CareDx, Inc.
Form 10-K
April 21, 2017

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, 2016

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 Global 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, 2016 as reported by The NASDAQ Global Market on such date was approximately $49,002,299. 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 April 18, 2017 was 21,391,266.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement relating to the 2017 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, 2016.

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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® and future post-transplant solutions, if any, and our ability to increase the commercial success of AlloMap;
- our ability to generate revenue from sales of Olerup SSP® products, sequence-based typing, or SBT Resolver™, XM-ONE, and future pre-transplant solutions, 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, including donor-derived cell-free DNA, or dd-cfDNA (which includes our AlloSure® test), and solutions for the surveillance of heart, kidney, and other solid organ transplant recipients;
- our plans and ability to continue updating our sequence specific primer, or SSP, 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, or HLA, typing, such as a quantitative real-time polymerase chain reaction, or q-PCR, methodology (which includes QTYPE™) 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 integrate our business with the business of Allenex AB, or Allenex, and to realize the anticipated benefits of the acquisition;
- 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 remediate the four material weaknesses in our internal control over financial reporting as of December 31, 2016; and
- our ability to comply with the requirements of being a public company.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the section entitled “Risk Factors” included in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed with the Securities and Exchange Commission, or SEC, as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all forward-looking statements by these cautionary statements.

PART I

ITEM 1. BUSINESS

Company Overview

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. Our first commercialized post-transplant testing solution, the AlloMap heart transplant molecular test, or AlloMap, is a gene expression testing service 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. We are also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, our proprietary next-generation sequencing-based test to detect donor derived cell-free DNA, or dd-cfDNA, after transplantation.

In April 2016, we acquired Allenex AB, or Allenex or Olerup. Through the Allenex acquisition, we also develop, manufacture, market and sell products that increase the chance of successful transplants by facilitating a better pre-transplant match between a donor and a recipient of stem cells and organs. Olerup SSP, a set of Human Leukocyte Antigen, or HLA, typing, is used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. Olerup SSP is used to type HLA alleles based on sequence-specific primer, or SSP, technology, is one of the market leaders and has long been a well-established brand name in Europe and select other markets for pre-transplant solutions. We frequently update typing kits to include newly discovered alleles, resulting in what we believe is one of the most up-to-date and comprehensive allele libraries for the SSP technology. We also offer XM-ONE®, which we believe is the first standardized test that quickly identifies a patient’s antigens against HLA Class I or Class II, as well as antibodies against a donor’s endothelium. This crossmatch test has primarily been used prior to kidney transplants, and more recent clinical trials are further demonstrating its value as a complement to traditional antibody testing prior to these types of transplants. In 2014, Allenex began active development of a new HLA typing product, QTYPE, and commercially launched the product at the end of September 2016. QTYPE uses real-time PCR, or q-PCR, methodology.

From 2011 to January 2017, Allenex, through its subsidiary, Olerup SSB AB, was the exclusive global distributor of the HLA sequence-based typing products SBT Resolver and Assign SBT from Conexio Genomics, or Conexio, which is an Australian-based company that specializes in the development of sequencing of HLA typing, among other technologies. Illumina, Inc. acquired Conexio, Inc. and, in January 2017, we acquired from Illumina the elements necessary to continue offering the SBT line of products to our customers and Conexio’s legacy customers that were not included in the initial distribution agreement.

Since the launch of AlloMap in January 2005, we have performed more than 93,000 commercial AlloMap tests, including 14,148 tests during 2016, in our Brisbane, California laboratory. Since the commercial launch of AlloMap

through December 31, 2016, we have received net proceeds of approximately $189.4 million from AlloMap testing revenues. During the year ended December 31, 2016, AlloMap was used in 100 of the approximately 125 heart transplant centers in the United States. As of December 31, 2016, substantially all of our testing and product revenues came from the United States and Europe, and substantially all of our assets and operations are located in the United States and Sweden. In 2013, we began a partnership with Diaxonhit SA, or Diaxonhit, the leading French provider of specialty in-vitro diagnostic solutions for transplantation, to expand our AlloMap offering in Europe for which we have secured a dedicated laboratory. On May 25, 2016, Diaxonhit announced that it had entered into a services agreement with University Hospital of Strasbourg to open a center dedicated to AlloMap testing. We

believe the lab meets all of the quality and safety requirements to ensure the accuracy and reproducibility of the results of AlloMap. Further, its Strasbourg, France location is centrally located in the heart of Europe, which is ideal for servicing heart transplant centers throughout Europe. As a result of our acquisition of Allenex, we have further increased our international presence.

AlloMap has received positive coverage decisions for reimbursement from Medicare and many of the largest U.S. private payers, including Aetna, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc., TRICARE National Insurance and WellPoint. We believe our success in achieving coverage and reimbursement confirms the value proposition of AlloMap to our key constituents.

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.

In addition to our current offering of surveillance solutions, we are also engaged in efforts to develop additional testing solutions in the heart transplant market and new testing solutions in other organ transplant markets. For instance, AlloSure, our development stage transplant surveillance solution, applies proprietary next generation sequencing to detect and quantitate genetic differences between 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, irrespective of the type of organ transplanted. In late 2015, we announced the completion of analytical validation of AlloSure. Samples used in the analytical validation included donor recipient pairs with unrelated 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 (2016).

As part of our development efforts for AlloSure, we initiated the Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial in May 2015. DART was designed to establish clinical validation, or the clinical performance characteristics of dd-cfDNA in detecting clinical and sub-clinical rejection in kidney allograft recipients. DART is a multicenter observational study of kidney transplant recipients where blood specimens are drawn periodically after transplant during follow up visits and also after treatment for acute rejection. DART was also designed to demonstrate the correlation of dd-cfDNA to renal function through comparison to both serum creatinine and estimated glomerular filtration rate. Patients will be followed in DART for a minimum of 18 months. We completed the first analysis of the data from DART in June 2016. By the time of completion 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 before enrollment was closed. The study demonstrated increased levels of dd-cfDNA in acute rejection using the non-invasive AlloSure assay. Based on the analytical validity and first analysis clinical validation data, we, in collaboration with clinical investigators, submitted two manuscripts that have been accepted for scientific peer-reviewed publication. The study reports appeared in the Journal of the American Society of Nephrology and the Journal Applied Laboratory Medicine in March 2017. With the relevant information from the first analysis, we plan to perform a second clinical trial named Renal Transplant Utility of Level of dd-cfDNA (Allosure): Impact on Patient Management, or TULIP. TULIP will further establish the clinical utility of our dd-cfDNA kidney solution and provide the framework to engage with payers in an effort to ensure future access to and reimbursement for this novel non-invasive test for transplant surveillance.

On November 29, 2016, we submitted our AlloSure test dossier to the Molecular Diagnostic Services Program, or MolDX, for a technical assessment in support of a coverage determination. Our submission was accepted by MolDx for technical assessment in early December 2016 and the assessment is currently in process and a coverage determination has not been made. The MolDX, launched in 2011, is administered by Palmetto GBA for the Centers for Medicare & Medicaid Services. Palmetto GBA is responsible for conducting a complete technology assessment to determine coverage, coding, and pricing for molecular diagnostic tests and other molecular pathology services

administered through MolDx. MolDx's policies are also followed by three other Medicare Administrative Contractors: Noridian, CGS, and WPS.

