CareDx, Inc.
Form 10-K
March 22, 2018
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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, 2017

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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. (Check one):

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	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, 2017 as reported by the Nasdaq Global Market on such date was approximately $19,496,286. 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 16, 2018 was 29,074,603.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2018 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, 2017.

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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 post-transplant solutions, if any, and our ability to increase the commercial success of these post-transplant solutions;
- our ability to generate revenue from sales of Olerup SSP®, Olerup SBT™, QTYPE™, XM-ONE®, and future pre-transplant products, if any, and our ability to increase the commercial success of these pre-transplant products;
- 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 sequence specific primer products and technology to maintain our leading position in the SSP market;
- our plans and ability to develop, commercialize, and/or distribute new Human Leukocyte Antigen typing, and possibly Next Generation Sequencing technology and pre-transplant solutions;
- our ability to obtain additional financing on terms favorable to us, or at all;
- our ability to regain eligibility to use Registration Statements on Form S-3 for capital-raising transactions;
- our ability to obtain, maintain and expand reimbursement coverage from payers for AlloMap, AlloSure and other future solutions, if any;
- the clinical adoption and use of AlloSure, if at all; as well as the establishment of a protocol for regular AlloSure testing, if at all;
- the outcome or success of our clinical trial collaborations and observational studies;
- our dependence on certain of our suppliers, service providers and other distribution partners;
- our compliance with federal, state and foreign regulatory requirements;
- the favorable review of our pre- and post-transplant offerings, and our future solutions, if any, in peer-reviewed publications;
- 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 anticipated cash needs and our anticipated uses of our funds, including our estimates regarding operating expenses and capital requirements;
- our ability to meet our obligations under our equity financing agreements, debt agreements and deferred purchase price commitments;
- anticipated trends and challenges in our business and the markets in which we operate;
- 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 successfully defend against or settle any litigation brought against us or other legal matters or disputes;
- our ability to expand internationally;
- 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

We are 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 surveillance solutions for transplant patients. In post-transplant diagnostics, we offer AlloMap®, which is a heart transplant molecular test, and in October 2017 we launched AlloSure®, which is a donor-derived cell free DNA, or "dd-cfDNA" test initially used for kidney transplant patients. In pre-transplant diagnostics, we 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.

AlloMap

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 received positive coverage decisions for reimbursement from Medicare. The 2017 reimbursement rate for AlloMap was $2,841. Effective January 1, 2018, the reimbursement rate for AlloMap is $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. and TRICARE.

Since the launch of AlloMap in January 2005, we have performed more than 107,000 commercial AlloMap tests, including 15,312 tests during 2017, in our Brisbane, California laboratory. Since the commercial launch of AlloMap through December 31, 2017, we have received net proceeds of approximately $219.6 million from AlloMap testing revenues.

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.

AlloSure

AlloSure, our recently launched commercial transplant surveillance solution for kidney transplant recipients, applies proprietary next generation sequencing to measure 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 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, but no positive coverage decisions have been made.

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.

In May 2015, we initiated the dd-cfDNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial. The first publication of results from the DART trial in March 2017 described the validation of clinical performance characteristics of dd-cfDNA in detecting rejection in kidney allograft recipients. DART is a multicenter observational study of kidney transplant recipients where blood specimens are drawn during surveillance follow-up visits periodically after transplant and also at the time of clinically suspected acute rejection. Patients will be followed in DART for up to 24 months. We completed the first analysis of the data from DART in June 2016. By the time of the first analysis, over 400 patients had enrolled in DART in 14 centers and we had collected specimens from over 1,260 patient visits. As of December 2017, we had approximately 2,100 patient visits. The data analyses demonstrated that increased levels of dd-cfDNA, determined by the AlloSure assay, discriminated active rejection 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.

In late 2017, we established the Kidney Allograft Outcomes AlloSure Registry, or KOAR, study to develop further data on the clinical utility of AlloSure for surveillance of kidney transplant recipients. We will invite 35 centers to join KOAR, and anticipate staggered activation of these study centers throughout 2018.

Pre-Transplant Diagnostics

With the acquisition of CareDx International AB, formerly Allenex AB, or Allenex, on April 14, 2016, 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. With the acquisition of the business assets of Conexio Genomics Pty Ltd, or Conexio, on January 20, 2017, we now offer a complete product range for sequence-based typing, or SBT, of HLA alleles. Olerup SBT is a test kit for sequence based HLA typing, while Assign SBT™ is the companion software for sequence analysis. In 2014, Allenex began active development of a new HLA typing product, Olerup QTYPE, which uses real-time polymerase chain reaction or, PCR, methodology. QTYPE was commercially launched at the end of September 2016. We also offer XM-ONE®, a standardized test that identifies a patient's antigens against HLA Class I or Class II, as well as antibodies against a donor's endothelium. This cross-match test is primarily used prior to kidney transplants.

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. 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 to offer a complete product range for SBT of HLA alleles.

As of December 31, 2017, substantially all of our testing and product 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 in two reportable segments: Post-Transplant Diagnostics and Pre-Transplant Diagnostics. 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 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 Products and Services

Post-Transplant

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

Our initial test, 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 immumosuppressants. The AlloMap test 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.

AlloMap uses gene expression technology to aid in the identification of heart transplant recipients at low risk of rejection. 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 is at low risk for rejection. The NPV for recipients with an AlloMap score below the threshold range for one or more years post-transplant 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.

Through December 31, 2017, we have performed more than 107,000 total commercial AlloMap tests. We estimate that there are approximately 141 centers performing heart transplants in the United States. In 2017, 125 of these centers used AlloMap.

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 stratification tool in estimating the probability that one or more of the clinical events in heart transplant recipients may occur in the future. AMV is available 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 recently launched commercial transplant surveillance solution, applies proprietary next generation sequencing to measure dd-cfDNA in the blood stream emanating from the donor kidney or heart. We believe AlloSure may help clinicians determine rejection-specific activity manifested as cell damage in the transplanted heart, kidney and other solid organs. 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 to determine the appropriate dosage levels of immunosuppressants.

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, 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 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 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 is 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 active 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 KOAR. KOAR is a multicenter, non-blinded, prospective observational cohort study of approximately 1,000 AlloSure patients to create a testing registry, including 300 patients at centers with planned renal surveillance biopsies at 12 months post-transplantation. The other 700 patients will be from centers that do not perform protocol surveillance biopsies. Outcomes in this sub-cohort, which represents the majority of the intended use population in the U.S., will be compared to the outcomes of the test and control cohorts.

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.

Pre-Transplant

Through the Allenex acquisition, we also 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. The Olerup branded pre-transplant products, include SSP, QTYPE, Gamma-Type, and SBT for HLA typing, and our cross-match test XM-ONE. The HLA genes are encoded on chromosome 6 and are involved in self- versus non-self-recognition. The SSP product line is used to type HLA alleles. These products are among the market leaders, and have long been a well-established brand name.

The 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.

In 2014, Allenex began active development of a new HLA typing product, QTYPE. QTYPE was commercially launched at the end of September 2016 for use on a limited range of instrument platforms, and will be available on a broader range of instrument platforms during 2018. QTYPE uses real time PCR methodology, and is based on SSP technology.

QTYPE will primarily focus 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. Clinical trials for CE marking of the pre-transplant QTYPE product are expected to commence in 2018.

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.

GammaType types an additional region in the HLA locus and provides additional resolution beyond other HLA typing kits, particularly for hematopoietic stem cell transplantation.

XM-ONE is the first standardized test that quickly identifies a patient’s antibodies against HLA Class I or Class II, as well as antibodies against a donor’s endothelium. This cross-match test has primarily been used prior to kidney transplants, and more recent clinical trials have further demonstrated its value as a complement to traditional antibody testing prior to other types of transplants. The cross-match test XM-ONE is primarily used prior to kidney transplantation to detect non-HLA antibodies against the donor’s endothelia, the lining of the organ’s cavities. Prior studies indicate that XM-ONE is a good complement to traditional antibody testing prior to kidney transplantation.

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 and AMV;
- validation 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;
- technology platform development to increase efficiency and lower costs in our testing and laboratory operations;
- updating SSP and QTYPE products for newly identified HLA alleles;
- further development of QTYPE to expand its addressable market;
    - demonstrating QTYPE performance on additional real time PCR instruments;
- investigating genetic alterations associated with the development of cancer in transplant patients who are at increased risk for malignancies because of chronic immunosuppression;
-

merging and analyzing internal and public clinical data sets to better understand factors that impact short and long term outcomes;

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- 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.

Our research and development expenses for the years ended December 31, 2017, 2016 and 2015 were $12.4 million, $12.4 million and $9.3 million, respectively.

dd-cfDNA for Kidney Transplants

Our recently completed 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 a now 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.

KOAR is the next step planned in the further development of data to support the clinical utility of AlloSure. The CMS Medicare Administrative Contractor (MAC), Palmetto (MolDX), in October 2017, recommended Medicare Coverage for AlloSure which is contingent on this further data development. The KOAR study commenced in January 2018. KOAR 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 substantially enhanced.

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 an LDT 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.

Other steps in our AlloSure development process have included publication of abstracts in association with professional meetings on the results of the clinical validity of AlloSure in our CARGO II sample and data repository and supporting an investigator-initiated study in heart patients at risk for ABMR.

Pre-Transplant Product Advancement and Development

Ongoing research and development in the pre-transplant arena encompasses four 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. SSP and QTYPE use technology platforms that can readily accommodate this increase in HLA allele assays.

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

Third, 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 pre- and post-transplant settings 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 post-transplant solutions. The reimbursement process can take six months or more to complete depending on the payer.

Reimbursement for AlloMap comes primarily from Medicare, private third party payers such as insurance companies and managed care organizations, Medicaid and hospitals. Reimbursement for AlloSure comes primarily from Medicare. 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. On November 20, 2017, Medicare released the final 2018 CLFS. 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

We are reimbursed by Medicare for AlloMap and AlloSure tests performed on patients covered by Medicare. Tests performed on patients covered by Medicare represented 30%, 34% and 36% of all tests in 2017, 2016 and 2015, respectively. Approximately 27%, 44% and 50% of all testing revenue was derived from Medicare for the years ended December 31, 2017, 2016 and 2015, 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., and TRICARE. 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 pre-transplant products have a broad international presence. We sell directly to customers in the United States, Germany, the Nordic Region, Benelux, Austria, Slovenia and Australia. We also sell through third-party distributors and sub-distributors throughout the rest of Europe, Asia, Africa, Canada and Central and South America.

In 2013, we initiated a commercial agreement with Diaxonhit, 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 are headquartered at our Brisbane, California laboratory, which is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and where we perform all AlloMap and AlloSure laboratory testing. 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 results are reported to the ordering clinician by fax or electronically via WebPortal within two business days of receipt of the sample. Rigorous quality control testing is conducted at every phase of the test process. 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 samples is drawn and sent overnight at ambient temperature to our laboratory. Cell-free DNA is purified from the plasma and the amount derived from the organ transplant is determined as an overall percentage of dd-cfDNA. Results are reported to the ordering clinician by fax or electronically within WebPortal within three days of receipt of the sample.

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; Fluidigm, which supplies us with instruments, 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; and Therapak, which supplies us with a proprietary buffer reagent. One of the reagents supplied to us by Therapak is, in turn, obtained by Therapak from Qiagen N.V. and is a proprietary formulation of Qiagen N.V.

