to purchase up to 140,000 shares of common stock of the Company at an initial exercise price of $8.60. The Perceptive Tranche A Warrant was exercised in full on October 22, 2018 on a cashless basis. Perceptive received 91,705 shares in connection with this transaction.

The Perceptive Credit Agreement contained financial covenants related to minimum cash balance and trailing twelve month revenue. As of November 20, 2018 (the repayment date of the Perceptive Credit Agreement), the Company was in compliance with the financial covenants.

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The following table summarizes the Company's carrying value of the Perceptive Credit Agreement (in thousands) on April 17, 2018, the issuance date (in thousands):

	April 17, 2018
Debt principal	$ 15,000
Less:	
Issuance cost	(669)
Discount related to issued warrants	(784)
Embedded derivative liability	(245)
Total debt discount	(1,698)
Carrying value	$ 13,302

On November 20, 2018, the Company paid off all obligations owing under, and terminated, the Perceptive Credit Agreement. The secured interests were terminated in connection with the Company's payoff of all of its obligations. In connection with the repayment of the Perceptive Credit Agreement, the Company incurred a $1.2 million prepayment penalty and a $0.4 million exit fee; the unamortized debt discount of $1.6 million and the embedded derivative liability of $0.2 million were extinguished. 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

On March 15, 2017, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with JGB pursuant to which the Company issued to JGB debentures (the "Debentures") with an aggregate principal amount of $27.8 million and warrants to purchase 1,250,000 shares of the Company's common stock (the "JGB Warrants") for net proceeds of $24.0 million (the "Financing"). The Company used $11.2 million of the net proceeds from the Financing to repay its existing indebtedness under the Loan Agreement with East West Bank and was required to maintain restricted cash of $9.4 million.

Under the Securities Purchase Agreement, the Debentures would have matured on February 28, 2020, accrued interest at 9.5% per year and were convertible into an aggregate of approximately 6,092,105 shares of the Company's common stock at a price of $4.56 per share (the "Conversion Price"), subject to adjustment for accrued and unpaid interest and upon the occurrence of certain transactions, at the holder's option.

Additionally, after September 1, 2017, upon the satisfaction of certain conditions, including the volume weighted-average price of the Company's common stock exceeding 250% of the Conversion Price for twenty consecutive trading days, the Company could have required that the Debentures be converted into shares of the Company's common stock, subject to certain limitations. Commencing on March 1, 2018, each of the holders of the Debentures had the right, at its option, to require the Company to redeem up to $937,500 of the outstanding principal amount of its Debenture per month. The Company was required to promptly, but in any event no more than one trading day after the holder delivers a redemption notice to the Company, pay the applicable redemption amount in cash or, at the Company's election and subject to certain conditions, in shares of the Company's common stock. If the Company elected to pay the redemption amount in shares of the Company's common stock, then the shares would have been delivered based on a price equal to the lowest of (a) 88% of the average of the three lowest volume weighted-average prices of the Company's common stock over the prior 20 trading days, (b) 88% of the prior trading day's volume weighted-average price, or (c) the Conversion Price.

After either a change of control transaction, as defined in the Debentures, or February 28, 2018, subject to the satisfaction of certain conditions, the Company could have redeemed all of the then outstanding principal amount of the Debentures for cash by paying the outstanding principal balance, accrued and unpaid interest, and a payment

premium. The payment premium would have been calculated by multiplying the outstanding balance and the following percentage: (i) 15% if the Debentures were prepaid on or prior to March 1, 2018, (ii) 8% if the Debentures were prepaid after March 1, 2018 but prior to March 1, 2019, and (iii) 5% if the Debentures were prepaid on or after March 1, 2019.

The Company's obligations under the Debentures could have been accelerated upon the occurrence of certain events of default as specified in the agreement. In the event of default and acceleration of the Company's obligations, the

Company would have been required to pay (i) 115% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debenture is accelerated prior to March 1, 2018, (ii) 108% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debentures were accelerated after March 1, 2018, but prior to March 1, 2019, and (iii) 105% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debentures were accelerated after March 1, 2019. The Company's obligations under the Debentures were secured under a Security Agreement by a senior lien on all of the Company's assets, other than its interest in CareDx International AB (formerly known as Allenex AB), which was subject to a negative pledge prohibiting the incurrence of additional or replacement debt.

The Debentures contained customary affirmative and restrictive covenants and representations and warranties, including financial reporting obligations, a restriction on the Company's ability to pay cash dividends on its common stock and limitations on indebtedness, liens, investments, distributions, transfers, corporate changes, deposit accounts and subsidiaries. The Company was also required to maintain a minimum cash amount at all times, achieve commercialization of AlloSure by a certain date and achieve certain gross profit targets for sales of its AlloMap product.

In connection with the Financing, on March 15, 2017, the Company and the Purchasers entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which, among other things, the Company agreed to prepare and file one or more registration statements with the SEC for the purpose of registering for resale any shares of Common Stock that may be issued by the Company upon the conversion or redemption of the Debentures or the exercise of the JGB Warrants.

The Debentures included certain embedded derivatives that require bifurcation, including settlement and penalty provisions. The embedded derivatives were remeasured at each reporting period and the change in fair value was recognized in the consolidated statements of operations. See also Note 4, Fair Value Measurements.