In April of 2016, we acquired Allenex with headquarters in Stockholm, Sweden. Allenex develops manufactures and sells kits for the pre-transplant market with an emphasis on HLA typing products. The immune system uses HLA markers to distinguish self- from non-self. In January 2017, we acquired assets from Conexio Genomics Pty Ltd., or Conexio, based in Freemantle, Australia. Conexio also develops and manufactures HLA typing products for the pre-transplant market. These transactions associated with pre-transplant products complement the post-transplant products we currently offer and are developing and will facilitate our ability to provide products across the transplant continuum (prior to and including the transplant as well as patient management post-transplant).

We are organized and operate in two reportable segments. See "Management's Discussion and Analysis of Financial Conditions and Results of Operations" included in Part II, Item 7 of this Annual Report on Form 10-K. 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.

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, again we changed our name, this time 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 IMX, a privately held development-stage company working 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 Stanford 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 creates an international transplant diagnostics company with product offerings along the pre and post-transplant continuum. Allenex's Olerup SSP line, which addresses HLA testing, is well recognized by the transplant community. 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.

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. For example, based on internal calculations derived from an internal analysis as of 2011, heart transplant recipients often incur lifetime costs of more than $1.9 million and kidney transplant recipients often incur lifetime costs of more than $1.1 million. 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 via the recipient's neck and threaded through blood vessels into the inner chamber of the heart. Four pieces of tissue are cut from the wall of the heart and sent to a laboratory for examination by a pathologist who uses a microscope to look for evidence of cellular rejection. Due to the limitations of biopsies, including (i) pathologist evaluations, which are subjective and dependent upon visual assessment and qualitative interpretation, (ii) the risk of sampling errors, and

(iii) the potential for complications and other health risks, these procedures are not frequently used by clinicians to tailor the use of immunosuppressants. The typical schedule of biopsy surveillance may involve eight to ten biopsies within the first six months after transplant and a total of ten to fifteen biopsies within the first year post-transplant. Because repeated biopsies incur cumulative risk and trauma to the recipient, the frequency of biopsy surveillance after one year has been 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 risks associated with such invasive procedures. Therefore, the main clinical test of transplanted kidney dysfunction is an investigation of serum creatinine levels. An increase in such levels is an indicator of kidney dysfunction, and though this test is widely used, literature suggests it may be nonspecific and detect dysfunction only after significant and irreversible renal function loss has occurred.

As the current solutions for the surveillance of organ transplant recipients provide only limited and infrequent information on the presence or absence of rejection, clinicians tend to administer relatively high levels of immunosuppression therapy to control rejection risk, which may be more than is required for an individual recipient and result in adverse health effects. Due in part to this long-term high level of immunosuppression therapy, illness and mortality rates among transplant recipients remain well above those of the general population and have not significantly improved in the last ten years.

Immunosuppression of Heart and Kidney Transplant Recipients

The risk 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 invasive procedural risks, discomfort, inconvenience, expense and the low rate of finding moderate to severe grade 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 risk profile of the individual recipient often causes clinicians to apply 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 receive more immunosuppressants than they may actually need. Improved post-transplantation diagnostics are necessary to achieve further gains in the long-term care and health outcomes of heart, kidney and other organ transplant recipients.

The Need for a Better Surveillance Solution

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;
- non-invasive procedure, without creating risks to the recipient;
- ease of administration;
- differentiation of rejection from non-rejection;
- ability to detect rejection earlier; and
- ability to provide results with timing and at a frequency that allows informed and effective treatment decisions.

Our Products and Services

Post-Transplant. We develop and provide a diagnostic surveillance testing solution for heart transplant recipients. Our initial test, AlloMap, is designed to help clinicians to regularly monitor for heart transplant rejection throughout the life of the recipient, modulate the use of immunosuppression and make more personalized treatment decisions. The AlloMap test uses a sample of the patient's blood. Blood draws are relatively painless and the process is routinely performed in two laboratories covering North America and Europe around the world. 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.

We are also in the process of commercializing AlloSure, our development stage kidney

transplant surveillance solution which applies proprietary next generation sequencing to detect dd-cfDNA after transplantation for detecting clinical and sub-clinical rejection in kidney allograft recipients.

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. Olerup SSP, a set of Human Leukocyte Antigen, or HLA, typing, is used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. Olerup SSP is used to type HLA alleles based on sequence-specific primer, or SSP, technology. It is one of the market leaders, and has long been a well-established brand name for pre-transplant solutions in Europe and other select markets. We frequently update typing kits to include newly discovered alleles, resulting in what we believe is one of the most up-to-date and comprehensive allele libraries for the SSP technology. We also offer XM-ONE®, which we believe 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 crossmatch test has primarily been used prior to kidney transplants, and more recent clinical trials are further demonstrating its value as a complement to traditional antibody testing prior to other types of transplants. In 2014, Allenex began active development of a new HLA typing product, Olerup QTYPE™, and commercially launched the product at the end of September 2016. QTYPE uses q-PCR methodology, and is based on SSP technology.

From 2011 to January 2017, Allenex, through Olerup SSB AB, was the exclusive global distributor of the HLA sequence-based typing products SBT Resolver and Assign SBT from Conexio, which is an Australian-based company that specializes in the development of sequencing of HLA typing, among other technologies. Illumina, Inc. acquired Conexio, Inc. and, in January 2017, we acquired from Illumina the elements necessary to continue offering the SBT line of products to our customers and Conexio's legacy customers that were not included in the initial distribution agreement.

Product Overview

Post-transplant products:

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, 2016, we have performed more than 93,000 total commercial AlloMap tests. We estimate that there are approximately 125 centers performing heart transplants in the United States. In 2016, 100 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 risk of 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 and 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.

Pre-transplant products:

Our pre-transplant products are from the Allenex and Conexio acquisitions. The Olerup branded pre-transplant products, include SSP (sequence-specific PCR), QTYPE, GAMMATYPE, and SBT Resolver for Human Leucocyte Antigens (HLA) typing, and CrossMatch Test XM-ONE. The HLA genes are encoded on chromosome 6 and are involved in self- versus non-self-recognition. The Olerup 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 16,250 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. Our custom developed software (SCORE) simplifies interpretation and documentation of laboratory results. We offer one of the most up-to-date and comprehensive libraries of HLA typing kits based on SSP technology.

Olerup QTYPE, an HLA typing kit based on real-time q-PCR methodology, was launched in September 2016 to complement the SSP line of products. 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 up to the 2-3 hours that it takes to do traditional SSP typing and the 5-7 hours that it takes with SSO (sequence -specific oligonucleotides). QTYPE comes with custom software, SCORE6.

Olerup GammaType, a diagnostics tool since 2015, types an additional region in the HLA locus and provides additional resolution beyond other HLA typing kits, particularly for hematopoietic stem cell transplantation. This product was in-licensed as part of the transaction whereby we acquired key assets from Conexio.

The sequence-based typing (SBT) product for typing HLA alleles uses specifically designed software, AssignBT, a sequence analysis software program that provides high resolution HLA typing. This software was also licensed as part of the recently announced transaction with Conexio.

The CrossMatch 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.

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 have been

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. Blood samples and clinical data from these two trials have been preserved in a multi-year, multicenter registry which we are sponsoring. We expect these samples and data to enable further discovery and product development of new indicators of rejection activity, or biomarkers, and new diagnostic solutions. We believe these repositories, which contain over 37,000 samples, are rich sources for further new product research and development because individual recipients were followed for 10 serial visits over one year or more, on average, and in many cases associated biopsy rejection grades and other clinical outcome endpoints are available for analysis, correlative studies and validation efforts that we believe will be useful for new product development.