Through our European commercial partner, Diaxonhit, we have contracted with a dedicated laboratory in France with HUS for AlloMap testing in Europe. We undertook a multi-step validation process to demonstrate that AlloMap test results released from the HUS laboratory are equivalent to AlloMap results generated by our main laboratory in the United States. We completed the technology transfer in January 2016, and patient samples can now be tested at HUS.

Manufacturing

We have historically purchased many of the components and raw materials used in our pre-transplant test 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 at our principal European executive offices located in Stadshagen, Stockholm, Sweden is used to support the production, packaging and labeling of our proprietary Olerup brand test kits: Olerup SSP, XM-One, and QTYPE. The facility is certified to Quality Management System, or QMS, to standards ISO 9001:2008, ISO 13485: 2012 and the Canadian Medical Devices Conformity Assessment System, or CMDCAS, for Medical Devices. 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. 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. SBT is manufactured and sold within Australia and transferred to Stockholm for further distribution to Europe, Asia, Africa and the Americas.

Sales and Marketing

Post-Transplant Sales and Marketing Team

CareDx has a direct field team in the United States that interacts with all aspects of the post-transplantation channel, including sales, marketing, medical science liaison, managed care, and patient care management representatives. As of December 31, 2017, our sales and marketing team consisted of 27 employees.

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.

Pre-Transplant Sales and Marketing Team

The pre-transplant 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, 2017, the sales and marketing team consisted of 21 employees, including sales, marketing, brand managers, and customer service representatives.

Competition

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

Post-Transplant

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 novel 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.

Pre-Transplant

Our competitors within the pre-transplant 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 emerging next generation sequencing, competitors include Illumina, Protrans, GenDx, Bio-Rad Laboratories, 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 Olerup brand product line competes favorably with One Lambda and Life Technologies as a leading supplier of HLA test kits based on performance, reputation and service.

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.

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, 2017, 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 quantitative polymerase chain reaction, or q-PCR, measurements, and in the analysis of genomic data and algorithm development.

AlloMap, AlloSure, Olerup SSP, XM-ONE 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.

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 2016 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 and Pennsylvania 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 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.

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. The FDA’s LDT guidance documents, if and when finalized, may significantly impact the timing, availability and reimbursement of our future tests, and could require us to modify our business model in order to maintain compliance with these new requirements. 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 requirements could conflict with CLIA

requirements and thereby 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.

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

Federal and State Self-Referral Prohibitions

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

Both the Stark Law and PORA contain exceptions for compensation paid to a physician for personal services rendered by the physician, provided that certain conditions are satisfied. We have compensation arrangements with a number of physicians for personal services, such as speaking engagements and specimen tissue preparation. 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 pre-transplant 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, 2017, we had 179 employees, of which 169 were full-time employees. We had 60 employees in manufacturing operations and support, 34 in research and development; 48 in sales and marketing and 37 in general and administrative positions. As of December 31, 2017, 118 employees were located in the United States and 61 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, none of our 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. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549 on official business days during the hours of 10 a.m. to 3 p.m. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0300.

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, 2017, our net loss was $55.5 million. As of December 31, 2017, we had an accumulated deficit of $268.0 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 AlloSure 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, 2017, we had cash and cash equivalents of $16.9 million and an accumulated deficit of $268.0 million. On March 1, 2018, we signed a binding commitment letter, or the Commitment Letter, with Perceptive Credit Holdings II, LP, or Perceptive, pursuant to which, subject to the conditions set forth therein, Perceptive committed to provide the Company with a term loan of up to $35.0 million, subject to funding in two tranches, or the New Term Loan. Refer to Note 18 of the notes to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10K for additional details on the New Term Loan.

Following this funding, we believe our existing cash and cash equivalents, and expected revenues, will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Even with the completion of the New Term Loan, we may require future additional financing to fund working capital, repay or restructure debt and pay our obligations as they come due. Additional financing might include one or more

offerings and one or more of a combination of equity securities, 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. Our ability to raise additional financing for working capital and to refinance our indebtedness will depend, in part, on the conditions of the capital markets, restrictions on the issuance of securities under the regulations implemented by the SEC and The Nasdaq Stock Market LLC and current stock valuation. Additional capital may not be available on attractive terms, or at all. Raising additional funds by issuing equity securities would result in dilution to our existing stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. 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. Any refinancing of our indebtedness could be at significantly higher interest rates, require additional restrictive financial and operational covenants, or require us to incur significant transaction fees, issue warrants or other equity securities, or issue convertible securities. Any debt arrangement we enter into may contain restrictive covenants, including restrictions on the ability of us and our subsidiaries to incur additional debt, grant liens, make investments, including acquisitions, and pay dividends and distributions. These restrictions and covenants may restrict our ability to finance our operations and engage in, expand, or otherwise pursue our business activities and strategies. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default and an acceleration of our obligations under a debt agreement. 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 would have to curtail our research and development and other activities and this would adversely affect our business and future prospects.

As a result of our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2016 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, we are currently ineligible to file new short form registration statements on Form S-3, and we are unable to access our existing Registration Statement on Form S-3 for sales of securities by us, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings “off the shelf” under Rule 415 of the Securities Act of 1933, as amended, or the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S-1. The ability to register securities for resale may also be limited as a result of the loss of Form S-3 eligibility.

As a result of our failure to timely file our Annual Report on Form 10-K for year ended December 31, 2016, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, we are currently ineligible to file new short form registration statements on Form S-3 and we are unable to conduct “off the shelf” offerings under Rule 415 of the Securities Act using our currently effective Registration Statement on Form S-3 (File No. 333-206277). In addition, if we seek to access the capital markets through a registered offering during the period of time that we are unable to use Form S-3, we may be required to publicly disclose the proposed offering and the material terms thereof before the offering commences, we may experience delays in the offering process due to SEC review of a Form S-1 registration statement and we may incur increased offering and transaction costs and other considerations. Disclosing a public offering prior to the formal commencement of an offering may result in downward pressure on our stock price. In addition, our inability to conduct an offering “off the shelf” may require us to offer terms that may not be advantageous (or may be less advantageous) to us or may generally reduce our ability to raise capital in a registered offering. If we are unable to raise capital through a registered offering, we would be required to conduct our financing transactions on

a private placement basis, which may be subject to pricing, size and other limitations imposed under the rules of The Nasdaq Stock Market LLC.

Assuming we continue to timely file our required Exchange Act reports, the earliest we would regain the ability to use Form S-3 is June 1, 2018.

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, 2017, revenue from Medicare for AlloMap and AlloSure represented 40% of post-transplant testing 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.

On June 10, 2016, CMS announced the proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the gapfill reimbursement rate for 2017, AlloMap reimbursement for patients covered by Medicare would have been reduced from $2,821 to $1,921, effective January 1, 2017. This reimbursement rate, determined by gapfill submissions from the Medicare contractors, was open to reconsideration until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the MACs and in November 2016 CMS released the final 2017 Clinical Laboratory Fee Schedule, or CLFS, reflecting the rate of reimbursement for AlloMap at $2,841, an increase of $20 compared to the 2016 fee schedule.

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 will begin in 2017, and the new market based rates will take effect January 1, 2018. 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 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 published in the CLFS 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 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 post-transplant tests, AlloMap and AlloSure, and Olerup 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 AlloMap, AlloSure and Olerup 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 AlloMap, AlloSure, or Olerup 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 or recently launched solutions, or that they will prove to be capable of reliably being used for organ surveillance in the heart or in other types of organs. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;
- obtain the necessary testing samples and related data;
- conduct clinical validation studies;
- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from ordering clinicians at a larger number of transplant centers;
- gain acceptance from ordering laboratories associated with transplant centers; and
- seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations.

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

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

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

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

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

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

The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations that could make AlloMap, AlloSure, Olerup 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, Olerup 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, Olerup 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 AlloMap, AlloSure, the Olerup product line and, subject to their development, our other solutions, and demonstrate the clinical and diagnostic benefits of these solutions and products. 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 141 centers managing heart transplant recipients in the United States. In 2017, AlloMap was used in 125 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 265 centers managing kidney transplant recipients in the United States. After the commercial launch of AlloSure on October 9, 2017, AlloSure was used in 32 of these centers during the remainder of 2017. 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 pre-transplant tests are sold to hundreds of laboratories mainly in Europe and the U.S. Laboratories order pre-transplant testing 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 Olerup product often requires the purchase of new and costly testing equipment. To attract new laboratory customers, the performance of our Olerup 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 AlloMap, AlloSure, Olerup 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 AlloMap, AlloSure and Olerup SSP products;
- our ability to successfully commercialize new diagnostic solutions and tests such as AlloSure, which was commercially launched on October 9, 2017, and QTYPE, which was commercially launched at the end of September 2016;
- the amount of our research and development expenditures;
- the timing of cash collections from third-party payers;
- the extent to which our current test and future solutions, if any, are eligible for coverage and reimbursement from third-party payers;
- the process of integrating new acquisitions, and the associated potential disruption to our business;
- changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business;
    - any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved or that otherwise may affect our intellectual property position;
- announcements by our competitors of new or competitive products;
- regulatory or legal developments affecting our test or competing products;
- total operating expenses; and
- changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts.

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

If the use of 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 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 dd-cfDNA, we will need to continue our efforts to complete and publicize research and trials, especially the KOAR 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. We acquired from Allenex a well-established business with products in the field of HLA typing. However, 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 q-PCR products including products offered by Thermo Fisher Scientific, Inc., or Thermo Fisher, as well as alternatives to PCR such as NGS products offered by Illumina. In addition to businesses focused on pre-transplantation such as Thermo Fisher's One Lambda and Immucor, Inc.'s LIFECODES, companies who that 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 pre-transplant 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 pre-transplantation offering. To compete successfully, we must continually update our product range and produce continually updated HLA test kits. 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 revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline.

From 2016 to 2017, our testing revenue grew from $29.7 million to $33.1 million, which represents annual growth of 12%. 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 diagnostic 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 AlloMap and AlloSure 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 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

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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 post-transplant 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 pre-transplant tests or enhancements to those tests;
- 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. In the event we become re-eligible to use a Registration Statement on Form S-3 to raise capital, 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.

Our debt agreements contain restrictive and financial covenants that may limit our operating flexibility.

Our existing debt agreements with JGB Collateral LLC and certain of its affiliates, or JGB, and Danske Bank A/S, or Danske, contain certain restrictive covenants that limit our ability to merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements, incur additional indebtedness or enter into various specified transactions. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate our existing debt agreements. Our debt agreements also contain certain financial covenants, including maintaining a minimum cash amount at all times, achieving commercialization of AlloSure by a certain date, achieving certain gross profit targets for sales of our AlloMap product, maintaining a minimum cash flow to debt service ratio and maximum leverage and solvency ratios and are secured by substantially all of our assets. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under our debt agreements or to satisfy all of the financial covenants. For example, as a result of our failure to file our Annual Report on Form 10-K for the year ended December 31, 2016 by April 17, 2017, we breached our obligation under our purchase agreement with JGB to make all required Exchange Act filings with the SEC on a timely basis. In addition, we did not file a registration statement with the SEC registering for resale the common stock underlying the securities issued to JGB in the financing by April 17, 2017 as required under our purchase agreement with JGB. On May 3, 2017, JGB waived any claim under our purchase agreement with JGB with the respect to the late filing of our Annual Report on Form 10-K for the year ended December 31, 2016 and any claim or right to receive liquidated damages for the late filing of the registration statement. Additionally as a result of our failure to file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 by May 22, 2017, we again breached our obligation under our purchase agreement with JGB to make all required Exchange Act filings with the SEC on a timely basis. Under the terms of our agreement with JGB, an event of default shall be deemed to have occurred if there is a material breach under the Stock Purchase Agreement with JGB, which is not cured, if possible to cure, within 15 trading days following notice of a breach sent by JGB to us.