The following table summarizes the Company's carrying value of the JGB Debt (in thousands) on the March 15, 2017 issuance date:

	March 15, 2017
Debt Principal	$27,780
Less: Issuance cost	(998)
Original issue discount	(2,780)
Original warrant valuation	(900)
Embedded Derivative Liability	(2,290)
Total debt discount	(6,968)
Carrying Value	$20,812

As a result of the issuance of 1,022,544 shares of the Company's common stock issued at a price per share equal to $1.12 pursuant to the amendments to the Conditional Share Purchase Agreements, the conversion price of the Debentures decreased from $4.56 per share to $4.40 per share, effective July 3, 2017, as described in Note 13.

As a result of the 2017 Public Offering in accordance with the anti-dilution provisions in the JGB Warrants and the Debentures, effective October 5, 2017, the conversion price of the Debentures decreased from $4.40 per share to $4.34 per share. On October 5, 2017, JGB elected to convert $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. As a result of the sale of the 651,240 shares of common stock pursuant to the underwriters' full exercise of their option to purchase additional shares in accordance with the anti-dilution provisions in the JGB Warrants and the Debentures, effective October 10, 2017, the conversion price of the Debentures was decreased from $4.34 per share to $4.33 per share. As of December 31, 2017, the JGB Debt had an outstanding principal balance of $26.5 million.

On March 1, 2018, the Company notified JGB of its intent to prepay on April 13, 2018 in full the outstanding principal and interest under the Debentures. Pursuant to the terms of the Debentures, on April 13, 2018, the Company would have been obligated to pay the full amount of the outstanding principal balance of the Debentures,

plus accrued and unpaid interest thereon and a prepayment premium equal to 8% of the outstanding principal balance in cash. In February and March 31, 2018, JGB converted the remaining $26.7 million of principal and accrued interest of the JGB Debt into an aggregate of 6,161,331 shares of the Company's common stock. In connection with these conversions in the three months ended March 31, 2018, 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 recorded as debt extinguishment expenses in the consolidated statements of operations.

Danske Bank Term Loan and Credit Facility

On June 25, 2013, Allenex entered into the Term Loan Facility with Danske in an aggregate principal amount of up to SEK 71,000,000 (approximately $7.8 million). The Term Loan Facility was available for utilization in advances of a minimum of SEK 5,000,000 (approximately $0.5 million in U.S. dollars) and if more, integral multiples of SEK 1,000,000 (approximately $0.1 million). The interest rate applicable to each advance shall be the percentage rate per annum calculated as the aggregate of (i) Stockholm Interbank Offered Rate ("STIBOR") (as defined in the Term Loan Facility) and (ii) the Margin (as described in the Term Loan Facility) at 3% conditional on the fulfillment of certain criteria. In March 2015, Allenex entered into a first amendment to the Term Loan Facility, pursuant to which additional loans were granted. In August 2015, Allenex entered into a second amendment to the Term Loan Facility, pursuant to which the term of the Term Loan Facility was extended. In December 2015, Allenex entered into a waiver and amendment agreement relating to the Term Loan Facility, pursuant to which the change of control provision was waived and amended. In March 2016, Allenex entered into another amendment to the Term Loan Facility, which modified the repayment schedule for advances under the Term Loan Facility.

On June 18, 2015, Allenex also entered into a short term credit facility with Danske with total available credit of SEK 8,000,000 (approximately $0.9 million). As of August 4, 2016, the available credit under the short term credit facility with Danske was increased to SEK 10,000,000 (approximately $1.2 million).

A quarterly debt covenant in the Term Loan Facility with Danske was violated on March 31, 2017, June 30, 2017, and September 30, 2017. The Company obtained a waiver for these violations. The waiver was conditional upon, among other things, the Company making a principal repayment of SEK 6,000,000 (approximately $0.7 million) by October 31, 2017. This amount was paid on October 31, 2017. The Company was not in compliance with certain debt covenants as of December 31, 2017 or March 31, 2018. The Company repaid the full outstanding amount of SEK 47,000,000 (approximately $5.6 million) plus accrued interest of SEK 142,000 (approximately $17,000), under the Danske Term Loan and Credit Facility on April 17, 2018.

FastPartner Subordinated Promissory Notes

On June 28, 2013, Allenex issued a SEK 9,400,000 (approximately $1.0 million) subordinated promissory note to FastPartner, which had an interest rate of 10.00%. On December 29, 2015, Allenex issued a SEK 2,000,000 (approximately $0.2 million) subordinated promissory note to FastPartner, which had an annual interest rate of 10.00%.

On March 7, 2016, Allenex issued a SEK 4,000,000 (approximately $0.4 million) subordinated promissory note to FastPartner, which had an annual interest rate of 10.00%. Pursuant to an intercreditor agreement, until the Term Loan Facility with Danske is repaid, FastPartner may not demand or receive payment of its subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. Allenex's obligations under the promissory note are secured by a pledge of Allenex shares to FastPartner. The full amount of the subordinated promissory note was due July 1, 2017.