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 studies retrospectively analyzing data from two (IMAGE and CARGO II) earlier trials that demonstrate how the variability in AlloMap scores over time may be useful in predicting the risks of rejection and graft dysfunction.

In May 2015, we initiated the DART trial to clinically validate AlloSure, our proprietary next-generation sequencing test. AlloSure measures the percent of dd-cfDNA in solid organ transplant recipients, regardless of the type of organ transplanted. However, DART is designed to establish clinical validation, or the clinical performance characteristics of dd-cfDNA in detecting acute rejection in kidney allograft recipients. DART is a multicenter observational study of the clinical status of renal transplant patients. Blood specimens are collected periodically at post-transplant follow-up visits, as well as at the time of any renal biopsies following treatment for acute rejection. DART is also designed to demonstrate the correlation of dd-cfDNA to renal function through comparison to both serum creatinine and estimated glomerular filtration rate. Patients will be followed in DART for a minimum of 18 months. At the end of December 2016, DART had enrolled over 400 patients in 14 centers. The study demonstrated increased levels of dd-cfDNA in acute rejection using the non-invasive AlloSure assay. With the relevant information from the first analysis, we have designed and are implementing a second clinical trial named TULIP. We believe TULIP will establish the clinical utility of our dd-cfDNA kidney solution.

Clinical trials for CE marking of the pre-transplant Olerup QTYPE product are expected to commence in 2017.

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. Our ongoing research and development 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 AlloMap Score Variability;
- 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;

- demonstration of QTYPE performance on additional real time PCR instruments; and
- investigation of genetic alterations associated with the development of cancer in these transplant patients who are at increased risk for malignancies because of chronic immunosuppression.

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 in developing future solutions.

Our research and development expenses for the years ended December 31, 2016, 2015 and 2014 were $12.4 million, $9.3 million and $3.8 million, respectively. The increase in research and development expenses for the year ended December 31, 2016 was mainly attributable to expenses incurred for the development of AlloSure and QTYPE.

During 2016, our European commercial partner, Diaxonhit, assisted with the design of a French Ministry of Health funded economic study for AlloMap reimbursement in Europe that commenced in April 2016 and is ongoing. Diaxonhit is a French publicly traded specialty diagnostics company with activities in France, Switzerland and Belgium, and is a leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer. Additionally, the French Ministry of Health has approved the funding of a study designed to demonstrate that AlloMap is non-inferior to biopsy as a method of evaluating the risk of acute cellular rejection among French heart transplant patients.

dd-cfDNA as a Biomarker for Organ Rejection

We are currently engaged in discovery and development efforts using dd-cfDNA to develop additional post-transplant diagnostic solutions, with an initial focus on a test for heart and kidney rejection. We believe dd-cfDNA may be useful as a biomarker for the detection of rejection related organ damage in solid organ transplant recipients. dd-cfDNA are short fragments of DNA that are released into the blood stream when cells die. dd-cfDNA assays have demonstrated market adoption and clinical utility in an adjacent market, having transformed pre-natal testing by providing a non-invasive, accurate method to detect genetic abnormalities in a fetus, without needing an invasive amniocentesis procedure. In a transplant recipient, we believe the differences in the relative amounts of dd-cfDNA from the donated organ and the recipient can be used to distinguish between patients with a healthy or damaged donor organ.

Initial studies such as Heart Transplants Are Genome Transplants: Universal Noninvasive Detection of Organ Transplant Rejection (Snyder T M et al., Proceedings N. Academy Sciences, 2011) and the Highly Sensitive Non-Invasive Cardiac Transplant Rejection Monitoring Using Targeted Qualification of Donor Specific Cell Free DNA (Hidestrand M et. al., J. Am. Coll. Cardiology, 2013) indicate that dd-cfDNA may be a universally applicable marker for rejection, not only for heart, but for kidney, liver and lung transplant recipients as well. Our initial studies and other external studies have reported that the proportions of dd-cfDNA in heart transplant recipients increase as much as five-fold during rejection episodes. Measuring the level and changes in the relative amount of dd-cfDNA in the blood stream may be a useful new method for detecting rejection. This technique involves measuring the dd-cfDNA released by dying cells from the donor organ into the recipient's blood stream. The level of donor specific dd-cfDNA from the transplanted organ can be monitored in the recipient's blood stream over time, and changes in organ status may be detected as changes in the donor dd-cfDNA level. The rationale for this approach arises from the observation that both acute and chronic rejection processes are associated with high levels of cell death in the transplanted organ.

In early 2015, we presented preliminary data demonstrating an increase of dd-cfDNA in the plasma of patients prior to organ rejection and the decrease of dd-cfDNA following immunosuppressive therapy for acute rejection in heart transplant recipients, using blood samples and clinical data from our CARGO II repository. These tests were conducted in our research facilities using our library of well annotated blood samples from primarily heart organ transplant patients. The results were presented at several professional medical society meetings.

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dd-cfDNA for Kidney Transplants

Our DART clinical trial is aimed at establishing the clinical validity of a dd-cfDNA-based solution for kidney transplant patients. We are applying expertise we gained developing AlloSure to develop a dd-cfDNA-based solution for other organ transplants, beginning with kidney transplants. We have a proprietary library of longitudinal blood and urine samples from kidney transplant recipients acquired during the course of our Kidney Transplanted Organ Rejection Gene expression Observational, or KARGO, study. With the relevant information from the first analysis, we have developed and are implementing a study design called TULIP. We believe this clinical trial will establish the clinical utility of our dd-cfDNA kidney solution and allow us to meaningfully engage with payers in an effort to ensure future access to and reimbursement for this novel non-invasive test for transplant surveillance.

An interventional clinical study to establish clinical utility of dd-cfDNA is expected to commence after initial results are obtained from the DART validation study. We may seek to acquire rights to access additional well-curated samples from other university hospitals and other sample repository consortiums in the United States with which we maintain relationships. We plan to expand the clinical validity evidence in support of commercialization for use in kidney transplant recipients. If developed, we would commercialize this solution. We recently designed and expanded our lab, which is Clinical Laboratory Improvement Amendments of 1988, or CLIA, and College of American Pathologists, or CAP, compliant, to accommodate clinical-grade next generation sequence testing and released a clinically validated Laboratory Developed Test, or LDT, under CLIA in December 2015.

We previously applied for and obtained FDA clearance for our AlloMap solution based on draft guidance published by the FDA in September 2006. That guidance was never finalized by the FDA and, at present, we do not anticipate seeking 510(k) clearance from the FDA for our dd-cfDNA-based kidney solution as part of our initial launch. If the FDA changes its current policy with respect to the regulation of LDTs, we may be required to seek FDA clearance or premarket approval for our dd-cfDNA-based kidney solution. The time required to develop and validate a test for kidney transplants depends on a number of factors, including the success and timing of developing a dd-cfDNA test for heart transplants and the time required to acquire sufficient samples.

dd-cfDNA for Heart Transplants

We believe that a dd-cfDNA-based solution for heart transplant recipients could provide additional value to clinicians, particularly in situations where a recipient’s AlloMap score does not suggest a low probability of acute rejection. Studies have reported a higher percentage of dd-cfDNA in the blood stream of patients with moderate or severe rejection as determined by an associated biopsy specimen. We believe a dd-cfDNA solution for heart could help clinicians to identify recipients with a higher probability of rejection and make any subsequent biopsy a more effective diagnostic tool, because the likelihood of detecting rejection in the biopsy specimen would be substantially enhanced.