A quarterly debt covenant in the Term Loan Facility with Danske was violated on June 30, 2016 and September 30, 2016. We obtained waivers for these violations. We were in compliance with all debt covenants at December 31, 2016. We were not in compliance with certain covenants at March 31, 2017, June 30, 2017 and September 30, 2017. We obtained a waiver for these violations. The waiver was conditional upon, among other things, us 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. We were not in compliance at December 31, 2017. On March 1, 2018, we signed a binding Commitment Letter with Perceptive, pursuant to which, subject to the conditions set forth therein, Perceptive

committed to provide the Company with a term loan of up to $35.0 million, subject to funding in two tranches. The term loan with Perceptive will also include restrictive and financial covenants that may limit our operating flexibility. Refer to Note 18 of the notes to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional details on the New Term Loan.

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 post-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.

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

As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements to expand our existing know-how, expertise and intellectual property in other fields, including for the development of other commercial tests. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our test offerings or distribution. We have limited experience with respect to acquiring other companies and limited experience with respect to the acquisition of strategic assets or the formation of collaborations, strategic alliances and joint ventures. 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. The risks we face in connection with acquisitions, including our recent acquisition of assets from Conexio, 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. For example, we completed our acquisition of ImmuMetrix, Inc., or IMX, in June 2014, and some risks remain, including the risks that the intellectual property we acquired in this acquisition may not lead to a successful product, risks associated with milestone payments due under the merger agreement and the probability of achieving them, and the risk that Stanford could terminate our patent license relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA if we do not meet certain performance and commercialization conditions. Additionally, the timing of the recent acquisition of Allenex may cause a heightened risk of any or all of the above factors, particularly in the near-term as we attempt to fully integrate the acquired operations. 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.

For example, in 2016 we acquired Allenex. Allenex’s technology and products are new to us, and accordingly we may need to make substantial investments of resources to support the integration of Allenex, which will result in increased operating expenses and divert resources and management attention from other areas of our business. Additional unanticipated costs or delays may be incurred in the course of integrating the respective businesses. We cannot make any assurances that these investments will be successful. As a result of any of the aforementioned challenges, as well as other challenges and factors that may be unknown to us, we may not be able to fully realize the anticipated strategic benefits of the acquisition, which includes a complementary product portfolio and significant cross-selling opportunities.

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 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 post-transplant business and kits for our pre-transplant 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, Fluidigm Corporation, which supplies us with instruments, laboratory reagents and consumables; Illumina, which supplies us with instruments, laboratory reagents, and consumables; Becton, Dickinson and Company, which supplies us with cell preparation tubes, and Therapak Corporation, which supplies us with a proprietary buffer reagent. One of the reagents supplied to us by Therapak Corporation is, in turn, obtained by Therapak Corporation from Qiagen N.V. and is a proprietary formulation of Qiagen N.V. We have no relationship with or control over, Qiagen N.V. We do not have guaranteed supply agreements with Thermo Fisher, Becton, Dickinson and Company, Therapak Corporation 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, Fluidigm Corporation, 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-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, some of which may be enhanced by our acquisitions of Allenex and the Conexio business assets.

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 and are distributing AlloMap tests directly in Canada. CareDx International currently distributes its products direct in Germany, Austria, Slovenia, Benelux, and in the Nordic countries. CareDx International also sells, via sub-distributors, in Canada and in significant markets in Europe such as France, Italy, UK and Turkey. We are also distributing via sub-distributors 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 new risks that, generally, we have not faced in the U.S., including:

- uncertain or changing regulatory registration and approval processes associated with AlloMap, AlloSure and other potential diagnostic solutions;
- 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, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors.

Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.

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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 have calculated the impact of the Tax Act in our year end income tax provision in accordance with our 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. In December 2017, Staff Accounting Bulletin No. 118, or SAB 118, was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, additional work may be necessary for a more detailed analysis of our deferred tax assets and liabilities. Any subsequent adjustment to the provisional amounts will be recorded in 2018 when the analysis is complete.

Under ASC Topic 740, Accounting for Income Taxes, 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 US 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 expect the new law to significantly reduce our tax rate in future periods, and our tax footnote reflects the effects of a federal tax rate reduction net of its valuation allowance. See Note 14 of the notes to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information. Certain provisions of the Tax Act continue to be refined and interpreted and we will continue to assess the overall impact that the Tax Act may have on our results of operations or financial condition. In addition, the Company is still evaluating the realizability of certain deferred tax assets.

Beginnin in 2018, companies may be subject to 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 under the SAB 118. We have not made an election with respect to GILTI. 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, as the rules become effective.

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 financial statements, including those contained in this Annual Report on Form 10-K. In addition, the preparation of our 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 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. Further, we were required to adopt Financial Accounting Standards Board Accounting Standards Updates related to revenue recognition in January 2018, which could have a material adverse effect on our financial condition and results of operations.

Risks Related to Acquisitions

Our acquisition of Allenex may not result in material benefits to our business and our development efforts.

Through the acquisition of Allenex, we expect to create an international transplantation diagnostics company with a strong presence and direct distribution in both the U.S. and Europe. Allenex's products are used to evaluate organ transplant patients prior to their transplant procedure with HLA matching diagnostic tests to ensure that a donor's organ is compatible with the transplant recipient's immune system to prevent rejection.

While Allenex has well-known products in the field of genomic HLA, Allenex faces market risk in the form of competition from other producers, a transition to more automated typing processes as well as new technologies, which may make it difficult for the business to maintain current market share and margins. The markets for clinical diagnostic products are competitive, and there are a number of companies which currently compete with Allenex for product sales. Allenex's competitors or new market entrants may be in a better position than we are to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic

partners. These competitors may also have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do, any of which may adversely affect the use of our genomic HLA products.

Additionally, the results from the acquisition of Allenex will be dependent on the performance of Allenex's new product candidate QTYPE, which was commercially launched at the end of September 2016. The development and commercialization of QTYPE may fail for many reasons, including:

- insufficient 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;
- inability for tests to perform on instruments already installed in HLA testing laboratories;
- failure to obtain or maintain necessary clearances or approvals to market the test; or
- lack of commercial acceptance by patients, clinicians, laboratories or third-party payers.

We have limited experience with respect to acquiring other companies and limited experience with respect to the acquisition of strategic assets or the formation of collaborations, strategic alliances and joint ventures. The acquisition of Allenex could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. We also may not realize the anticipated benefits of this acquisition.

We may not be able to successfully integrate our business with the business of Allenex, and we may not be able to achieve the anticipated strategic benefits from our acquisition of Allenex.

The integration of Allenex will be a time-consuming process. The integration process will require substantial management time and attention, which may divert attention and resources from other important areas, including our existing business. In addition, we may not be able to fully realize the anticipated strategic benefits of the combination, which includes a complementary product portfolio and significant cross-selling opportunities. The failure to successfully integrate the combined operations, including retention of key employees, could impact our ability to realize the full benefits of our acquisition of Allenex. If we are not able to achieve the anticipated strategic benefits of the combination, it could adversely affect our business, financial condition and results of operations, and could adversely affect the market price of our common stock if the integration or the anticipated financial and strategic benefits of the acquisition are not realized as rapidly as, or to the extent anticipated by investors and analysts. Failure to achieve these anticipated benefits could result in increased costs and decreases in future revenue and/or net income following the acquisition.

Charges to earnings resulting from acquisition and integration costs may materially adversely affect the market value of our common stock following the completion of the acquisition.

As part of the acquisition of Allenex, we paid a substantial amount of cash and assumed Allenex's debt. The assumed indebtedness subjects us to increased fixed obligations, increased interest expense, and included covenants or other restrictions that could impede our ability to manage our operations. We may also discover liabilities or deficiencies associated with the acquisition of Allenex and the assets acquired from Conexio that were not identified in advance, which may result in significant unanticipated costs.

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

We are accounting for the business combination with Allenex under the acquisition method of accounting in accordance with United States generally accepted accounting principles, or U.S. GAAP. The purchase price of Allenex was allocated to the fair value of the identifiable tangible and intangible assets and liabilities that were acquired from Allenex. The excess of the purchase price over Allenex's net assets and intangibles was allocated to goodwill when acquired. 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. Accordingly, we recorded a goodwill impairment charge of $2.0 million as of March 31, 2017, which represented the remaining goodwill

balance in Allenex. For information about this $2.0 million charge, see Note 6 of the notes to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. We are also accounting for the business combination with IMX in 2014 under the acquisition method of accounting. We have $12.0 million of goodwill on our balance sheet generated in connection with our acquisition of IMX.

Under 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 the acquisition of IMX continues 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. In connection with our annual goodwill assessment on December 1, 2017, we performed a qualitative assessment and determined that it is not likely that the fair value of the Post-Transplant reporting unit is less than the carrying value and therefore a quantitative test to assess potential goodwill was not necessary.

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 acquisition of the assets of Conexio may not result in material benefits to our business and our development efforts.

Through the acquisition of Conexio's business assets, we expect to expand our sales of the SBT product line. We 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 the SBT line of products.

In addition, we are required to make quarterly payments to Conexio of 20% of the gross revenue from the sale of the SBT line of products using the purchased assets up to an aggregate total of $0.7 million. We also assumed all obligations under the lease of the Conexio facilities, and any liabilities for product warranty claims related to the sale of these products up to $35,000.

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. 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. These revenue recognition criteria for cash basis payers will change 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 recognized on a cash basis if the conditions for recognizing revenue on an accrual basis are not met. For the years ended December 31, 2017 and 2016, approximately 37% of our testing revenue was recognized on a cash basis.

For new diagnostic solutions such as AlloSure, 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 product, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected.

Coverage and reimbursement by a commercial payer may depend on a number of factors, including a payer's determination that our current and future solutions 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 solutions 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".

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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 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., and TRICARE. 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.

Until 2016, AlloMap was billed using an unlisted 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.

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 2016 and 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.

If the FDA's recently published draft guidance setting forth a comprehensive regulatory scheme for laboratory-developed tests, or LDTs, becomes final, we would incur substantial costs and delays associated with trying to obtain premarket clearance or approval for those solutions.

The FDA has traditionally chosen not to exercise its authority to regulate 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 decides to regulate AlloSure and other future solutions under development as medical devices, it could require extensive 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. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may 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 and our solutions under development in foreign jurisdictions, we are subject to rules and regulations in those jurisdictions relating to our testing. In some foreign countries, including countries in the European Union, 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 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 will begin in 2017, and the new market based rates took effect January 1, 2018. 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.

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, 2017, 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. 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 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. 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 dd-cfDNA-based transplant diagnostics, we have submitted a patent application to cover some of our initial 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.

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.

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

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

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

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

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

position would be harmed.