On July 1, 2017, the Company entered into a note agreement with FastPartner (the "FastPartner Note Agreement") pursuant to which, among other things, Allenex and FastPartner agreed that all amounts owed under the above subordinated promissory notes would be governed by the FastPartner Note Agreement and to defer repayment of the principal outstanding amount of SEK 15,400,000 (approximately $1.9 million) plus accrued interest of $0.5 million until March 31, 2019. Interest began accruing on such amount at a rate of 10% per annum, and in the event the Company makes any cash amortization repayments to JGB of the JGB Debt, or any replacement debt, Allenex will repay in cash a portion of the amount outstanding under the FastPartner Note Agreement equal to 8% of any such

cash amortization repayment. As of each of March 31, 2018 and December 31, 2017, the principal outstanding amount remained at SEK 19,757,000 (approximately $2.4 million). The Company repaid the full amount outstanding of SEK 21,300,000 (approximately $2.5 million), including accrued interest of SEK 1,600,000 (approximately $0.2 million), under the FastPartner Note Agreement on April 17, 2018.

Mohammed Al Amoudi Subordinated Promissory Note

On June 28, 2013, Allenex issued a SEK 10,600,000 (approximately $1.2 million) subordinated promissory note to Mohammed Al Amoudi, which provides for an annual interest rate of 10.00%. Pursuant to an intercreditor agreement, until the Term Loan Facility with Danske is repaid, Mohammed Al Amoudi may not demand or receive payment of his subordinated promissory note, or foreclose on any collateral securing Allenex's obligations under the subordinated promissory note, without Danske's prior written consent. Allenex's obligations under the promissory note are secured by a pledge of Allenex shares to Mohammed Al Amoudi. The full amount of the subordinated promissory note was due July 1, 2017.

On July 1, 2017, the Company entered into a note agreement with Mohammed Al Amoudi (the "Al Amoudi Note Agreement") pursuant to which, among other things, Allenex and Mohammed Al Amoudi agreed to defer repayment of the principal outstanding amount of SEK 10,600,000 (approximately $1.3 million) plus accrued interest of $0.5 million until March 31, 2019. Interest began accruing on such amount at a rate of 10% per annum, and in the event the Company makes any cash amortization repayments to JGB of the JGB Debt, or any replacement debt, Allenex will repay in cash a portion of the amount outstanding under the Al Amoudi Note Agreement equal to 6% of any such cash amortization repayment. As of each of March 31, 2018 and December 31, 2017, the principal outstanding amount remained at SEK 14,575,000 (approximately $1.7 million). The Company repaid the full amount outstanding of SEK 15,700,000 (approximately $1.9 million), including accrued interest of SEK 1,200,000 (approximately $0.1 million) under the Al Amoudi Note Agreement on April 17, 2018.

Loan Agreement with SSP Primers Aktieboulag

On February 25, 2015, Allenex entered into a SEK 14,000,000 (approximately $1.5 million) loan agreement with SSP Primers Aktieboulag, pursuant to which SEK 4,000,000 (approximately $0.4 million) was paid on March 7, 2016. The loan amount outstanding as of December 31, 2017 was SEK 10,000,000 (approximately $1.2 million) plus accrued interest of SEK 650,000 (approximately $0.1 million) and was fully paid on February 26, 2018.

11. STOCKHOLDERS' EQUITY

Private Placement Transaction and Subsequent Financing

On April 14, 2016, the Company completed a Private Placement transaction for the offering of 591,860 units ("Units") to certain accredited investors (the "Private Placement"). Each Unit was comprised of: (i) one share of common stock, (ii) five shares of Series A Preferred, and (iii) three warrants, each to purchase one share of common stock. The purchase price was $23.94 per Unit (the equivalent of $3.99 per share of common stock, assuming conversion of the Series A Preferred). The aggregate gross proceeds to the Company from the Private Placement were approximately $14.2 million, of which $1.8 million was paid in satisfaction of placement agents, escrow agent, legal fees as well as other direct issuance costs. The Company and certain stockholders representing a majority of the Company's outstanding shares of common stock entered into voting agreements on April 14, 2016, pursuant to which each

stockholder agreed to vote certain of its shares of the Company's common stock in favor of granting the Company the Requisite Stockholder Approval.

The proceeds from the Private Placement were allocated between the common stock, preferred stock and warrants issued based on their relative fair values. The estimated fair values of the common stock, preferred stock and warrants were $1.9 million, $9.3 million and $3.0 million, respectively, as of the transaction date. The warrants were recorded as a liability and are subject to ongoing remeasurement. The shares of Series A Preferred were initially recorded as temporary equity upon the closing of the Private Placement and subsequently reclassified to common stock after their conversion to common stock on June 16, 2016. See Note 13 for a description of the accounting of for the warrants.

Concurrent to the Private Placement, the Company also entered into commitment letters pursuant to which the Former Majority Shareholders agreed to purchase the Company's equity securities in the Subsequent Financing, which investment was completed on June 15, 2016. In the Subsequent Financing, the Company issued to the Former Majority Shareholders 334,169 Units, which consisted of (i) an aggregate of 334,169 shares of common stock, (ii) an aggregate of 1,670,845 shares of Series A Preferred that were all converted into shares of the Company's common stock upon obtaining the Requisite Stockholder Approval on June 16, 2016, and (iii) 1,002,507 warrants, each of which is exercisable for one share of the Company's common stock. The aggregate gross proceeds to the Company from the Subsequent Financing were $8.0 million.