We have completed internal studies with our collection of samples. We have established our proprietary strategy for quantification of donor specific dd-cfDNA and we have completed initial proof of concept studies. We now offer AlloSure as a laboratory developed test for a limited number of heart transplant centers and physicians as part of our Utility of Donor-Derived Cell-Free DNA in Association with Gene-Expression profiling (AlloMap) in Heart Transplant Recipients (D-OAR), 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.

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 some of the sequence diversity is of unclear clinical impact, many newly identified HLA alleles need to be integrated into ongoing updates of the Olerup SSP and QTYPE kits. We have been updating, and intend to continue to update, our HLA typing kits with newly identified alleles. Olerup SSP and QTYPE use technology platforms that can readily accommodate this increase in HLA allele assays.

Second, depending on the specific indication, different levels of HLA typing resolution and follow up confirmatory testing are required. The Olerup SSP and QTYPE flexible platforms are complemented with the sequence based SBT Resolver; 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 are working closely together to advance the synergies of products across the pre- and post-transplant continuum.

Reimbursement

We have been successful in achieving reimbursement from many payers. 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. 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.

For many years and consistent with other diagnostic tests, AlloMap had been billed using an unlisted Current Procedural Terminology, or CPT, code. In February 2015 Medicare assigned a Category 1 CPT code for AlloMap.

Following this assignment of a Category 1 CPT code, in September 2015, the Centers for Medicare & Medicaid Services, or CMS, issued a proposed Clinical Laboratory Fee Schedule, or CLFS, Preliminary Determinations for calendar year 2016. In the draft, CMS proposed changes in reimbursement for a number of established molecular diagnostic tests, including AlloMap. Under the proposed fee schedule, AlloMap reimbursement would have been reduced by 77% from $2,821 to $645. In October 2015, CMS reversed its preliminary CLFS and restored the final pricing determinations for AlloMap in the 2016 CLFS to $2,821. This matched the previous rate set by a number of Medicare Administrative Contractors, or MACs. CMS deferred any formal Category 1 CPT pricing determinations until 2017.

On June 10, 2016, CMS announced its proposed gapfill pricing for patients covered by Medicare. CMS initially proposed that reimbursement for AlloMap be reduced from the current rate of $2,821 to $732. On September 30, 2016, CMS published a gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would have been $1,921. We submitted a request for reconsideration of the reimbursement rate 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. 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.

Medicare

We are reimbursed for a substantial portion of our AlloMap tests performed on recipients covered by Medicare. These represented 34%, 36% and 37% of all AlloMap tests in 2016, 2015 and 2014, respectively. Approximately 44%, 50% and 51% of all testing revenue was derived from Medicare reimbursements for the years ended December 31, 2016, 2015 and 2014, respectively. Medicare reimbursement for AlloMap began in 2006.

Private Payers and Medicaid Payers

We are reimbursed for a substantial portion of the AlloMap tests we perform on patients covered by private payers and Medicaid payers. Coverage policies approving AlloMap for reimbursement have been adopted by many of the largest private payers, including Aetna, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc., TRICARE National Insurance and WellPoint, and a number of state Medicaid programs. 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.

International

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 our partner, Diaxonhit, and second, through royalties on Diaxonhit’s net earnings from sales of AlloMap. Diaxonhit will pay 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.

Our agreement with our Canadian partner, LifeLabs Medical Laboratory Services, was terminated in August 2015 and we now sell AlloMap directly in Canada with a focus on Ontario, Canada’s largest province.

The Olerup line of pre-transplant products has a broad international presence. Our Swedish affiliate makes direct sales of these products to customers throughout the Nordic region, while the team in Austria sells directly to customers in Germany, Benelux, Austria and Slovenia. The Austrian affiliate also manages our relationships with third-party distributors and sub-distributors to offer our pre-transplant products throughout the rest of Europe, Asia and Africa. Finally, our US-based Olerup affiliate offers these products in U.S. and Canada, as well as South and Central America through a network of distributors and sub-distributors.

Testing and Laboratory Operations

Our laboratory operations are headquartered at our Brisbane, California laboratory, which is certified under CLIA, and where we perform all AlloMap laboratory testing in support of our U.S. and Canadian patients. Through our European commercial partner, 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. We believe that our laboratory

capacity will be adequate to meet demand for AlloMap for the next few years.

We have also expanded our existing California lab facilities to accommodate CLIA-compliant space specifically designed for clinical-grade next-generation sequencing, or NGS, testing. This laboratory space has been established to support future products, such as AlloSure, that target dd-cfDNA for the surveillance of organ transplant recipients. The expanded facility also includes a state-of-the-art laboratory information management system containing best-in-class NGS bioinformatics and customized software modules.

When AlloMap is ordered by a clinician, 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 are tested in triplicate and results are reported to the ordering clinician by fax within three 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.

We rely solely on single suppliers to provide certain laboratory instruments and reagents used to perform AlloMap. These sole source suppliers include Thermo Fisher Scientific Inc., or Thermo Fisher, which supplies us with instruments, laboratory reagents, a master mix formula and consumables; 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 completed all the verification and validation studies with Thermo Fisher for the development of a custom master mix. All three full scale validation lots passed our acceptance testing. We now routinely purchase this material for routine use in the production of its AlloMap test plates.

Manufacturing

We have historically purchased many of the components and raw materials used in our Olerup product line of 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. 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 quality management systems. Subsequent audits by the registrar have been and will continue to be carried out at regular intervals to ensure we are maintaining our system in compliance with ISO standards. 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.

Sales and Marketing

Post-transplant Sales and Marketing Team

Our sales organization consists of a direct sales team in the United States that interacts with all aspects of the post-transplantation channel, including sales, medical science, reimbursement, customer service and field

laboratory/draw site support. As of December 31, 2016, our sales and marketing team consisted of 16 employees, including transplant account sales executives, reimbursement account managers and customer service personnel.

In 2016, AlloMap was used in 100 of the approximately 125 heart transplant centers in the United States. Our marketing focuses on the clinical and economic benefits of AlloMap and the scientific validation that supports our test. Our strategy includes continued marketing to and education of clinicians and administrators at treatment centers

that have used our test to increase the number of clinicians at those centers using our test, assist transplant centers with scheduling AlloMap tests for patients, and to have centers adopt formal protocols for AlloMap use.

Pre-transplant Sales and Marketing Team

The pre-transplant sales team has sales offices in Vienna, Austria; Stockholm, Sweden; and West Chester Pennsylvania. The office in Austria has eight employees and is responsible for sales and distribution of Olerup products in Europe. Direct sales are conducted for customers in Germany, Benelux, Austria and Slovenia. Distributors and sub-distributors are used for the rest of Europe, Asia and Africa. The Swedish office, with three sales and marketing employees, makes direct sales to customers throughout the Nordic region. Finally, the office in Pennsylvania, with seven employees, is responsible for direct sales of pre-transplant products in the U.S. Through distributors and sub-distributors, it also offers Olerup products in Canada, as well as South and Central America.

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.

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 (NGS), competitors include Abbott, Illumina, Protrans, GenDx, Bio-Rad laboratories, Immucor and R.O.S.E. We also face completion 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 based on performance, reputation and service competes favorably behind One Lambda and Life Technologies as a leading supplier of HLA test kits.