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

AlloMap, AlloSure, Olerup SSP, Olerup XM-ONE, 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. One of our most significant licenses covers PCR technology used in AlloMap and may be required for future solutions we develop. We license this technology from Roche Molecular Systems, Inc. In connection with our acquisition of IMX, we obtained another significant license. This one is an exclusive license from Stanford University to a patent relating to the diagnosis of rejection in organ transplant recipients using dd-cfDNA. This technology is critical to AlloSure, our newest dd-cfDNA-based solution for solid organ recipients. Our rights to use these and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses. We are obligated under these licenses to, among other things, pay certain royalties upon commercial sales of our products. These licenses generally last until the expiration of the last to expire of the patents included within the licenses that cover our use within our products, but the licenses may be terminated earlier in certain circumstances. Termination of any of these licenses could prevent us from producing or selling some or all of our products, and a failure of the licensors to abide by the terms of the licenses or to prevent infringement by third parties could harm our business and negatively impact our market position. 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 2017 our stock price ranged from $0.76 to $7.98 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, such as the assets we acquired from Conexio;
- 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 16% of our common stock as of December 31, 2017. 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 an effective registration statement registering an aggregate of 8,534,261 shares of our common stock for resale, and such shares are currently freely tradable in the public market. We have also filed an additional registration statement registering an aggregate of 2,814,299 shares of our common stock for resale and such shares will become freely tradable once the registration statement is declared effective. 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

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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. Furthermore, our Debentures and related documents with JGB and our term loan facility with Danske prohibit us from paying dividends without the respective lender's prior consent, and we may in the future become subject to additional contractual restrictions on, or prohibitions against, the payment of dividends. Our proposed term loan with Perceptive would impose similar restrictions on the payment of dividends.

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) 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 and other requirements will increase our costs and require additional management resources. We enhanced our U.S. finance and accounting systems, procedures and controls at the beginning of 2016 and acquired Allenex on April 14, 2016. 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. However, as of December 31, 2016, we identified the following four material weaknesses in our internal control over financial reporting relating to: (i) certain areas of our financial statement close process, specifically with respect to an incorrect classification of the deferred consideration payable to the former majority shareholders of Allenex within our statement of cash flows following the Allenex acquisition, ensuring that our bonus accrual and contingent liability balances were accurate, ensuring the proper application of foreign exchange rates in our consolidation process, and ensuring the proper review of terms and conditions of a debt agreement, (ii) a failure to design and implement transaction level or management review controls for the oversight, integration and consolidation of the acquired entities or controls to assess the completeness and accuracy of information, including key inputs and assumptions used by third party specialists, used in estimating the fair value of assets acquired and liabilities assumed, (iii) a failure to properly apply the revenue recognition criteria to certain contractual arrangements with payers, specifically with respect to controls over the proper analysis and review of the terms and conditions of contractual arrangements and controls over the review of our aged accounts receivables, and (iv) a failure in the design and implementation of controls over our accounting for inventory overhead absorption. We remediated these material weaknesses as of December 31, 2017. We cannot be certain that the measures we have taken to date or any measures we may take in response to these material weaknesses in the future will be sufficient to remediate such material weaknesses or to avoid potential future material weaknesses. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate.

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 Exchange Act, restatements of our consolidated financial statements or other corrective disclosures, a decline in our stock price, suspension or delisting of our common stock from the Nasdaq Global Market, SEC investigations, civil or criminal sanctions, an inability to access the capital and commercial lending markets, defaults under our debt and other agreements or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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 $1.0 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, 2017:

Location	Function	Square Footage
United States		
Brisbane, California	Corporate headquarters, research and development and clinical laboratory	46,000
West Chester, Pennsylvania	Sales office and distribution	6,336
Europe		
Stockholm, Sweden	European administration, research and development and clinical laboratory	23,874
Vienna, Austria	Sales office and distribution	1,744
Australia		
Fremantle	Sales office and distribution, research and development and clinical laboratory	2,721

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. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 2, 2018, there were approximately 132 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.

Price Range of Our Common Stock

The following table sets forth the high and low sales price per share of our common stock as reported on the Nasdaq Global Market for the period indicated:

Year Ended December 31, 2016	High	Low
First Quarter	$6.84	$4.07
Second Quarter	$6.08	$4.01
Third Quarter	$5.06	$3.28
Fourth Quarter	$4.08	$2.50
Year Ended December 31, 2017	High	Low
First Quarter	$2.90	$1.35
Second Quarter	$1.66	$0.76
Third Quarter	$4.59	$1.05
Fourth Quarter	$7.98	$3.65

Stock Performance Graph

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

Dividend Policy

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Our outstanding debentures issued in March 2017 restrict our ability to pay cash dividends on our common stock, and we may also enter into credit agreements or other borrowing arrangements in the future that will further restrict our ability to declare or pay cash dividends on our common stock. In addition, our proposed term loan with Perceptive would impose similar restrictions on the payment of dividends. Any determination to declare or pay dividends in the future will be at the discretion of our board of directors and will depend on a number of factors, including our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may

deem relevant.

Sales of Unregistered Securities

There were no sales of unregistered securities by us during the fourth quarter of 2017.

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 2017.

ITEM 6. SELECTED CONSOLIDATED 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 financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data at December 31, 2017 and 2016 and the selected statements of operations data for each of the years ended December 31, 2017, 2016 and 2015 have been derived from our audited 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,				
	2017	2016	2015	2014	2013
	(In thousands, except share and per share data)				
Revenue:					
Testing revenue	$33,106	$29,680	$27,881	$25,842	$21,672
Product revenue	14,634	$10,715	—	—	—
Collaboration and license revenue	584	$236	263	1,464	426
Total revenue	48,324	40,631	28,144	27,306	22,098
Operating expenses:					
Cost of testing	12,345	10,882	10,273	8,541	9,078
Cost of product	9,026	10,240	—	—	—
Research and development	12,388	12,385	9,333	3,846	3,176
Sales and marketing	12,808	11,166	8,349	6,472	5,892
General and administrative	18,913	20,725	12,247	8,436	4,809
Goodwill impairment	1,958	13,021	—	—	—
Change in estimated fair value of contingent consideration	1,180	(456)	(126)	(1,239)	—
Total operating expenses	68,618	77,963	40,076	26,056	22,955
Gain (loss) from operations	(20,294)	(37,332)	(11,932)	1,250	(857)
Interest expense, net	(5,863)	(1,860)	(1,587)	(2,116)	(2,149)
Other expense, net	(1,490)	(1,920)	(188)	(78)	(13)
Change in estimated fair value of common stock warrant and derivative liabilities	(29,622)	(250)	—	225	(523)
Loss before income taxes	(57,269)	(41,362)	(13,707)	(719)	(3,542)
Income tax benefit	1,709	1,606	—	1,500	—
Net income (loss)	(55,560)	(39,756)	(13,707)	781	(3,542)
Net loss attributable to noncontrolling	(91)	(287)	—	—	—

interest					
Net income (loss) attributable to CareDx, Inc.	$(55,469)	$(39,469)	$(13,707)	$781	$(3,542)
Net (loss) income per share:					
Basic	$(2.38)	$(2.39)	$(1.16)	$0.13	$(3.50)
Diluted	$(2.38)	$(2.39)	$(1.16)	$0.10	$(3.50)
Shares used to compute net (loss) income per share:					
Basic	23,332,503	16,496,911	11,860,885	5,815,928	1,010,795
Diluted	23,332,503	16,496,911	11,860,885	9,283,001	1,010,795

Balance Sheet Data:

	As of December 31,	
	2017	2016
	(In thousands)	
Cash and cash equivalents	$16,895	$17,258
Working capital	(16,139)	(14,159)
Total assets	83,565	76,730
Total debt	34,059	23,944
Accumulated deficit	(268,022)	(212,553)
Total CareDx, Inc. stockholders' (deficit) equity	(6,134)	19,482

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 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 Developments

We are 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 surveillance solutions for transplant patients.

AlloMap

Our first commercialized post-transplant 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 received positive coverage decisions for reimbursement from Medicare. The 2017 Medicare reimbursement rate for AlloMap was $2,841. Effective January 1, 2018, Medicare reimburses us $3,240 for AlloMap testing of Medicare beneficiaries, which represents 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., and TRICARE.

We have 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 107,000 commercial AlloMap tests, including 15,312 tests during 2017, and we have received net proceeds of approximately $219.6 million from AlloMap testing revenues. During the year ended December 31, 2017, AlloMap was used in 125 of the approximately 141 heart transplant centers in the United States.

AlloSure

AlloSure, our recently launched commercial transplant surveillance solution for kidney transplant recipients, applies proprietary next generation sequencing to measure 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 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, but no positive coverage decisions have been made.

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 transplants, appeared in the November 2016 issue of The Journal of Molecular Diagnostics.

In May 2015, we initiated the dd-cfDNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial. The first publication of results from the DART trial in March 2017 described the validation of clinical performance characteristics of dd-cfDNA in detecting rejection in kidney allograft recipients. DART is a multicenter observational study of kidney transplant recipients where blood specimens are drawn during surveillance follow-up visits periodically after transplant and also at the time of clinically suspected acute rejection. Patients in DART will be followed for up to 24 months. We completed the first analysis of the data from DART in June 2016. By the time of the first analysis, over 400 patients had enrolled in DART in 14 centers and we had collected specimens from over 1,260 patient visits. As of December 2017, we had approximately 2,100 patient visits. The data analyses demonstrated that increased levels of dd-cfDNA, determined by the AlloSure assay, discriminated active rejection 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.

In late 2017, we established the Kidney Allograft Outcomes AlloSure Registry, or KOAR, study to develop further data on the clinical utility of AlloSure for surveillance of kidney transplant recipients. We will invite 35 centers to join KOAR, and we anticipate staggered activation of these study centers throughout 2018.

Pre-Transplant Diagnostics

With the acquisition of CareDx International AB, formerly Allenex AB or Allenex, on April 14, 2016, 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. With the acquisition of the business assets of Conexio Genomics Pty Ltd, or Conexio, on January 20, 2017, we now offer a complete product range for sequence-based typing, or SBT, of HLA alleles. Olerup SBT is a test kit for sequence based HLA typing, while Assign SBT™ is the companion software for sequence analysis. In 2014, Allenex began active development of a new HLA typing product, Olerup QTYPE, which uses real-time polymerase chain reaction, or PCR, methodology. QTYPE was commercially launched at the end of September 2016. We also offer XM-ONE, a standardized test that identifies a patient’s antigens against HLA Class I or Class II, as well as antibodies against a donor’s endothelium. This cross-match test is primarily used prior to kidney transplants.

Financial Operations Overview

Testing Revenue

Our testing revenue is derived from AlloMap and AlloSure tests, which represented 69%, 73% and 99% of our total revenues for the years ended December 31, 2017, 2016 and 2015, respectively. Our testing 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 AlloMap and AlloSure 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 an AlloMap or AlloSure test result report to the ordering physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

Product Revenue

We began recognizing product revenue following the acquisition of Allenex in the second quarter of 2016. Our product revenue is derived primarily from sales of pre-transplant Olerup products and other related product lines. Product revenue represented 30% and 26% of total revenue for the years ended December 31, 2017 and 2016. We recognize product revenue from the sale of products to end-users, distributors and strategic partners when persuasive evidence of a sale exists, the product is complete and tested and has been shipped, which coincides with transfer of title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and we do not have significant obligations for future performance. When collectability is not reasonably assured, we defer the revenue over the cash collection period. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts given to the buyer.

Collaboration, License and Other Revenue

Collaboration and 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 periodically review our estimated periods of performance based on the progress under each arrangement and account for the impact of any change in estimated periods of performance on a prospective basis.