The proceeds from the Subsequent Financing were allocated between the common stock, preferred stock and warrants issued based on their relative fair values. The estimated fair values of the common stock, preferred stock and warrants were $1.0 million, $5.3 million and $1.7 million, respectively, as of the transaction date. The warrants were recorded as a liability and are subject to ongoing remeasurement. The shares of Series A Preferred were initially recorded as temporary equity upon the closing of the Subsequent Financing and subsequently reclassified to common stock after their conversion to common stock on June 16, 2016.

Following the closing of the Private Placement, the Company agreed to a number of requirements, including submitting the Private Placement to the Company's stockholders for approval, which was obtained on June 16, 2016, and granting certain registration rights, including the registration of shares sold in the Private Placement on a registration statement on Form S-3. On May 27, 2016, the Company filed a registration statement on Form S-3 with the SEC to register for resale the shares of common stock issued or issuable upon conversion of the Series A Preferred and upon exercise of the warrants sold in the Private Placement. The registration statement on Form S-3 was declared effective by the SEC on July 12, 2016.

Upon obtaining the Requisite Stockholder Approval on June 16, 2016, each share of Series A Preferred was converted into one share of the Company's common stock. In addition to the warrants issued to certain accredited investors in the Private Placement, on April 14, 2016, the Company issued warrants to purchase an aggregate of 200,000 shares of common stock to certain of its placement agents (the "Placement Agent Warrants"). All of the warrants issued in the Private Placement and the Placement Agent Warrants became exercisable once the Company obtained the Requisite Stockholder Approval on June 16, 2016.

The Company engaged M.M. Dillon & Co. Group ("M.M. Dillon"), an investment banking firm, to act as one of its financial advisors and placement agents in connection with the Private Placement and Subsequent Financing of the Company's common stock and the consummation of any private placement of its securities that the Company may choose to pursue. A member of the Company's board of directors is a managing director of M.M. Dillon, and as such, the Company considered M.M. Dillon to be a related party. As a result of the Private Placement and Subsequent Financing, the Company paid approximately $1.1 million in placement fees to its placement agents, of which $0.2 million pertained to fees paid to M.M. Dillon. Additionally, M.M. Dillon also received Placement Agent Warrants to purchase 100,000 shares of the Company's common stock.

2016 Public Offering

On September 26, 2016, the Company completed a public offering ("the 2016 Public Offering") pursuant to which the Company issued and sold an aggregate of 2,250,000 shares of common stock at a public offering price of $4.00 per share. The aggregate gross proceeds were $9.0 million, and $7.8 million net of issuance costs.

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 $1.25 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 the three months ended March 31, 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 ("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.

12. 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 $0.3 million for the year ended December 31, 2018.

13. WARRANTS

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

Private Placement, Placement Agent and Subsequent Financing Warrants

The warrants issued in the Private Placement and the Placement Agent Warrants (as described in Note 11) are considered freestanding instruments that are contingently redeemable and classified as liabilities on the Company's consolidated balance sheet as of December 31, 2018. The warrants became exercisable to purchase common stock after the Company obtained the Requisite Stockholder Approval on June 16, 2016. Upon the closing of the Private Placement on April 14, 2016, the Company recorded an estimated fair value of $3.3 million relating to warrants to purchase 1,975,580 shares of common stock that were issued in the Private Placement. The warrants were comprised of warrants to purchase 1,775,580 shares of common stock that were issued to certain accredited investors measured at an estimated fair value of $3.0 million, and Placement Agent Warrants to purchase 200,000 shares of common stock measured at an estimated fair value of $0.3 million. The Placement Agent Warrants were issued for services performed by placement agents as part of the Private Placement and were treated as equity issuance costs and were recorded in stockholders' equity on the Company's consolidated balance sheets to offset the Private Placement proceeds allocated to the Series A Preferred and common stock.

Additional warrants were issued on June 15, 2016 to the Former Majority Shareholders upon the closing of the Subsequent Financing (as described in Note 11). The warrants issued in the Subsequent Financing were also considered freestanding instruments being accounted for using the same methodology as described above. On June 15, 2016, the Company recorded an estimated fair value of $1.7 million for warrants to purchase an aggregate of 1,002,507 shares of common stock issued in the Subsequent Financing.

The initial total estimated fair value of the warrant liability was $5.0 million following the closings of the Private Placement, the issuance of Placement Agent Warrants and the Subsequent Financing on April 14, 2016. As of December 31, 2017, the total estimated fair value of the warrant liability was $12.2 million. The corresponding remeasurement charge of $11.3 million for the same year, was recorded in change in estimated fair value of common stock warrant and derivative liabilities on the Company's consolidated statements of operations.

In connection with the 2016 Public Offering, in accordance with the anti-dilution provisions in the warrants issued in connection with the Private Placement and the Subsequent Financing, the exercise price of the 1,775,580 and 1,002,507 Private Placement and Subsequent Financing warrants, respectively, was adjusted from $4.98 per share to $4.00 per share, which was the price paid by investors in the 2016 Public Offering.

In connection with the issuance of 1,022,544 shares of the Company's common stock at $1.12 in connection with the amendments to the Conditional Share Purchase Agreement, the exercise prices of the warrants issued in the Private Placement and Placement Agent Warrants were adjusted from $4.00 and $3.99 per share, respectively, to $1.12 per share.