Post-Transplant

Our competition within the post-transplant markets 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, and 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 test 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.

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 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 which may directly or indirectly compete with AlloMap, AlloSure and 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.

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 solution 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 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, 2016, we have 16 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. 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. As part of our April 2016 acquisition of Allenex and its subsidiaries, 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.

AlloMap, AlloSure, Olerup SSP, XM-ONE and CareDx are registered trademarks of ours in the United States.

We have developed trade secrets and know-how since our inception. These 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.

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 test 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, which was amended in January 2007, July 2007, October 2008 and September 2014, as so amended, 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 are 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 2017, pursuant to a Settlement Agreement and Mutual Release, dated September 11, 2014, or the Settlement Agreement. As part of the Settlement Agreement, we will continue (i) a downward adjustment of the combination services percentage used to determine the portion of the AlloMap service that is royalty bearing under the terms of the Roche License until September 30, 2017 and (ii) to report and pay quarterly royalties within 45 days of the end of each quarter. Roche has agreed that subject to our timely payment of all applicable royalties through such date, no further royalties will be payable by us for periods after September 20, 2017.

In June 2014, we entered into an amended and restated license agreement with Stanford, or the Stanford License, 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.

In January 2017, we completed a transaction to acquire Conexio business assets in order to continue selling the SBT product line. We purchased rights to many of the assets, such as machinery, facility lease, know-how and the opportunity to retain key Conexio employees to continue producing and selling the SBT line of products.

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 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. The standards applicable to the testing which we perform may change over time. 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. We expect the next regular inspection under the CLIA to occur in 2018.

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 which accept specimens 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 or our products sold in the United States, as well as our facilities in Stockholm, Sweden used to produce some of them. 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. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as IVDMIAs. According to the draft guidance, IVDMIAs do not fall within the scope of LDTs over which 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.

On October 3, 2014, the FDA published two draft guidance documents that set forth the FDA's proposed risk-based framework for regulating LDTs. The draft guidance documents provide the anticipated details through which the FDA would propose to establish an LDT oversight framework, including premarket review for higher-risk LDTs, such as those that have the same intended use as FDA-approved or cleared companion diagnostics currently on the market. The FDA allotted 90 days for comment from stakeholders in order to further advance their thinking on their regulatory oversight of LDTs. In addition, the FDA convened a public meeting January 8-9, 2015, also for the purpose of stakeholders to provide input into the FDA process. On January 13, 2017, the FDA posted a "discussion paper" in which the agency outlined a substantially revised "possible approach" to the oversight of LDTs. The discussion paper explicitly states that it not a final version of the July 2014 draft guidance, and that it does not represent the agency's "formal

position.” Rather, the document represents the latest iteration of the agency’s thinking on LDTs, which the agency posted to “spur further dialogue.”

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 our dd-cfDNA test and all 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 before it can be commercialized. We cannot predict the ultimate timing or form of any FDA final guidance or regulation of LDTs, or when we must obtain regulatory approval or clearance for our LDT solutions. 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, nor can there be any 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 used or disclosed by healthcare providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

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 Stark and PORA. However, we cannot be certain that regulators would find these arrangements to be in compliance with Stark, 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 prohibition.

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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 provisions of the Affordable Care Act are effective on various dates. 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.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Act

Another development affecting the healthcare industry is the increased use of the federal False Claims Act, and in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act 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, 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. In addition, the federal government has pursued enforcement actions under the False Claims Act in connection with off-label promotion of products. 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 Devices Directive (98/79/EC) (IVDD), a European Union (EU) Directive. Some of our products are currently labeled by self-declaration based on their intended. Others have been 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 Canadian Medical Devices Conformity Assessment System (CMDCAS), which is a system designed to implement Canadian regulations requiring some medical devices be designed and manufactured under a registered quality management system (QMS). The SCC and Health Canada's Therapeutic Products Directorate (TPD) developed this system. It came into effect January 1, 2003.

Employees

At December 31, 2016, we had 161 regular employees, including 41 in manufacturing operations and support; 48 in research and development; 34 in sales and marketing and 38 in general and administrative positions. As of December 31, 2016, 106 employees were located in the United States and 55 were located outside of the United States.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. Most of our employees in Sweden are represented by a union. None of our employees 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, 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. 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 expect to continue to incur additional losses for the next several years. For the year ended December 31, 2016, our net loss was $39.8 million. As of December 31, 2016, we had an accumulated deficit of $212.6 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 diagnostic 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;
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- 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 related to our acquisition of Allenex.

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 will require additional financing.

On April 14, 2016, we acquired 98.3% of the outstanding common stock of Allenex AB, or Allenex. Under the terms of the Conditional Share Purchase Agreements entered into on December 16, 2015, as amended, and the tender offer prospectus dated March 7, 2016, and as a result of the tender offer, the aggregate purchase consideration paid by us was approximately $34.1 million and consisted of (i) $26.9 million of cash, of which $5.7 million (which represents SEK 50,620,000 as of the acquisition date) was deferred purchase consideration originally payable to Midroc Invest AB, FastPartner AB and Xenella Holding AB, or the 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 Majority Shareholders was subsequently extended to July 1, 2017. In addition, interest began accruing on our obligations to the Majority Shareholders at a rate of 10.0% per year commencing on January 1, 2017 and will continue to accrue until the date the obligations are paid in full. Of the total cash consideration, $8.0 million of cash payable to the Majority Shareholders was deposited into an escrow account by us and subsequently invested in us by the Majority Shareholders through a purchase of our equity securities in a subsequent financing, or the Subsequent Financing. Upon the completion of the Subsequent Financing, certain contingencies in the Conditional Share Purchase Agreements were waived, and the deferred purchase consideration is due to the 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 these 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 anticipate concluding this process in Q2 or Q3 of 2017. On June 8, 2016, we delisted Allenex’s common stock from Nasdaq OMX Stockholm AB.

On April 14, 2016, we completed a private placement transaction for the sale of 591,860 units, or Units, at a purchase price of $23.94 per Unit, or the Private Placement. The aggregate gross proceeds to us from the Private Placement were approximately $14.2 million. Concurrently, we also entered into Commitment Letters pursuant to which the Majority Shareholders agreed to purchase our equity securities in the Subsequent Financing. We made payments of approximately $1.1 million and $97,000 in placement fees and other offering expenses, respectively, to placement agents as part of closing the sale of the 591,860 Units in the Private Placement. On June 15, 2016, we completed the Subsequent Financing for the sale of an additional 334,169 Units to the Majority Shareholders. The aggregate gross proceeds to us from the Subsequent Financing were approximately $8.0 million. Securities issued in the Subsequent Financing were issued and sold at the same price and on substantially the same terms as the securities issued in the

Private Placement.

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On September 26, 2016, we completed an underwritten public offering, or the Public Offering, pursuant to which we issued and sold an aggregate of 2,250,000 shares of our common stock at a public offering price of $4.00 per share, or the Public Offering. The aggregate gross proceeds to us were approximately $9.0 million, and $7.8 million net of issuance costs. The Public Offering was made pursuant to our registration statement on Form S-3, which was declared effective by the SEC on December 4, 2015, a base prospectus dated December 4, 2015 and a prospectus supplement dated September 21, 2016. Piper Jaffray & Co. acted as the sole underwriter for the Public Offering.