Cost of Testing

Cost of testing reflects the aggregate costs incurred in delivering our test results to clinicians. The components of our cost of testing are materials and service costs, direct labor costs, including stock-based compensation, equipment and infrastructure expenses associated with testing samples on-site, logistics and specimen processing charges to collect and transport samples and allocated overhead including rent, information technology, equipment depreciation, utilities and royalties. Due to the significant fixed costs of testing, cost per test and gross margin are sensitive to changes in test volume. Costs associated with performing tests (except royalties) are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of testing as a percentage of revenue may vary significantly from period to period because we do not recognize all revenue in the period in which

the associated costs are incurred. Royalties for licensed technology, calculated as a percentage of test revenues, are recorded as license fees in cost of testing at the time the test revenues are recognized.

Cost of Product

Cost of product reflects the aggregate costs incurred in delivering our products to customers. The components of cost of product are material costs, manufacturing and kit assembly costs, direct labor costs, including equipment and infrastructure expenses associated with preparing kitted products for shipment, shipping, distributorship agreements 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-down of impaired, slow moving or obsolete inventory.

Research and Development Expenses

Research and development expenses, including clinical operations, represent costs incurred to develop new pre- and post-transplant diagnostic solutions, high quality evidence in support of test use, as well as continued efforts related to improving our existing product 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. We record accruals for estimated study costs comprised of work performed by contract research organizations under contract terms.

Sales and Marketing Expenses

Sales and marketing expenses represent costs incurred to sell, promote and increase awareness of our existing product lines to clinicians, hospital laboratories and payers. These efforts also include education of patients, clinicians, payers, and other relevant decision makers. Sales and marketing expenses include payroll and related expenses, educational and promotional expenses, and infrastructure expenses, including allocated facility and overhead costs. Compensation related to sales and marketing includes annual salaries and eligibility for periodic commissions or bonuses based on the achievement of predetermined sales goals or other management objectives.

General and Administrative Expenses

General and administrative expenses include costs for our executive, finance, accounting and human resources functions. Costs consist primarily of payroll and related expenses, professional service fees related to audit and accounting, certain financing transaction expenses, and legal and other contract and administrative services. We will continue to incur expenses as a result of operating as a public company.

Goodwill Impairment

We test goodwill and indefinite-lived intangibles for impairment at least annually and more frequently if impairment indicators are present. On January 1, 2017, we adopted Accounting Standards Update, or ASU, No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, or 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 our carrying amount. We have determined that we operate in two reportable segments associated with the delivery of diagnostic tests and the development and commercialization of diagnostic products. The reporting unit's carrying value is compared to its fair value. The estimated fair values of the reporting units are determined using either the market approach, income approach or a combination of the market and income approach. Goodwill is considered impaired if the carrying value of the reporting unit exceeds its estimated fair value. The income approach uses expected future operating results and failure to achieve these expected results may cause a future impairment of goodwill at the reporting unit. If the carrying value of the reporting unit exceeds its estimated fair value, an impairment charge is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss should not exceed the total amount of goodwill allocated to the reporting

unit. 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, and identified an impairment of $2.0 million related to the goodwill allocated to the Pre-Transplant reporting unit. See Note 6 of the notes in Part II, Item 8 of this Annual Report on Form 10-K for additional discussion regarding the impairment charge recorded.

In connection with our annual goodwill assessment on December 1, 2017, we performed a qualitative assessment and determined that it is not likely that the fair value of the Post-Transplant reporting unit is less than the carrying value and therefore a quantitative test to assess potential goodwill was not necessary. In 2016, the fair value of the Pre-Transplant reporting unit was $1.7 million, which was lower than its carrying value. Based on our analysis, the

implied fair value of the goodwill was lower than the carrying value of the Pre-Transplant reporting unit, resulting in a goodwill impairment charge of $13.0 million for the period ended December 31, 2016.

Change in Estimated Fair Value of Contingent Consideration

The consideration for our business combination with ImmuMetrix, Inc., or IMX, which occurred in June 2014, includes a future issuance of 227,845 shares of our common stock that is contingent upon the achievement of a specified milestone. We recorded a contingent consideration liability at its fair value at the acquisition date in June 2014. We revalue our contingent consideration obligation each reporting period. Changes in the fair value of our contingent consideration obligation are recognized as a component of operating expense within our consolidated statements of operations.

Interest Expense

Interest expense is associated with borrowings under our loan agreements.

Other Expense

For the year ended December 31, 2017, other expense primarily consisted of debt advisory fees, debt extinguishment charges related to our prior debt facility with East West Bank and foreign currency translation adjustments. For the year ended December 31, 2016, other expense primarily consisted of expenses related to a potential financing that did not eventuate.

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

The freestanding warrants issued in connection with the Private Placement, Subsequent Financing and warrants issued to the placement agents in connection with the Private Placement are recorded at their estimated fair value. We determined that the debentures and the warrants issued in connection with the JGB Debt were also free standing instruments.

The terms of the warrants include price-based anti-dilution adjustment provisions, which preclude us from classifying the warrants in equity. As such, the warrants are classified as liabilities on the consolidated balance sheet. The full fair value of the warrants was allocated on day one to the common stock warrant liability and, in the case of JGB warrants, the residual value, after allocation of the fair value of the derivative liability discussed below, was ascribed to the debentures.

The JGB debentures are classified as liabilities on the consolidated balance sheet and include certain embedded derivatives that required bifurcation, including settlement and penalty provisions. The warrants and embedded derivative will be remeasured at each reporting period with changes recorded in change in estimated fair value of common stock warrant and derivative liabilities on the consolidated statements of operations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. 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 financial statements.

On January 1, 2017, we adopted ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, or ASU 2017-01, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. We adopted ASU 2017-01 on a prospective basis and the adoption of ASU 2017-01 did not have a material impact on our consolidated financial statements.

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. Our adoption of ASU 2017-04 did not have a material impact on our consolidated financial statements.

Revenue Recognition

Testing Revenue

We recognize revenues for tests delivered when the following criteria are met: (i) persuasive evidence that an arrangement exists, which may include a contract or a coverage policy; (ii) delivery has occurred or services rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured.

The first criterion is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with us for the test. The second criterion is satisfied when we perform the test and deliver the test result to the ordering physician. The third criterion is satisfied if the third-party payer’s coverage decision or reimbursement contract specifies a price for the test. The fourth criterion is satisfied based on management’s judgments regarding the collectability of the fees charged under the arrangement.

If all criteria set forth above are met, revenue is recognized when the test results are delivered. When the first, third or fourth criteria are not met but third-party payers make a payment to us for tests performed, we recognize revenue on a cash basis in the period in which the payment is received.

For tests performed where an agreed upon reimbursement rate and a predictable history of collection exists, such as in the case of Medicare, we recognize revenue on an accrual basis upon delivery of a patient result report to the ordering physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to collect. We determine the amount we expect to collect based on a per payer, per contract or agreement basis, after analyzing historical payment trends. The expected amount is typically lower than the agreed upon reimbursement amount due to several factors, such as the amount of patient co-payments and claim denials. In all other situations, where we do not have sufficient history of collection and are unable to determine a predictable pattern of payment, we recognize revenue upon the receipt of cash. Occasionally, we may receive requests from third-party payers for refunds for previously paid-for tests. We maintain a liability for actual overpayments and estimated future refund claims based on historical experience. Accruals for overpayments and refunds are recorded as a reduction of revenue.

In 2017, 2016 and 2015, approximately 62%, 64% and 68%, respectively, of our testing revenue was recognized on the accrual basis.

The approximate number of delivered AlloMap tests and AlloMap tests for which we recognized revenue in accordance with our revenue recognition policies discussed above, were as follows:

	Year Ended December 31,		
	2017	2016	2015
AlloMap tests delivered	15,312	14,148	13,059
AlloMap tests for which revenue was recognized	10,316	9,677	9,155
AlloMap tests for which revenue was recognized, delivered prior to the period presented	1,336	1,442	1,324

Since the launch of AlloSure on October 9, 2017 through December 31, 2017, we delivered 282 patient test results. We recognized revenue of approximately $0.5 million in accordance with our revenue recognition policies discussed above.

We did not recognize revenue for the remaining AlloMap or AlloSure tests because either there was no contract, no coverage policy in place, insufficient payment history or we had not received payment for those tests from a payer. We will continue to make requests for payment from payers and patients and/or appeal payment decisions made by third-party payers. As a result, we may receive payment for a portion of these tests.

Effective January 1, 2018, under Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, or ASC 606, we will begin to recognize revenue for tests in the period in which results are delivered for those payers for which we historically waited until cash was received to record revenue. This will affect the comparability of our revenues from period to period. We will present the impact of ASC 606 on our revenue recognition in our Quarterly Reports on Form 10Q. We will continue to regularly review payer data for revenue recognition criteria and account for any changes on a prospective basis.

The process for determining the appropriate amount expected to be collected involves judgment, and considers such factors as, historical payment trends, current economic conditions and regulatory changes. The ultimate amounts of collections could be different from the amounts we estimate.

Product Revenue

We recognize product revenue from the sale of products to end-users, distributors and strategic partners when persuasive evidence of an arrangement exists, the product is complete and tested and has been shipped or delivered, as required to transfer title and risk of loss, the sales price is fixed and determinable, collection of the resulting receivable is reasonably assured, there are no material contingencies and we do not have significant obligations for future performance. When collectability is not reasonably assured, we defer the revenue until the cash is received. Provisions for estimated future product returns and allowances are recorded in the period of the sale based on the historical and anticipated future rate of returns. Revenue is recorded net of any discounts given to the buyer.

Collaboration and License Revenue

Revenue from our collaboration and license agreements was not more than 5% of total revenue for each period presented. Collaboration and 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.

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 remeasure this liability each reporting period and record changes in the fair value as a component of operating expenses.

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

Purchased Intangible Assets

Acquired intangible assets with indefinite useful lives are related to purchased in-process research and development, or IPR&D, projects and are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D 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.

We test IPR&D for impairment on an annual basis and in between annual tests if we become aware of any events or changes that would indicate that it is more likely than not that the fair values of the assets are below their carrying amounts. The IPR&D annual impairment test is performed as of December 1 of each 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 the asset to its carrying value, without consideration of any recoverability test. We have not identified any such impairment losses to date.

In September 2017, we performed a qualitative assessment on the in-process research and development asset and determined that the fair value of the asset was not below its carrying value and therefore no impairment charge was recorded. The IPR&D balance was reclassified as an intangible asset with a finite life on September 30, 2017 based on confirmation of the Medicare reimbursement rate for AlloSure, the Company’s dd-cfDNA solution, which was commercially launched on October 9, 2017.

Impairment of Long-lived Assets

We evaluate our long-lived assets for indicators of possible impairment when events or changes in circumstances indicate 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. Should an impairment exist, the impairment loss would be measured 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.

Goodwill

Goodwill represents the excess of the cost of an acquisition over the sum of the amounts assigned to tangible and identifiable intangible assets acquired, less liabilities assumed. Goodwill is not subject to amortization, but is tested for impairment on an annual basis and whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable.

We have determined that we operate in two reportable segments: Post-Transplant (associated with the delivery of diagnostic tests), and Pre-Transplant (associated with the development and commercialization of diagnostic products). Each reporting unit’s carrying value is compared to its fair value. We estimated fair values of the reporting units using

either the market approach, income approach or a combination of the market and income approach. Goodwill is considered impaired if the carrying value of the reporting unit exceeds its estimated fair value. The income approach uses expected future operating results, and failure to achieve these expected results may cause a future impairment of goodwill at the reporting unit. If the carrying value of the reporting unit exceeds its estimated fair value, the second step of the goodwill impairment test is performed by comparing the carrying value of the goodwill in the reporting unit to its implied fair value. The implied fair value is calculated by allocating all of the assets and liabilities of the reporting unit, including any unrecognized intangible assets, in a hypothetical analysis that calculates the implied fair value of goodwill in the same manner as if the reporting unit was being

acquired in a business combination. An impairment charge is recognized for the excess of the carrying value of goodwill over its implied estimated fair value. See Note 6—"Goodwill and Intangible Assets" to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the results of our goodwill impairment test.