JGB Warrants

In connection with the issuance of the JGB Debt (as described in Note 10), the Company issued the 1,250,000 warrants (the "JGB Warrants"). The exercise price of the JGB Warrants was $5.00 per share, and the JGB Warrants are exercisable from September 16, 2017 through September 15, 2022. Warrants were accounted as liabilities and the initial estimated fair value of the common stock warrant liability was $0.9 million. As of December 31, 2017, the estimated fair value of the common stock warrant liability was $6.6 million. The corresponding remeasurement expense for the year ended December 31, 2017 $5.7 million, and was recorded in change in estimated fair value of common stock warrant and derivative liabilities on the Company's consolidated statements of operations.

Pursuant to an agreement with the Former Majority Shareholders, the aggregate number of shares of common stock issuable upon exercise of the JGB Warrants increased from 1,250,000 shares to 1,296,679 shares and the exercise price of the JGB Warrants decreased from $5.00 to $4.82 per share, effective July 3, 2017.

As a result of the 2017 Public Offering, effective October 5, 2017, the aggregate number of shares of common stock issuable upon exercise of the JGB Warrants increased from 1,296,679 shares to 1,332,620 shares and the exercise price of the JGB Warrants decreased from $4.82 to $4.69 per share. As a result of the sale of the 651,240 shares of common stock pursuant to the underwriters' full exercise of their option to purchase additional shares to cover over-allotments in the 2017 Public Offering, effective October 10, 2017, the aggregate number of shares of common stock issuable upon exercise of the JGB Warrants increased from 1,332,620 shares to 1,338,326 shares and the exercise price of the JGB Warrants decreased from $4.69 to $4.67 per share.

On January 1, 2018, the Company adopted new accounting guidance (refer to Note 2) and reclassified the warrants to purchase 1,338,326 shares of common stock issued to JGB from liability to equity at the fair value of $6.6 million. As of September 30, 2018, the JGB Warrants were fully exercised.

Perceptive Tranche A Warrant

In connection with the Perceptive Credit Arrangement (as described in Note 10), on April 17, 2018, the Company issued the Perceptive Tranche A Warrant to purchase up to 140,000 shares of common stock of the Company at an initial exercise price of $8.60. The Perceptive Tranche A Warrant met the equity classification in accordance with ASU No. 2017-11 as described in Note 2. The Perceptive Tranche A Warrants were exercised in full on October 22, 2018 on a cashless basis. Perceptive received 91,705 shares of common stock in connection with this transaction.

As of December 31, 2018, outstanding warrants to purchase common stock were:

	Classified as	Original Term	Exercise Price	Number of Shares Underlying Warrants
Original issue date:				
August 2009	Equity	10 years	$ 21.78	33,473
July 2010	Equity	9 years	$ 21.78	6,694
August 2012	Equity	7 years	$ 21.78	167,182
January 2015	Equity	5 years	$ 6.96	34,483
April 2016 (a)	Liability	7 years	$ 1.12	323,021
April 2016 (b)	Liability	5 years	$ 1.12	91,436
				656,289

(a) Issued on April 14, 2016 in connection with the Private Placement to certain accredited investors. In accordance with the anti-dilution provisions, the exercise price of the warrants issued in connection with such private placement was adjusted from $4.98 to $4.00, which was the price paid by investors in the Company's underwritten public offering of common stock, which closed on September 26, 2016. As a result of the issuance of 1,022,544 shares of the Company's common stock at $1.12 in connection with the amendments to the Conditional Share Purchase Agreement, the exercise price was adjusted from $4.00 to $1.12, effective July 3, 2017.

(b) Issued on April 14, 2016 in connection with the Private Placement to placement agents. As a result of the issuance of 1,022,544 shares of the Company's common stock at $1.12 in connection with the amendments to the Conditional Share Purchase Agreement, the exercise price was adjusted from $3.99 to $1.12, effective July 3, 2017.

14. 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 287,491 shares of common stock reserved for future issuance under the 2014 Plan as of December 31, 2018.

2016 Inducement Plan

On April 21, 2016, the Company adopted the 2016 Inducement Equity Incentive Plan (the “Inducement 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 Inducement 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 Inducement Plan are substantially similar to the Company’s 2014 Plan. There were 34,687 shares of common stock reserved for future issuance under the Inducement Plan as of December 31, 2018.

The Inducement 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 Inducement Plan starting June 2016.

Stock Options and Restricted Stock Units (“RSUs”)

The following table summarizes options and RSUs activity under the Company’s 2014 Equity Incentive Plan and 2016 Inducement Plan and related information:

	Shares Available for Grant	Stock Options Outstanding	Weighted-Average Exercise Price	Number of RSU Shares	Weighted-Average Grant Date Fair Value
Balance—December 31, 2017	156,429	1,941,473	4.21	439,926	4.39
Additional options authorized	1,957,075	—	—	—	—
Common stock awards for services	(25,509)	—	—	—	—
RSUs granted	(847,734)	—	—	847,734	13.89
RSUs vested	—	—	—	(272,806)	8.59
Options granted	(1,116,683)	1,116,683	14.78	—	—
Options exercised	—	(472,645)	3.13	—	—
Repurchases of common stock under employee incentive plans	67,656	—	—	—	—
RSUs forfeited	46,490	—	—	(46,490)	5.63
Options forfeited	82,576	(82,576)	5.26	—	—
Options expired	1,878	(1,878)	3.51	—	—
Balance—December 31, 2018	322,178	2,501,057	$ 9.10	968,364	$ 11.49

The total intrinsic value of options exercised was $6.8 million, $0.2 million and less than $0.1 million in the years ended December 31, 2018, 2017 and 2016, respectively.