On March 15, 2017, we completed a convertible debt financing with institutional investors 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 and we are required to maintain restricted cash of $9.4 million, which is restricted as to withdrawal and is not available to us to fund our operations or repay indebtedness. We intend to use the remaining net proceeds for continuing operations and to fund the commercialization of AlloSure. The Debentures mature on February 28, 2020, accrue interest at 9.5% per year and are convertible into shares of our common stock at a price of $4.56 per share, or the Conversion Price, at the holder's option. The Debentures include warrants to purchase up to an aggregate of 1.25 million shares of our common stock. The warrants have an exercise price of $5.00 (subject to adjustment in certain circumstances), become exercisable commencing on September 16, 2017 and expire on September 15, 2022. After September 1, 2017, upon the satisfaction of certain conditions, including the volume weighted average price of our common stock exceeding 250% of the Conversion Price for twenty consecutive trading days, we can require that the Debentures be converted into shares of our common stock, subject to certain limitations. Commencing on March 1, 2018, each of the holders of the Debentures will have the right, at its option, to require us to redeem up to $937,500 of the outstanding principal amount of its Debenture per month. We will be required to promptly, but in any event no more than one trading day after the holder delivers a redemption notice to us, pay the applicable redemption amount in cash or, at our election and subject to certain conditions, in shares of our common stock. If we elect to pay the redemption amount in shares of our common stock, then the shares will be delivered based on a price equal to the lesser of (a) a 12% discount to the average of the three lowest volume weighted average prices of our common stock over the prior 20 trading days, (b) a 12% discount to the prior trading day's volume weighted average price, or (c) the Conversion Price. We may only opt for payment in shares of our common stock if certain conditions are met, and any repayments made through the issuance of common stock will result in dilution to our existing stockholders. Our obligations under the Debentures can be accelerated upon the occurrence of certain events of default as specified in the agreement, including any failure to deliver cash or shares if any holder of the Debentures elects to require us to redeem a Debenture. In the event of default and acceleration of our obligations, we would be required to pay (i) 115% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debenture is accelerated on or prior to March 1, 2018, (ii) 108% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debenture is accelerated after March 1, 2018, but prior to March 1, 2019, and (iii) 105% of all amounts of principal and interest then outstanding under the Debentures in cash if the Debenture is accelerated on or after March 1, 2019.

Notwithstanding the prior transactions, we will require additional financing and/or refinancing of our current debt obligations to fund working capital, repay debt and to pay our obligations, including our obligations under a term loan facility, or the Term Loan Facility, with Danske Bank A/B, or Danske, and our obligations to FastPartner AB and Mohammed Al Amoudi under our outstanding promissory notes with such parties. Our obligations under the promissory notes are secured by a pledge of shares of Allenex. We may pursue financing and refinancing opportunities in both the private and public debt and equity markets through sales of debt or equity securities. Additional financing might include one or more offerings and one or more of a combination of discounted or at-the-market common stock, securities convertible into or exchangeable for shares of common stock, warrants or other rights to purchase or acquire common stock.

Absent the receipt of additional financing and provided that Danske does not demand repayment of debt, we will be unable to fund our operations and make scheduled loan payments beyond the quarter ended June 30, 2017 unless we

substantially reduce our costs and operations, including research and development activities, marketing activities and programs and other general and administrative expenses. As a result of our obligations and lack of immediately available financial resources, there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, and/or refinance our Allenex indebtedness in the near term, we will be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements as of December 31, 2016 and 2015 and for each of the three

years in the period ended December 31, 2016, included in our Annual Report on Form 10-K for the year ended December 31, 2016, included a “going concern” explanatory paragraph indicating that our recurring losses from operations and need for additional capital raise substantial doubt about our ability to continue as a going concern.

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, require us to incur significant transaction fees and also require that we 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, 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, 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). As a result, we are currently unable to conduct an “at the market” offering pursuant to our August 2015 Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. 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 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 April 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, 2016, payments from Medicare for AlloMap represented 44% 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.

In 2016, CMS used a process referred to as "gapfill" to establish reimbursement rates for Allomap for 2017. The gapfill process consisted of a number of steps, including: (i) CMS obtained preliminary proposed reimbursement for AlloMap from the eight Medicare Administrative Contractors, or MACs; (ii) CMS obtaining final reimbursement submission for AlloMap from the eight MACs; and (iii) a reconsideration period, with requests for reconsideration submitted through October 31, 2016. On June 10, 2016, CMS announced the proposed gapfill pricing from the MACs for patients covered by Medicare, which initially proposed that reimbursement for AlloMap be reduced from the 2016 National Limitation Amount of $2,821 to $732. On September 30, 2016, CMS published a final gapfill reimbursement rate determination from the MACs, under which payment for the AlloMap test would have been $1,921. 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 AlloMap price.

Ultimately, the proposed gapfill rates were not implemented. However, if an AlloMap reimbursement rate that is significantly lower than the current reimbursement rate is published in the Clinical Laboratory Fee Schedule, or CLFS, in the future, it could cause us to discontinue AlloMap testing for Medicare patients because providing AlloMap 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. Medicare reimbursement for AlloMap began in 2006 and has continued through three successive MACs. 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 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 could impact the coverage or payment amount for our test 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 test 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 AlloMap test.

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Our financial results currently are largely dependent on sales of one post-transplant test, AlloMap, 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.

A majority of our revenue is currently dependent on sales of AlloMap for heart transplant recipients and secondarily from sales of Olerup products for pre-transplant matching of donors and recipients. We expect that sales of AlloMap and Olerup products will account for a substantial portion of our revenue for at least the next two years. Although we are in the process of commercializing AlloSure, our dd-cfDNA-based solution for solid organ transplant recipients, and QTYPE for more rapid testing of pre-transplant organs and tissues, even if we are successful in developing these new tests, we expect that adoption will take many quarters, during which our financial results will depend on the performance of our existing solutions and tests. Although we are in the process of commercializing AlloSure for kidney transplant recipients - the first group of patients for which the test will be available - even if we are successful in developing this test, we do not expect to receive approval for reimbursement of this test, which will drive its value as a contributor to our revenue stream, for at least the next several fiscal quarters. If we are unable to increase sales of AlloMap or Olerup products or successfully develop and commercialize other solutions, tests or enhancements, such as QTYPE, which was commercially launched at the end of September 2016, our revenues and our 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 we 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, including solutions related to the acquisition of Allenex, are a key to our growth strategy. New test 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. While we have engaged in discovery and development activity for AlloSure, our dd-cfDNA solution for solid organ transplant recipients, we will be required to devote considerable additional efforts and resources to the further research and development of this test to demonstrate its clinical validity and utility before it will be fully adopted for use in recipients of various types of donated organs. Our planned new diagnostic solutions for organs other than the heart or kidney are at much earlier stages of development. dd-cfDNA solutions are a novel technology, and to date have not been used commercially in the field of transplantation surveillance. In connection with the acquisition of Allenex, we acquired two new potential commercial opportunities, QTYPE and XM-ONE, to address pre-transplantation testing needs. In 2014 and 2015, Allenex expended significant resources to develop QTYPE. QTYPE was commercially launched at the end of September 2016. XM-ONE is a research product for larger medical centers and we are working to establish broader commercial use. We cannot assure you 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 assure you 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 which could make AlloMap, 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, Olerup products and our solutions under 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, Olerup SSP 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.

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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, 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 125 centers managing heart transplant recipients in the United States. In 2016, AlloMap was used in 100 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.