Finite-lived Intangible Assets

Our finite-lived intangible assets resulted from the acquisition of Allenex and Conexio. We amortize finite-lived intangible assets using the straight-line method, over their estimated useful lives. The estimated useful lives range from two years to fifteen years and are based on management's estimate of the extent of the economic benefit resulting from these assets. We test for impairment on an annual basis and in between annual tests if we become 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.

Other

Warrants

On April 14, 2016 and June 15, 2016, we completed the Private Placement and Subsequent Financing, respectively, which included the issuance of freestanding warrants to certain accredited investors and placement agents to purchase shares of our common stock. On March 15, 2017, we entered into a Securities Purchase Agreement with JGB, pursuant to which we issued the JGB Debt and 1,250,000 warrants. We determined that the warrants were free standing instruments. The full fair value of the warrants was allocated on day one to the common stock warrant liability and the residual value, after allocation of the fair value of the derivative liability discussed below, was ascribed to the debentures.

The terms of our outstanding warrants include price-based anti-dilution adjustment provisions, which preclude the Company from classifying the warrants in equity. Our outstanding warrants are therefore classified as liabilities on the consolidated balance sheet and recorded at their estimated fair value. The warrants are remeasured each reporting period with changes recorded in change in estimated fair value of common stock warrant and derivative liabilities on the consolidated statements of operations. We utilize a Monte Carlo simulation model to estimate the fair value of our outstanding warrants. The Monte Carlo simulation model uses multiple input variables to estimate the probability that market conditions will be achieved. These variables include our stock price, the expected term of the warrants, the volatility of our stock prices and our peers' stock prices over such expected term, and the risk-free interest rate for the expected term of the warrants. The variables used in this simulation model are reviewed on a quarterly basis and adjusted, as needed. If we issue common stock at a price lower than the exercise price or issue stock options or other securities (other than securities issued pursuant to our stock or option plans or employment agreements, securities issued or issuable upon exercise or exchange of convertible securities outstanding as of the date the warrants were issued or securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors) with an exercise price that is lower than the current exercise price of the warrants, the exercise price of the warrants shall be adjusted to be equal to such lower price.

Embedded Derivatives

The JGB Debt includes certain embedded derivatives that require bifurcation, including settlement and penalty provisions. 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 include 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 are reviewed on a quarterly basis and adjusted, as needed.

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

Segment Information

We use the management approach for segment disclosure, which designates our internal organization used by our management for making operating decisions and assessing performance as the source of our reportable segments. We manage our business on the basis of two reportable segments as Post-Transplant, a segment focused on discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients, and Pre-Transplant, a segment that develops, manufactures, markets and sells 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.

Factors Affecting Our Performance

The Number of AlloMap and AlloSure Tests We Receive and Report

The growth of our post-transplant business is tied to the number of AlloMap and AlloSure tests we receive and report. Historically, less than two percent of AlloMap tests 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 score report. As a result, the number of samples received largely correlates directly to the number of patient result reports.

The Number of Pre-Transplant Diagnostic Products We Sell

The growth of our pre-transplant business is tied to the sales of the Olerup SSP, Olerup QTYPE, Olerup SBT and Olerup XM-ONE product lines. The pre-transplant sales organization is located in Stockholm, Sweden, Vienna, Austria, Fremantle, Australia and West Chester, Pennsylvania. Pre-transplant products are sold directly to customers in 12 countries. The pre-transplant business also uses distributors to sell products in approximately 60 countries.

How We Recognize Revenue

We recognize revenues for tests and products delivered when the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery has occurred or services rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured.

For testing revenue, the first criterion is satisfied when a third-party payer makes a coverage decision or enters into a contractual arrangement with us for the test. The second criterion is satisfied when we perform the test and deliver the test result to the ordering physician. The third criterion is satisfied if the third-party payer’s coverage decision or reimbursement contract specifies a price for the test. The fourth criterion is satisfied based on our judgments regarding the collectability of the fees charged under the arrangement. Such judgments include review of past payment history. AlloMap and AlloSure tests may be considered investigational by some payers and not covered under their reimbursement policies. Others may cover the test, but not pay a set or determinable amount. As a result, in the absence of a reimbursement agreement or sufficient payment history, collectability cannot reasonably be assured so revenue is not recognized at the time the test is delivered.

If all of the criteria set forth above are met, revenue is recognized on an accrual basis in the period when the test results are delivered. When the first, third or fourth criteria are not met but third-party payers make a payment to us for tests performed, we recognize revenue on a cash basis in the period in which the payment is received.

Revenue for tests performed is recognized on the accrual basis net of adjustments for differences between amounts billed and the estimated receipts from payers. The amount we expect to collect may be lower than the agreed upon amount due to several factors, such as the amount of patient co-payments, the existence of secondary payers and claim denials. Estimated receipts are based upon historical payment practices of payers. Differences between estimated and actual cash receipts are recorded as an adjustment to revenue, which have been immaterial to date.

Following the criteria above, Medicare and certain other payers with agreed upon reimbursement rates and a predictable history of collections allow us to recognize the related revenue on an accrual basis under U.S. GAAP. For the years ended December 31, 2017, 2016 and 2015, 37%, 36% and 32%, respectively, of our testing revenue was recognized when cash was received. Because we often need to appeal prior to being paid for certain tests, it can take over a year for a test to result in revenue being recorded and, for a portion of our tests, we may never realize revenue. Under ASC 606, revenue recognition criteria will change to recognize revenue based on the expected reimbursement rate when test results are delivered.

We will need to monitor payments for each payer to determine an expected amount of reimbursement under ASC 606 starting January 1, 2018. Because the timing and amount of cash payments received from payers are difficult to predict, we expect our revenue will fluctuate in any given quarter. In addition, when we introduce new products, we do not expect we will be able to recognize revenue from new products on an estimated reimbursement basis for some period of time.

Pre-transplant products are sold in the form of manufactured lab kits either directly to labs involved in pre-transplant testing or to distributors who sell to labs. Revenue from the sale of these products is recognized on an accrual basis when the risk and benefits of owning the kits are transferred to the customer and this occurs either upon shipment or receipt as determined by the contractual terms with customers that cover the transfer of ownership.

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 ordering physicians.

On June 10, 2016, Centers for Medicare & Medicaid Services, or CMS, announced proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the gapfill reimbursement rate for 2017, AlloMap reimbursement for patients covered by Medicare would have been reduced from $2,821 to $1,921, effective January 1, 2017. This reimbursement rate, determined by gapfill submissions from the MACs, was open to reconsideration submissions until October 31, 2016. We submitted a request for reconsideration of the reimbursement rate determined by the MACs and in November 2016 CMS released the 2017 Clinical Laboratory Fee Schedule reflecting the final rate of reimbursement at $2,841, an increase of $20 compared to the 2016 fee schedule.

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 will begin in 2017 and the new market based rates will take effect January 1, 2018. On November 20, 2017, Medicare released the preliminary 2018 Clinical Laboratory Fee Schedule. Effective January 1, 2018, Medicare plans to reimburse us $3,240 for AlloMap testing of Medicare beneficiaries, which represents a 14% increase over the 2017 reimbursement rate.

Reimbursement for AlloSure

On September 26, 2017 we announced that the Molecular Diagnostics Services, or MolDX, Program developed by Palmetto GBA has 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.

Acquisition of Allenex and Conexio Assets

With the acquisition of Allenex, on April 14, 2016, 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. With the acquisition of the business assets of Conexio on January 20, 2017, we now offer a complete product range for SBT of HLA alleles. Olerup SBT is a test kit for sequence based HLA typing, while Assign SBT™ is the companion software for sequence analysis. In 2014, Allenex began active development of a new HLA typing product, Olerup QTYPE, which uses real-time PCR methodology. QTYPE was commercially launched at the end of September 2016. We also offer XM-ONE, a standardized test that identifies a patient's antigens against HLA Class I or Class II, as well as antibodies against a donor's endothelium. This cross-match test is primarily used prior to kidney transplants.

Development of Additional Products

We rely on sales of AlloMap, Olerup SSP, Olerup SBT and XM-ONE to generate the majority of our revenue. Our product development pipeline includes other transplant diagnostic solutions to help clinicians and transplant centers make personalized treatment decisions throughout a transplant patient's lifetime. Currently, our product development pipeline includes new products such as AlloSure, which was commercially launched on October 9, 2017, and Olerup QTYPE, which was commercially launched at the end of September 2016 with ongoing commitment to including additional instrument testing platforms. We expect to invest in research and development in order to develop additional products. Our success in developing new products 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 experiments and clinical studies 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 obtained 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 AlloMap and AlloSure 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, 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)
Other expense, net	(1,490)	(1,920)	430
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 Revenue

Testing 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 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.

Collaboration and License Revenue

Collaboration and license 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

Cost of testing 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 pre-transplant 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 pre-transplant sales and marketing payroll related expenses, due mainly to pre-transplant 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 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 Pre-transplant entity. No additional goodwill impairment was recorded in the year ended December 31, 2017.

Change in Estimated 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.

Other Expense, Net

Other expense decreased $0.4 million, or 22%, in 2017 compared to 2016. The decrease reflects a net $2.1 million charge in 2016 to expense financing costs associated with a proposed six-month bridge loan that did not materialize. This decrease was primarily offset by an increase in foreign exchange translation losses of $0.9 million, a $0.3 million loss on a $1.25 million conversion of JGB debt, $0.3 million debt extinguishment fees on East West Bank debt, and $0.1 million in JGB Debt issuance costs.

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 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 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 re-measurement of the deferred tax asset, partially offset by valuation allowance.

Comparison of the Years Ended December 31, 2016 and 2015

(In thousands)

	Year Ended December 31,		
	2016	2015	Change
Revenue:			
Testing revenue	$29,680	$27,881	$1,799
Product revenue	10,715	—	10,715
Collaboration and license revenue	236	263	(27)
Total revenue	40,631	28,144	12,487
Operating expenses:			
Cost of testing	10,882	10,273	609
Cost of product	10,240	—	10,240
Research and development	12,385	9,333	3,052
Sales and marketing	11,166	8,349	2,817
General and administrative	20,725	12,247	8,478
Goodwill impairment charge	13,021	—	13,021
Change in estimated fair value of contingent consideration	(456)	(126)	(330)
Total operating expenses	77,963	40,076	37,887
Loss from operations	(37,332)	(11,932)	(25,400)
Interest expense, net	(1,860)	(1,587)	(273)
Other expense, net	(1,920)	(188)	(1,732)
Change in estimated fair value of common stock warrant and derivative liabilities	(250)	—	(250)
Income tax benefit	1,606	—	1,606
Net loss	(39,756)	(13,707)	(26,049)
Net loss attributable to noncontrolling interest	(287)	—	(287)
Net loss attributable to CareDx, Inc.	$(39,469)	$(13,707)	$(25,762)

Testing Revenue

The number of AlloMap test results delivered increased by 1,089; or 8%; in 2016 compared to 2015. Testing revenue increased by $1.8 million, or 6%, in 2016 compared to 2015 due to the increase in test volume, partially offset by a mix shift from reimbursement from Medicare to commercial insurance, including cash basis payers with whom

achieving revenue recognition takes more time.