The total fair value of RSUs vested during 2018 was $2.3 million. As of December 31, 2018, the total intrinsic value of outstanding RSUs was approximately $24.3 million and there were $8.5 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a weighted-average period of 3.20 years.

Options outstanding that have vested and are expected to vest at December 31, 2018 are as follows:

Number of Shares Issued	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value (In thousands)

			(Years)	
Vested	1,020,905	$ 5.26	6.72	$ 20,299
Expected to Vest	1,301,026	11.77	9.04	17,728
Total	2,321,931			$ 38,027

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, 2018 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, 2018, 2017 and 2016 using the Black-Scholes Model was $9.05, $1.60 and $2.05, respectively.

The total fair value of options that vested during 2018 was $1.2 million. As of December 31, 2018, there were approximately $8.7 million of unrecognized compensation costs related to stock options, which are expected to be recognized over a weighted-average period of 3.25 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 month 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 2018 that ended on June 30, 2018, 42,534 shares were purchased for aggregate proceeds of $0.3 million from the issuance of shares, which occurred on July 2, 2018. The Company issued 76,710 shares and 71,639 shares of common stock during the years ended December 31, 2018 and December 31, 2017, respectively, pursuant to the ESPP. The Company received proceeds of $0.3 million and $0.1 million from the purchases of shares during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the Company had 372,568 shares available for issuance under the ESPP.

Board of Directors Stock Awards Granted for Services

For the years ended December 31, 2018, 2017 and 2016, 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, 2018, there were a total of 246,398 shares issued to the Company's directors, for a total fair value of $1.1 million. Stock-based compensation expense associated with the awards was $0.3 million, $0.2 million and $0.3 million for the years ended December 31, 2018, 2017 and 2016, 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,		
	2018	2017	2016
Employee Stock Options			
Expected term (in years)	5.9	5.9	5.9
Expected volatility	69.69 %	57.34 %	42.10 %
Risk-free interest rate	2.77 %	2.01 %	1.52 %
Expected dividend yield	— %	— %	— %
Employee Stock Purchase Plan			
Expected term (in years)	0.5	0.5	0.5
Expected volatility	59.94 – 105.32 %	62.27 – 98.58 %	77.05 – 90.81 %
Risk-free interest rate	1.61 – 2.14 %	0.65 – 1.13 %	0.37 – 0.49 %
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, 2018, 2017 and 2016, included in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of testing	$821	$188	$144
Research and development	1,631	405	449
Sales and marketing	986	157	156
General and administrative	3,700	994	1,249
	$7,138	$1,744	$1,998

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.

15. INCOME TAXES

Loss before income taxes for the years ended December 31, 2018, 2017 and 2016 is summarized as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
United States	$(41,109)	$(50,132)	$(21,753)
Foreign	(7,106)	(7,137)	(19,609)
	$(48,215)	$(57,269)	$(41,362)

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

	As of December 31,		
	2018	2017	2016
Current			
Federal	$24	$74	$49
State	—	(4)	11
Foreign	139	68	32
Total Current	163	138	92
Deferred			

Federal	13	42	(251)
State	4	1	(49)
Foreign	(1,614)	(1,890)	(1,398)
Total Deferred	(1,597)	(1,847)	(1,698)
Income tax benefit	$(1,434)	$(1,709)	$(1,606)

The Company's actual provision for tax differed from the amounts computed by applying the U.S. federal income tax rates of 21% and 34% to loss before income taxes as a result of the following:

	Year Ended December, 31,		
	2018	2017	2016
Federal tax rate	21.0 %	34.0 %	34.0 %
Stock-based compensation	1.3 %	-0.2 %	-0.5 %
Change in valuation allowance	-9.4 %	38.0 %	-16.8%
Foreign rate differential	2.4 %	-1.1 %	-1.3 %
Warrant revaluation	-10.0%	-17.5%	-0.2 %
Interest expense	-1.7 %	-1.8 %	0.0 %
Acquisition costs	—	0.0 %	-1.2 %
Goodwill impairment	—	-1.2 %	-10.8%
Impact of 2017 Tax Cuts and Jobs Act on change in deferred tax assets	—	-46.5%	—
Other	-0.6 %	-0.7 %	0.7 %
Effective income tax rate	3.0 %	3.0 %	3.9 %

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

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$52,135	$49,374
Tax credit carryforwards	6,235	5,798
Accruals	3,068	583
Property and equipment	1,571	1,184
Other	812	633
Gross deferred tax assets	63,821	57,572
Valuation allowance	(60,327)	(54,934)
Total deferred tax assets	3,494	2,638
Deferred tax liabilities:		
Purchased intangibles	(6,429)	(7,554)
Other	(33)	(17)
Total deferred tax liabilities	(6,462)	(7,571)
Net deferred tax liabilities	$(2,968)	$(4,933)

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 $5.4 million and

decreased by $21.4 million during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company had domestic federal net operating loss carryforwards of $207.5 million, domestic state net operating loss carryforwards of $80.9 million, and foreign net operating loss carryforwards of $8.7 million that can reduce future taxable income. The domestic federal and state net operating loss carryforwards will begin to expire in 2019 and 2028, respectively. The foreign net operating loss carryforwards can be carried forward indefinitely.