Product Revenue

Product revenue reported for the year ended December 31, 2016 was $10.7 million related to the sales or our pre-transplant products. The Allenex acquisition occurred on April 14, 2016 and therefore 2016 is not comparable to 2015.

Collaboration and License Revenue

Collaboration and license revenue decreased slightly in 2016 compared to 2015 primarily due to a decrease in royalties received under our services agreement with CardioDx, Inc.

Cost of Testing

Cost of testing increased by approximately $0.6 million, or 6%, in 2016 compared to 2015 primarily due to higher headcount related expenses of $0.2 million and laboratory material costs of $0.3 million to support testing volume growth. The increase also reflects higher royalties paid to Roche of $0.1 million resulting from the increase in testing revenue on which the royalty is based.

Cost of Product

Cost of product reported for the year ended December 31, 2016 of $10.2 million was incurred by us as a result of the acquisition of Allenex on April 14, 2016, and represents cost of product from our sales of pre-transplant products. Cost of product includes $4.0 million of amortization of the acquisition-related mark-up in the value of inventory and $1.0 million of acquisition-related amortization of intangible assets.

Research and Development

Research and development expenses increased $3.1 million, or 33%, in 2016 compared to 2015. The increase reflects a $1.6 million increase in headcount related expenses; $1.0 million of expense incurred due to our acquisition of Allenex on April 14, 2016, primarily for the development of Olerup QTYPE; and an increase in clinical trial expenditures to support the clinical validity and utility of AlloSure.

Sales and Marketing

Sales and marketing expenses increased by approximately $2.8 million, or 34%, in 2016 compared to 2015. The increase reflects our acquisition of Allenex on April 14, 2016. We incurred approximately $3.4 million of sales and marketing expense related to the pre-transplant business, including costs for trade shows and marketing efforts for the commercial launch of QTYPE at the end of September 2016 and includes $0.7 million of acquisition-related amortization of purchased intangible assets. This increase was partly offset by reduced spending on discretionary marketing activities related to AlloMap.

General and Administrative

General and administrative expenses increased by approximately $8.5 million, or 69%, in 2016 compared to 2015. This increase reflects approximately $2.0 million of general and administrative expenses incurred by the pre-transplant business subsequent to the acquisition. The increase also reflects $5.6 million of audit, legal, tax, and other professional and consulting fees incurred primarily in connection with our acquisition of Allenex. The remaining increase reflects employee related costs, fees for consulting, and professional service fees and financial advice related to the first corporate consolidation of the pre-transplant business, enhancing our internal controls, financing activities and legal defense.

Goodwill impairment

We tested goodwill for impairment as of December 1, 2016. We performed step one of our annual goodwill impairment test and determined that the fair value of the Pre-Transplant reporting unit was $1.7 million, which was lower than its carrying value. A reduction in our forecasted revenue and operating results for the Pre-Transplant reporting unit was the primary cause of the reduction in fair value as compared with our forecast as of the acquisition of Allenex in April 2016. Our forecasted revenues and operating results were adversely impacted by an earlier-than-expected market adoption of NGS and/or q-PCR technology and increased competition from other companies that compete with or will compete with our pre-transplant products. We then were required to perform the

second step of the two-step process for the Pre-Transplant reporting unit. The second step of the analysis included allocating the calculated fair value of the reporting unit to its assets and liabilities, using a present value analysis, in order to determine an implied fair value of goodwill. Based on the Company's analysis, the implied fair value of the goodwill was lower than the carrying value of the Pre-Transplant reporting unit. Accordingly, we recorded a goodwill impairment charge of $13.0 million on December 1, 2016.

Change in Fair Value of Contingent Consideration

We revalued the contingent consideration liability for the years ended December 31, 2016 and 2015 and recognized non-cash gains of $0.5 million and $0.1 million, respectively, within our consolidated statement of operations as a result of changes in the market value of our common stock during those periods.

Interest Expense, Net

Interest expense increased by $0.3 million, or 17%, in 2016 compared to 2015. In connection with our acquisition of Allenex on April 14, 2016, we assumed its existing debt and incurred interest expense of $0.5 million on the assumed debt following the acquisition. In 2015, we incurred a loss on extinguishment of debt of $0.6 million resulting from our pay-off of a term loan in January 2015.

Other Expense, Net

Other expense increased $1.7 million in 2016 compared to 2015. The increase reflects a $2.1 million expense related to a potential financing that did not eventuate. These charges were partially offset by $0.4 million of foreign currency transactions gains.

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

The freestanding warrants issued in connection with the Private Placement, Subsequent Financing and warrants issued to the placement agents in connection with the Private Placement are recorded at their estimated fair value. The warrants were remeasured on December 31, 2016 and a remeasurement charge of $0.3 million was recognized.

Income Tax Benefit

In conjunction with the acquisition of acquisition of Allenex, a tax benefit of $1.6 million was recognized in 2016. This benefit primarily resulted from the expectation that amortization of the various intangible assets acquired, when completed and placed in service, is not expected to be deductible for tax purposes. Accordingly, a deferred tax liability was recorded at the acquisition date for the difference between the financial reporting and tax basis of the intangible assets.

Liquidity and Capital Resources

We have incurred significant losses and negative cash flows from operations since our inception and had an accumulated deficit of $268.0 million at December 31, 2017. As of December 31, 2017, we had cash and cash equivalents of $16.9 million, and $34.1 million of debt outstanding under our debt and capital lease obligations, net of debt discount, of which $15.7 million is current.

Deferred Purchase Consideration

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex for an aggregate purchase consideration of approximately $34.1 million which consisted of (i) $26.9 million of cash, of which $6.2 million (which represented SEK 50,620,000 as of the Allenex acquisition date), and which was recorded at its fair value of $5.7 million, was deferred purchase consideration originally payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB, or 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 our common stock valued at $7.2 million. 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 our obligations to the Former Majority Shareholders at a rate of 10.0% per year commencing on January 1, 2017 and was scheduled to continue to accrue until the date the obligations were paid in full. Of the total cash consideration, $8.0 million of cash payable to the Former Majority Shareholders was deposited into an escrow account by us and subsequently invested in us by the Former Majority Shareholders through a purchase of our equity securities in the Subsequent Financing, which was completed on June 15, 2016. Upon the completion of the Subsequent Financing, certain contingencies in the conditional share purchase agreements entered into with the Former Majority Shareholders, or the Conditional Share Purchase Agreements, were waived, and the deferred purchase consideration was due to the Former Majority Shareholders by no later than July 1, 2017. Our deferred purchase consideration obligations are secured by a pledge of shares of Allenex. We determined at the date of the acquisition that the contingencies would be waived. We

intend to complete compulsory acquisition proceedings under Swedish law to purchase the remaining shares of Allenex. We will do so in accordance with all applicable Swedish law, and concluded this process in March 2018. On June 8, 2016, we delisted Allenex's common stock from Nasdaq OMX Stockholm AB.

On July 1, 2017, we entered into amendments to the Conditional Share Purchase Agreements with the Former Majority Shareholders, pursuant to which, among other things, we agreed (i) to immediately convert approximately $1.1 million of the $6.3 million deferred purchase consideration owed by us to the Former Majority Shareholders under the Conditional Share Purchase Agreements, or the Deferred Obligation, into 1,022,544 shares of our common stock at a per share price equal to $1.12; (ii) to make an immediate cash payment of $0.5 million; (iii) to 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) that approximately $2.1 million of the Deferred Obligation would become payable on December 31, 2017, unless earlier converted into 1,791,762 shares of common stock prior to that date, of which issuance of shares is subject to approval by our stockholders.

On November 14, 2017, we entered into amendments to the Conditional Share Purchase Agreement with the Former Majority Shareholders, whereby we immediately repaid the total remaining deferred purchase consideration of $4.7 million, plus accrued interest.

Allenex Notes

On June 28, 2013, Allenex issued promissory notes, or the Allenex Notes, to FastPartner and Mohammed Al Amoudi in an aggregate amount of SEK 9,400,000 and SEK 10,600,000, approximately $1.1 million and $1.3 million, respectively. An additional SEK 2,000,000 and SEK 4,000,000 were issued to FastPartner in 2015 and 2016, totaling approximately $4.1 million, including accrued interest to be due on July 1, 2017. On July 1, 2017, Allenex entered into new note agreements with each of FastPartner and Mohammed Al Amoudi, pursuant to which, the parties agreed to defer repayment of the amounts owed under the Allenex Notes until March 31, 2019. Refer to Note 18 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding our requirement to repay the Allenex Notes using the proceeds from the Perceptive Term Loan.

Danske Bank Term Loan

On June 25, 2013, Allenex entered into a Term Loan Facility Agreement with Danske Bank A/S, or Danske, which had an outstanding principal amount of SEK 50,000,000 (approximately $6.1 million) on December 31, 2017. A quarterly debt covenant, was violated on June 30, 2016 and September 30, 2016. We obtained waivers for these violations. We were not in compliance with certain covenants at March 31, 2017, June 30, 2017 or September 30, 2017. We obtained a waiver for these violations. The waiver was conditional upon, among other things, us 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. We are not in compliance with the quarterly covenants on December 31, 2017. Refer to Note 18 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding our requirement to repay the Danske Bank Term Loan Facility using the proceeds from the Perceptive Term Loan.

JGB Debt

On March 15, 2017, we completed a convertible debt financing with JGB for net proceeds of $24.0 million. The proceeds from the convertible debt facility were used to pay off our $11.2 million debt facility with East West Bank. In addition, the debt agreement requires us to maintain a minimum of $9.4 million of cash at a named financial institution. These funds are restricted as to withdrawal and are not available to us to fund our operations or repay indebtedness. Refer to Note 18 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details regarding our requirement to repay the JGB Debt using the proceeds from the Perceptive Term

Loan.

Going Concern

As of December 31, 2017, we had cash and cash equivalents of $16.9 million and an accumulated deficit of $268.0 million. On March 1, 2018, we entered into a binding commitment letter with Perceptive, pursuant to which Perceptive committed to provide us with a term loan of up to $35.0 million, subject to funding in two tranches. We are required to use the proceeds from the Perceptive Term Loan, in part, to repay the JGB Debt, the Allenex Notes

and the Danske Bank term loan. We believe that our existing cash balance and expected revenue along with the net proceeds from our debt financing, will be sufficient to meet our anticipated cash requirements for a period of at least 12 months from the issuance of our consolidated financial statements.

We may require future additional financing to fund working capital and pay our obligations as they come due. Additional financing might include one or more offerings and one or more of a combination of equity securities, 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.

Our financial statements have been prepared assuming we will continue as a going concern through twelve months from the filing date of our Annual Report on Form 10-K for the year ended December 31, 2017, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassifications of assets and liabilities that might be necessary if we can no longer continue as a going concern.

The following table summarizes our cash flows for the years ended December 31, 2017, 2016 and 2015:

	Year Ended December 31,		
	2017	2016	2015
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$(14,307)	$(16,523)	$(9,752)
Investing activities	(6,164)	(21,117)	(1,199)
Financing activities	20,004	24,927	4,408
Effect of exchange rate on cash and cash equivalents	104	83	—
Net decrease in cash and cash equivalents	$(363)	$(12,630)	$(6,543)

Cash Flows from Operating Activities

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

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, including: a $29.6 million loss on the revaluation of warrants and derivative liabilities to estimated fair value, $3.8 million of depreciation and amortization, a $3.5 million amortization of debt discount and noncash interest expense, $2.0 million of goodwill impairment, and a $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 and included our spending on research and development with total costs of $12.4 million in the year ended December 31, 2016, and our $8.5 million of increased general and administrative cost mostly related to our acquisition of Allenex. 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.

Net cash used in operating activities for the year ended December 31, 2015 was $9.8 million. Our net loss of $13.7 million included $2.1 million of net non-cash expenses. These net noncash expenses included stock-based compensation expense of $1.3 million, depreciation and amortization expense of $0.8 million and $0.2 million for the amortization of debt issuance costs associated with new debt, and a loss on extinguishment from previous debt. These non-cash expenses were partially offset by a non-cash revaluation gain of $0.1 million on a contingent consideration liability related to our acquisition of IMX, in June 2014. This revaluation gain was driven by a decrease in our stock price.

Cash Flows from Investing Activities

For the year ended December 31, 2017, net cash used in investing activities was $6.2 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.

For the year ended December 31, 2015, net cash used in investing activities was $1.2 million for purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 was $20.0 million, which primarily reflected the proceeds from the 2017 Public Offering of $18.3 million, the JGB debt proceeds of $24.0 million and $1.0 million related to the exercise of warrants. These amounts were offset by $12.8 million of East West Bank extinguishments, $1.5 million principal payments on Danske debt, $0.1 million of capital lease obligations and the restriction of $9.4 million of cash related to our JGB debt.

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, 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.

Net cash provided by financing activities for the year ended December 31, 2015 of $4.4 million consisted primarily of $15.6 million in net proceeds received from a new term loan in January 2015, and proceeds of $0.2 million from the issuance of common stock as part of our employee stock purchase plan and the exercise of stock options, partially offset by the payoff of a previous term loan and capital leases of $11.5 million.

Contractual Obligations

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 the information required under this item.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

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 balance sheets contain certain recorded assets and liabilities in foreign countries, primarily Sweden, Australia and Austria. 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.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-02, Leases (Topic 842), which, for operating leases, requires the lessee to recognize a right-of-use 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, on a generally straight-line basis. This guidance will be effective for us in fiscal year 2019 and must be adopted using a modified retrospective transition approach. Early adoption is permitted. We are currently assessing the impact of this guidance will have on its consolidated financial statements.

In March 2016, the FASB issued ASU No 2016-09, Compensation - Stock Compensation (Topic 718) -Improvements to Employee Share-Based Payment Accounting, or ASU 2016-09. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. This ASU will be effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. Early adoption is permitted. We are currently assessing the potential effects of this ASU on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, or ASU 2016-10. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), or ASU 2016-08. These amendments provide additional clarification and implementation guidance on the previously issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09, which is based on principles that govern the recognition of revenue at an amount an entity expects to be entitled to when products are transferred to customers. The amendments in ASU 2016-10 provide clarifying guidance on materiality of performance obligations; evaluating distinct performance obligations; treatment of shipping and handling costs; and determining whether an entity’s promise to grant a license provides a customer with either a right to use an entity’s intellectual property or a right to access an entity’s intellectual property. The amendments in ASU 2016-08 clarify how an entity should identify the specified good or service for the principal versus agent evaluation and how it should apply the control principle to certain types of arrangements. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses certain issues on assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. In December 2016, the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which makes technical corrections and improvements to the new revenue standard. These ASUs will be effective for us in the first quarter of fiscal year 2018.

The guidance may be applied (i) retrospectively to each prior period presented, or (ii) retrospectively with the cumulative effect recognized as of the date of adoption. We have selected the modified retrospective approach with the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained earnings. We have substantially completed an evaluation of the impact of adopting this guidance will have on our consolidated financial statements and disclosures. We currently anticipate that we will record a cumulative adjustment to retained earnings and accounts receivable of approximately $2.0 million to $3.0 million, as of January 1, 2018 to reflect the adoption of Topic 606. The adjustment is primarily related to the change in revenue recognition for cash basis tests which will be recognized when the results have been delivered as opposed to in the period in which cash is received. The adoption of ASU 2014-09 will create additional disclosures for us.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, 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, with early adoption permitted. Adoption of the ASU is retrospective. We do not expect the adoption of ASU 2016-15 to have a material impact on its condensed 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), or 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. Early adoption is permitted. We do not expect the adoption of ASU 2016-18 to have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business, or ASU 2017-01. In an effort to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of ASU 2017-01 are effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. We adopted ASU 2017-01 on a prospective basis and the adoption of ASU 2017-01 did not have a material impact on our consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-04"). This guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable. ASU 2017-04 is effective for all interim and annual reporting periods beginning after December 15, 2019. We adopted ASU No. 2017-04 on January 1, 2017 on a prospective basis.

In February 2017, the FASB issued ASU No. 2017-05, Other Income—Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20) Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets, or ASU 2017-05. ASU 2017-05 clarifies the scope of derecognition of assets, defines in substance nonfinancial asset, adds guidance for partial sales of nonfinancial assets and clarifies the recognition of gains and losses from the transfer of nonfinancial assets in contracts with noncustomers. ASU 2017-05 will become effective for all interim and annual reporting periods beginning after December 15, 2018 and may be adopted using a full retrospective or a modified retrospective approach. We are required to adopt the amendments in ASU 2017-05 at the same time it adopts the amendments in ASU 2014-09. We do not expect the adoption of ASU 2017-05 to have a material impact on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting, or 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. Early adoption is permitted. Any updates will be applied prospectively. We do not currently have modifications of share based payments.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Exchange Risk

Our pre-transplant business has operations in Sweden, Austria, Australia and sells to countries throughout the world. As a result, we are subject to significant foreign currency exposures, including transacting in foreign currencies, investment in a foreign entity, as well as assets and debts denominated in foreign currencies. Our testing revenue is primarily denominated in U.S. dollars. Our product revenue is denominated primarily in Euro, Swedish

Krona, Australian dollars and U.S. dollars. Consequently, our revenue denominated in foreign currency is subject to foreign currency exchange risk. A portion of our operating expenses are incurred outside of the U.S. and are denominated in Euro, Swedish Krona 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, 2017 would have negatively impacted our annual financial results by $1.0 million and our product revenue by $1.0 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.

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business, including interest rate risk. We had cash and cash equivalents of $16.9 million and $17.3 million at December 31, 2017 and 2016, respectively, which consisted of bank deposits and money market funds. Additionally, we had debt of $34.1 million as of December 31, 2017, of which $6.8 million was subject to variable interest rates.

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 $0.1 million on our consolidated financial statements.

CareDx, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CareDx, Inc. (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), convertible preferred stock and stockholders' (deficit) equity and cash flows for each of the three 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 referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for each of the three 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 since 2009.

Redwood City, California

March 22, 2018

CareDx, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share data)

	As of December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$16,895	$17,258
Accounts receivable	2,991	2,768
Inventory	5,529	5,461
Prepaid and other assets	1,352	1,186
Total current assets	26,767	26,673
Property and equipment, net	2,075	2,931
Intangible assets, net	33,139	33,124
Goodwill	12,005	13,839
Restricted cash	9,579	143
Other noncurrent assets	—	20
Total assets	$83,565	$76,730
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$3,391	$3,065
Accrued payroll liabilities	5,013	3,851
Accrued and other liabilities	3,735	5,320
Accrued royalties	-	263
Deferred revenue	39	42
Deferred purchase consideration	407	5,445
Derivative liability	14,600	—
Current portion of long-term debt	15,721	22,846
Total current liabilities	42,906	40,832
Deferred rent, net of current portion	913	1,301
Deferred revenue, net of current portion	730	759
Deferred tax liability	4,933	6,057
Long-term debt, net of current portion	18,338	1,098
Contingent consideration	1,672	492
Common stock warrant liability	18,712	5,208
Other liabilities	1,315	1,222
Total liabilities	89,519	56,969
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 10,000,000 shares authorized at December 31, 2017 and 2016; no shares issued and outstanding at December 31, 2017 and 2016	—	—
Common stock: $0.001 par value; 100,000,000 shares authorized at December 31,	29	21

2017 and 2016; 28,825,019 and 21,278,373 shares issued and outstanding at December 31, 2017 and 2016, respectively		
Additional paid-in capital	264,204	235,673
Accumulated other comprehensive loss	(2,345)	(3,659)
Accumulated deficit	(268,022)	(212,553)
Total CareDx, Inc. stockholders' (deficit) equity	(6,134)	19,482
Noncontrolling interest	180	279
Total stockholders' (deficit) equity	(5,954)	19,761
Total liabilities and stockholders' (deficit) equity	$83,565	$76,730

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

CareDx, Inc.

Consolidated Statements of Operations

(In thousands, except share and per share data)

	Year Ended December 31,		
	2017	2016	2015
Revenue:			
Testing revenue	$33,106	$29,680	$27,881
Product revenue	14,634	10,715	—
Collaboration and license revenue	584	236	263
Total revenue	48,324	40,631	28,144
Operating expenses:			
Cost of testing	12,345	10,882	10,273
Cost of product	9,026	10,240	—
Research and development	12,388	12,385	9,333
Sales and marketing	12,808	11,166	8,349
General and administrative	18,913	20,725	12,247
Goodwill impairment	1,958	13,021	—
Change in estimated fair value of contingent consideration	1,180	(456)	(126)
Total operating expenses	68,618	77,963	40,076
Loss from operations	(20,294)	(37,332)	(11,932)
Interest expense, net	(5,863)	(1,860)	(1,587)
Other expense, net	(1,490)	(1,920)	(188)
Change in estimated fair value of common stock warrant and derivative liabilities	(29,622)	(250)	—
Loss before income taxes	(57,269)	(41,362)	(13,707)
Income tax benefit	1,709	1,606	—
Net loss	(55,560)	(39,756)	(13,707)
Net loss attributable to noncontrolling interest	(91)	(287)	—
Net loss attributable to CareDx, Inc.	$(55,469)	$(39,469)	$(13,707)
Net loss per share attributable to CareDx, Inc. (Note 3):			
Basic	$(2.38)	$(2.39)	$(1.16)
Diluted	$(2.38)	$(2.39)	$(1.16)
Weighted average shares used to compute net loss per share attributable to CareDx, Inc.:			
Basic	23,332,503	16,496,911	11,860,885
Diluted	23,332,503	16,496,911	11,860,885

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

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CareDx, Inc.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Year ended December 31,		
	2017	2016	2015
Net loss	$(55,560)	$(39,756)	$(13,707)
Other comprehensive loss:			
Foreign currency translation adjustments	1,306	(3,727)	—
Net Comprehensive loss	(54,254)	(43,483)	(13,707)
Comprehensive loss attributable to noncontrolling interest, net of tax	(99)	(355)	—
Comprehensive loss attributable to CareDx, Inc.	$(54,155)	$(43,128)	$(13,707)

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

CareDx, Inc.

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

(In thousands, except share data)

	Convertible Preferred Stock Shares	Amount	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Noncontrolling Interest	Total Stockholders' (Deficit) Equity
Balance at December 31, 2014	—	—	11,803,970	12	200,661	—	(159,377)	—	41,296
Issuance of common stock for Board of Director services	—	—	38,121	—	223	—	—	—	223
Issuance of common stock for cash upon exercise of stock options	—	—	23,576	—	46	—	—	—	46
Issuance of common stock under equity incentive plans	—	—	36,696						