As of December 31, 2018, the Company had credit carryforwards of approximately $4.6 million and $5.8 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. The Company has not performed a Section 382 analysis subsequent to the 2007 tax year to determine if a change occurred and whether the use of net operating loss carryforwards and credit carryforwards will be limited to offset future taxable income. For financial statement purposes, the Company has included the federal and state net operating losses and credits in the deferred tax assets with a full valuation allowance. 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,		
	2018	2017	2016
Balance at the beginning of the year	$3,164	$5,252	$2,431
Additions based on tax positions related to the current year	285	186	332
Additions (decreases) based on tax positions related to prior years	—	(2,274)	2,489
Balance at the end of the year	$3,449	$3,164	$5,252

Approximately $0.5 million of the $3.4 million of net unrecognized tax benefit as of December 31, 2018, if recognized, would impact the Company's effective tax rate. During the year ended December 31, 2018, 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, 2018, December 31, 2017 and December 31, 2016 the Company had $0.3 million of cumulative interest and penalties related to unrecognized tax benefits. The Company does not anticipate a significant change in the unrecognized tax benefits over the next twelve months.

The Company files U.S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to net operating loss and credit carryovers, the domestic federal and state income tax returns are subject to tax authority examination from inception. In 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, 2017. 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.

16. 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 previously operated and reported its operating results in two reportable segments: Post-Transplant and Pre-Transplant. In the third quarter of 2018, the Company completed a business reorganization to support the Company's strategy to become a global transplant care leader. The position of the head of the former Pre-Transplant segment was eliminated, and global functional leaders who report to CODM were identified to manage sales and marketing, research and development, manufacturing and quality and other global functions. These changes resulted in changes to the presentation of financial information provided to the CODM for resource allocation and management performance assessment. The CODM continues to review revenue and cost of sales by testing services and products, as reported in the consolidated statements of operations. Earnings before interests, taxes, depreciation and amortization and operating results are reviewed at the consolidated level only. Effective September 30, 2018, the Company reports a single operating segment.

As of December 31, 2018 and 2017, there are no changes to the segment financial information reporting, except that the Company does not report results of former Post and Pre-Transplant segments. Such information is no longer prepared and therefore has not been provided to the CODM since the Company completed its reorganization during the reporting period ending September 30, 2018.

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):

	Years Ended December 31,		
	2018	2017	2016
Testing services revenue			
United States	$59,683	$32,598	$29,492
Rest of World	617	508	188
	$60,300	$33,106	$29,680
Product revenue			
United States	$5,881	$4,189	$3,006
Europe	7,506	7,980	6,270
Rest of World	2,287	2,465	1,439
	$15,674	$14,634	$10,715
License and other revenue			
United States	$499	$498	$194
Europe	96	86	42
	$595	$584	$236
Total United States	$66,063	$37,285	$32,692
Total Europe	$7,602	$8,066	$6,312
Total Rest of World	$2,904	$2,973	$1,627
Total	$76,569	$48,324	$40,631

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

	December 31, 2018	December 31, 2017
Long-lived assets:		
United States	$ 3,235	$ 1,206
Europe	625	776
Rest of World	274	93
Total	$ 4,134	$ 2,075

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, 2018. 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)			
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
2017				
Consolidated Statements of Operations Data:				
Total revenue	$11,584	$12,046	$12,191	$12,503
Net loss attributable to CareDx, Inc. used to compute basic net loss per share	$(5,562)	$(3,968)	$(14,268)	$(31,671)
Net loss per common share attributable to CareDx, Inc., basic	$(0.26)	$(0.19)	$(0.63)	$(1.13)
Net loss per common share attributable to CareDx, Inc., diluted	$(0.26)	$(0.19)	$(0.63)	$(1.13)
Shares used in calculation of net loss per share attributable to CareDx, Inc., basic	21,343,782	21,412,480	22,526,615	27,983,033
Shares used in calculation of net income loss	21,343,782	21,412,480	22,526,615	27,983,033

per share attributable to CareDx, Inc., diluted

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, 2018. 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, 2018, 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. 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 its internal controls over financial reporting were effective as of December 31, 2018.

Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for “emerging growth companies.”

Changes in Internal Control over Financial Reporting

None.

ITEM 9B. OTHER INFORMATION

None.

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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, 2018 in connection with the Annual Meeting of Stockholders to be held in 2019, or the 2019 Proxy Statement. To the extent that we do not file the 2019 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 2019 Proxy Statement. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2018. To the extent that we do not file the 2019 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 2019 Proxy Statement. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2018. To the extent that we do not file our 2019 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 2019 Proxy Statement. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2018. To the extent that we do not file the 2019 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 2019 Proxy Statement. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2018. To the extent that we do not file the 2019 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.

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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
2.1†	Agreement and Plan of Merger, dated May 17, 2014, by and between Registrant, Monitor Acquisition Corporation, ImmuMetrix, Inc. and Mattias Westman, as Holders' Agent.	S-1/A	333-196494	2.1	07/15/2015
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated June 9, 2014, by and between the Registrant, Monitor Acquisition Corporation, ImmuMetrix, Inc. and Mattias Westman, as Holders' Agent.	S-1/A	333-196494	2.2	06/25/2014
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	001-36536	3.1	08/28/2014
3.2	Amended and Restated Bylaws of the Registrant.	10-Q	001-36536	3.4	08/28/2014
4.1	Form of Registrant's common stock certificate.	10-K	001-36536	4.1	03/31/2015
4.2	Sixth Amended and Restated Investors Rights Agreement, dated July 1, 2009, as amended on March 29, 2012, June 10, 2014, and July 14, 2014, between the Registrant and certain holders of the Registrant's capital stock named therein.	10-K	001-36536	4.2	03/31/2015
4.3#	1998 Equity Incentive Plan and forms of agreements thereunder.	S-1	333-196494	10.2	06/03/2014
4.4#	2008 Equity Incentive Plan and forms of agreements thereunder.	S-1	333-196494	10.3	06/03/2014
4.5#	ImmuMetrix, Inc. 2013 Equity Incentive Plan	S-1	333-196494	10.19	06/03/2014
4.6#	2014 Equity Incentive Plan and forms of agreements, as amended.	8-K	001-36536	10.1	06/26/2018
4.7#	Form of Option Agreement under the 2014 Equity Incentive Plan for New Options.	SC TO-I	005-88252	99(d)(3)	10/12/2017
4.8#	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-8	333-197493	4.5	7/18/2014
4.9#	2016 Inducement Equity Incentive Plan.	S-8	333-211538	4.1	5/23/2016

Exhibit Number	Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date
4.10#	Form of Warrant.	8-K	001-36536	10.3	4/14/2016
4.11	Form of Common Stock Purchase Warrant issued to the Purchasers on March 15, 2017.	8-K	001-36536	4.2	3/15/2017
10.1#	Chief Executive Employment Agreement, dated September 19, 2012, by and between the Registrant and Peter Maag.	S-1	333-196494	10.6	06/03/2014
10.2#	Offer Letter, dated July 31, 2006, by and between the Registrant and James Yee.	S-1	333-196494	10.7	06/03/2014
10.3#	Offer Letter, dated October 18, 2011, by and between the Registrant and Michael D. Goldberg.	10-K	001-36536	10.15	03/31/2015
10.4#	Offer Letter, dated April 8, 2014, by and between the Registrant and George Bickerstaff, III.	10-K	001-36536	10.14	03/31/2015
10.5#	Offer Letter, between the Registrant and Michael Bell, dated as of April 21, 2017.	10-K	001-36536	10.43	04/21/2017
10.6#	Offer Letter, between the Registrant and Sasha King, dated October 20, 2017.	10-K	001-36536	10.6	03/22/2018
10.7#	Offer Letter, dated November 16, 2018, between the Registrant and Reginald Seeto, MBBS.	8-K	001-36536	10.1	11/26/2018
10.8#	Form of Change of Control and Severance Agreement between the Registrant and each of its executive officers.	S-1	333-196494	10.11	06/03/2014
10.9#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-196494	10.1	06/03/2014
10.10#	Executive Incentive Compensation Plan.	10-K	001-36536	4.1	03/31/2015

Exhibit Number	Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date
10.11 #	Outside Director Compensation Policy.	10-K	001-36536	10.18	03/31/2015
10.12	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	06/03/2014
10.13†	PCR Patent License Agreement, dated November 16, 2004, by and between the Registrant and Roche Molecular Systems, Inc., and amendments thereto.	S-1	333-196494	10.14	06/03/2014
10.14†	Distribution and Licensing Agreement, dated June 20, 2013, by and between the Registrant and Diaxonhit SA.	S-1/A	333-196494	10.15	06/25/2014
10.15†	Amended and Restated Exclusive Agreement, dated January 27, 2014, by and between the Board of Trustees of the Leland Stanford Junior University and ImmuMetrix, Inc.	S-1/A	333-196494	10.17	07/15/2014
10.16†	Settlement Agreement and Mutual Release, dated September 11, 2014, by and between the Registrant and Roche Molecular Systems, Inc.	10-Q	001-36536	10.14.1	11/14/2014
10.17†	Business Sale Agreement, between CareDx Pty Ltd and Conexio Genomics Pty Ltd., dated as of January 12, 2017.	10-Q	011-36536	10.6	06/09/2017
10.18	Sales Agreement, dated August 31, 2018 by and between the Registrant and Jeffries LLC.	S-3	333-227168	1.1	08/31/2018

Exhibit Number	Description	Incorporated by Reference Form	File No.	Exhibit	Filing Date
10.19†	License and Commercialization Agreement, dated May 4, 2018, between the Registrant and Illumina, Inc.	10-Q/A	001-36536	10.3	10/09/2018
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 139 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
Chief Executive Officer

Date: March 6, 2019

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	Chief Executive Officer	March 06, 2019
Peter Maag	and Director	
	(Principal Executive Officer)	
/s/ MICHAEL BELL	Chief Financial Officer	March 06, 2019
Michael Bell	(Principal Financial and Accounting Officer)	
/s/ MICHAEL D. GOLDBERG	Director	March 06, 2019
Michael D. Goldberg		
/s/ GEORGE W. BICKERSTAFF, III	Director	March 06, 2019
George W. Bickerstaff, III		

/s/ FRED E. COHEN	Director	March 06, 2019
Fred E. Cohen		
/s/ RALPH SNYDERMAN	Director	March 06, 2019
Ralph Snyderman		
/s/ WILLIAM HAGSTROM	Director	March 06, 2019
William Hagstrom		