Our Olerup 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 SSP product often requires the purchase of new and costly testing equipment. To attract new laboratory customers, the performance of our Olerup SSP 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, 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 and Olerup SSP products;
- our ability to commercialize new diagnostic solutions and tests such as AlloSure 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, such as Allenex, 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 and our other solutions is not supported by studies published in peer-reviewed 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 clinical trials involving AlloMap 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 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, 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.

We are in the process of completing clinical trials demonstrating the clinical use of AlloSure, our development stage transplant surveillance solution, and clinical performance characteristics of dd-cfDNA. 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 that provide evidence of the utility of dd-cfDNA and validate AlloSure as a solution.

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Transplant centers may not adopt AlloMap 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. 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- and post-transplant surveillance to increase as there are numerous established and startup companies in the process of developing novel products and services for the transplant market which may directly or indirectly compete with AlloMap or our development pipeline. Allenex has a well-established business with well-known products in the field of HLA typing based on Olerup SSP. However, competition from other companies, especially those with an eye toward transitioning to more automated typing processes, could impact Allenex’s 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 Linkage Bioscience and Thermo Fisher Scientific, Inc. as well as alternatives to PCR such as NGS products offered by Illumina. In addition to companies focused on pre-transplantation such as Thermo Fisher Scientific Inc.’s One Lambda and Immucor, Inc.’s LIFECODES businesses, companies who have not historically focused on transplantation, but with 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 test, 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 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 Olerup SSP typing kits on a timely basis, our ability to attract and retain patients 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 Olerup SSP 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 patients, 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 initiatives such as the Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, study 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 new clinical collaborations and enter into new ones, our efforts to commercialize AlloSure and our development of other new products could be delayed.

In the past, we have entered into clinical trial 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 trial 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 assure you 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 depends, in large part, on our ability to perform AlloMap 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 to 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 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 2015 to 2016, our testing revenue grew from $27.9 million to $29.7 million, which represents annual growth of 6%. 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 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.

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If our laboratory facility in the U.S. becomes inoperable, we will be unable to perform AlloMap 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. Additionally, through our partnership with Diaxonhit we have recently validated a dedicated laboratory for AlloMap testing in Europe through the Strasbourg University Hospital Central Immunology Laboratory. 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 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, this insurance 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, 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 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 or future solutions following validation and other required procedures. We cannot assure you that we would be able to find another CLIA-certified facility willing or able to adopt AlloMap 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.

Any additional laboratories opened in Europe would need to undergo a multi-step validation process demonstrating that AlloMap test results provided from such laboratory are equivalent to AlloMap results generated by our Brisbane, California laboratory. Training and other preparation is required before the laboratory is operational, and any commercial partner in Europe may encounter unanticipated obstacles. We do not have access to redundant facilities in Europe and our exclusive arrangement with Diaxonhit precludes the engagement by us of another collaboration partner whose laboratories we could use in the event that our primary facility is harmed or rendered inoperable. Without immediate access to an alternative facility, any disruption to our European partner’s laboratory may result in delays in the delivery of test results, patient claims, loss of customers or harm to our reputation.

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 recipient 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 the diagnostic 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 the recipient blood samples that are analyzed in our Brisbane, California laboratory. Our business will suffer if these service providers do not support AlloMap or the other solutions that we may develop. For example, these laboratories may determine that the effort to process 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:

- complete development of AlloSure, our proposed dd-cfDNA test for heart and kidney, or 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 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 dd-cfDNA test for heart and kidney transplant recipients and additional solutions for the surveillance of transplantation of other organs and our new HLA typing product, QTYPE, commercially launched at the end of September 2016, that reduces the time required to match donor organs and tissue with potential recipients prior to transplantation and uses real-time PCR;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in commercialization;
- competing technological and market developments;
- whether our diagnostic solutions become subject to additional FDA or other regulation; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. For example, in August 2015 we entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. for

selling additional shares of our common stock to the public through an “at the market” offering. 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 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, 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 this Annual Report on Form 10-K 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, because 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, commencing April 18, 2017 we began accruing liquidated damages payable to JGB at a rate of approximately $7,000 per day, which damages will continue to accrue at the same rate on a daily basis until the registration statement is filed with the SEC. As of February 29, 2016, we were also in violation of one of our financial covenants under our loan agreement with East West Bank. This violation was waived and memorialized in a written amendment to the loan agreement dated May 12, 2016 and, as of December 31, 2016, we were in compliance with our debt covenants under our loan agreement with East West Bank. We paid off all obligations owing under, and terminated, our loan agreement with East West Bank effective March 15, 2017. A debt covenant in the Term Loan Facility with Danske was violated due to insufficient working capital in Allenex, at each of June 30, 2016, September 30, 2016 and December 31, 2016. We obtained waivers from Danske for each of these violations of the debt covenant. However, the waiver we received for the covenant violation as of December 31, 2016 is conditional because it is based on preliminary consolidated financial statements for Allenex as of and for the three months and year ended December 31, 2016 prepared under International Financial Reporting Standards as adopted in Sweden and for regulatory reporting in Sweden, which financial statements are currently subject to further review and audit in Sweden, and the final consolidated financial statements for Allenex may change materially. Any change to the preliminary Allenex financials that served as a basis for the conditional waiver could result in a withdrawal of the conditional waiver and could result in Allenex being in default under the Term Loan Facility, at which point Danske could demand repayment of the debt. Additionally, while Allenex received waivers from Danske for each of these violations, due to continuing liquidity matters, we determined that it is not probable that Allenex was in compliance with this covenant as of March 31, 2017. Danske has the ability to demand repayment of the debt if the violation is not resolved. For these reasons, the long-term debt due to Danske was classified as a current liability in the consolidated balance sheet as of December 31, 2016. Additionally, if the loan was no longer available or Danske demanded repayment of the debt, we may not have sufficient capital to operate which could have a material adverse

effect on our business, financial condition and results of operations. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under our debt agreements.

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 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. Examples include our 2014 acquisition of ImmuMetrix, Inc., or IMX, a privately held development-stage company working on dd-cfDNA-based solutions in transplantation and other fields, our acquisition of Allenex in April 2016 and our acquisition of certain assets of Conexio Genomics Pty Ltd, or Conexio, in January 2017. 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 acquisition of IMX, our acquisition of Allenex and 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;
- acquired technology or research and development expectations 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;

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- 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 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 University 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, on April 14, 2016, we acquired 98.3% of the outstanding common stock of 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. If we fail to successfully integrate Allenex, we may not realize the benefits expected from the transaction and our business may be harmed.

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 Allenex's 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.

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In addition, the marketing, sale and use of AlloMap 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.

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 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, perform reliable services.

We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use to perform AlloMap. These sole source suppliers include Thermo Fisher Scientific Inc., 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 Scientific Inc., 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 polymerase chain reaction, or PCR, instrument used in AlloMap, is no longer in production. Thermo Fisher Scientific Inc. has committed to provide service and support of this instrument through 2020. We believe that there are relatively few suppliers other than Thermo Fisher Scientific Inc., Becton, Dickinson and Company and Qiagen N.V. that are currently capable of supplying the instruments, reagents and other supplies necessary for AlloMap. 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 Scientific Inc., 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 AlloMap 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 who order AlloMap rely on the continued availability of our test and have an expectation that results will be reported within two to three business days. If we are unable to provide

results within a timely manner, clinicians may elect not to use our test 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 and damage our reputation, any of which could 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. Allenex currently distributes its products in Germany, Austria, Slovenia, Benelux, Canada, China and India. Allenex also sells, via sub-distributors, to certain countries in 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 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 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. For example, on June 23, 2016, the United Kingdom, or the UK, held a referendum pursuant to which voters elected to leave the European Union, commonly referred to as Brexit. As a result of UK voters' election to leave the European Union, the British government is expected to begin negotiating the terms of the UK's future relationship with the European Union. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the European Union markets, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout

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Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. In addition, Brexit may also increase the possibility that other countries may decide to leave the European Union in the future.

Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; 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.

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. AlloMap testing in Europe is being conducted through an exclusive distribution agreement with a sole collaborator. 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.

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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.

Risks Related to the Allenex Acquisition

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;
- 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.

Each of our and Allenex's business relationships may be subject to disruption due to uncertainty associated with the acquisition.

During the post-acquisition transition period, and until the Allenex business is fully integrated, customers, vendors, licensors, suppliers and other third parties with whom we and Allenex do business or otherwise have relationships may experience uncertainty on whether the integration will be successful, and this uncertainty could materially affect their decisions with respect to existing or future business relationships. These third parties may also attempt to negotiate changes to existing business agreements, which could result in additional obligations imposed on us. These types of disruptions could have a material adverse effect on our business, financial condition and results of operations.

The market price of our common stock may decline due to increased selling pressure as a result of the acquisition or the subsequent equity financing.

In connection with the acquisition of Allenex, we issued an aggregate of 1,375,029 shares of common stock to the holders of Allenex shares, and in connection with our equity financings completed in April and June 2016, we issued an aggregate of 8,534,261 shares of common stock. The common stock issued as consideration in the acquisition was freely tradable upon consummation of the acquisition, and the common stock issued in the equity financings are freely tradable following the effectiveness of the 2016 Form S-3 on July 12, 2016. Sales of a substantial number of our shares of common stock in the public market in connection with the acquisition or the equity financings, or the perception that these 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.

Allenex shareholders who may not have the ability or desire to hold shares in a U.S. company may determine to sell shares of common stock, or investors may perceive that such sales may occur, either of which may adversely affect the market for, and the market price of, our shares of common stock.

The uncertainties associated with our combination with Allenex may result in a loss of key personnel.

Our employees may perceive uncertainty about their future role with the combined business until strategies with regard to the combined business are announced or executed. Any uncertainty may affect our ability to attract and retain our key personnel, or the key employees of Allenex.

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 that were not identified in advance, which may result in significant unanticipated costs.

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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 is allocated to the fair value of the identifiable tangible and intangible assets and liabilities that are acquired from Allenex. The excess of the purchase price over Allenex's net assets and intangibles is allocated to goodwill. We are also accounting for the business combination with ImmuMetrix in 2014 under the acquisition method of accounting. We have a substantial amount of goodwill on our balance sheet generated in connection with our acquisitions of Allenex and ImmuMetrix as part of our business growth strategy. Our goodwill of approximately $13.8 million as of December 31, 2016 represented approximately 18.0% of our total assets as of that date.

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 acquisitions of Allenex and ImmuMetrix continue to have fair values that meet or exceed 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, 2016, we performed step one of our annual goodwill impairment test and determined that the fair value of the Olerup reporting unit was $1.7 million, which was lower than its carrying value. A reduction in our forecasted revenue and operating results for the Olerup 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 Olerup 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 our analysis, the implied fair value of the goodwill was lower than the carrying value of the Olerup reporting unit. Based on the results of the impairment test, we recorded an impairment charge of $13.0 million of Allenex's goodwill. For information about this $13.0 million impairment charge, see Note 6 of the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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.

We may not realize the full value of the inventory acquired pursuant to our combination with Allenex.

We acquired a significant amount of inventory pursuant to the business combination with Allenex. In the event we are unable to sell all or substantially all of the inventory we acquired at reasonable prices, or at all, we may be required to write-off excess or obsolete inventory, which could have a material adverse impact on our financial condition and results of operations.

Full integration of our business with Allenex may not be achieved until we acquire the remaining shares of Allenex shareholders.

Although we currently hold 98.3% of the outstanding shares in Allenex, full integration of the Allenex business may not be achieved until we have compulsorily acquired the remaining shares of Allenex in accordance with Swedish law.

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 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 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. We do not recognize revenue for test results delivered without a contract for reimbursement, or an established coverage policy and a history of payment. Revenue for AlloMap 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, 2016 and 2015, approximately 37% and 32%, respectively, our AlloMap 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.

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

- not experimental or investigational;
- medically necessary;
- 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 the results of their assessments for informational purposes 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 and future solutions such as AlloSure could be limited. Payment for diagnostic tests furnished to Medicare beneficiaries is typically made based on a fee schedule set by CMS. In recent years, payments under these fee schedules have decreased and may decrease further. Any third-party payer may stop or lower payment at any time, which could substantially reduce our revenue. See the risk factor above titled "We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance".

Since each payer makes its own decision as to whether to establish a policy to reimburse for a test, seeking payer coverage and other approvals is a time-consuming and costly process. We cannot assure you that adequate coverage and reimbursement for AlloMap 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, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc. and WellPoint, and a number of state Medicaid programs. 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 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 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.

Decisions by CMS with respect to coding could also affect our revenue. For example, on September 25, 2013, CMS released the preliminary payment determinations for the CLFS for 2014. CMS proposed to not recognize certain Current Procedural Terminology codes, or CPT codes, called Multianalyte Assays with Algorithmic Analyses codes,

or MAAA codes, as valid for Medicare purposes under the CLFS because it determined that an algorithm is not a clinical diagnostic test. This preliminary determination would have reversed a CMS final determination released on November 6, 2012 for 2013 that withdrew a proposal to not cover algorithmic analysis and stated that laboratories performing MAAA tests for Medicare beneficiaries should continue to bill for these tests in 2013 as they were then billed under the CLFS. When the final payment determination for 2014 was issued, CMS stated instead that it will continue to consider each test classified by the CPT as a MAAA on its own merits, and payment amounts would be determined using a gapfill methodology if the Medicare contractor determines the code is payable.

Until 2016, AlloMap was billed using an unlisted CPT code, but in 2016 a new CPT Category 1 MAAA code was added that specifically describes the test. The AlloMap test also has been assigned a second Z code™ identifier through a program for molecular diagnostics, 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.

Our transition from an outsourced billings and collections vendor to an in-house staff has negatively affected our cash collection cycle.

During 2015, we transitioned our billing and collections functions for our AlloMap testing from on outside vendor to an in-house staff. On July 1, 2015, these functions began being performed by in-house staff recruited and hired by us directly. During this process, we also transitioned from the outside vendor's software, which was familiar and compatible with our accounting system and procedures, to a new software system designed for use by in-house departments in billing and collections of medical diagnostic tests. Since the transition and despite hiring experienced personnel, we have experienced a slowdown in collections and are working to remediate the slowdown. There is risk that billing and collections will not be smooth until the procedures are improved and become routine, including that payments may not be collected timely, communication errors with insurers regarding specifics of the insurance claims may occur, insurers' deadlines may not be met, claims may expire, payments may not be properly applied to outstanding receivables, and revenue may not be recorded accurately. There is also a risk that the combination of a software system changeover, the hiring of new personnel with lack of experience with the specific nature of our billing procedures with insurers, payments being directed to a new lockbox, new reports with changes to our billing and cash collections data and other changes to the process will result in lost or reduced collections compared with prior periods or otherwise have an adverse effect on our operations, cash flows and revenue.

Healthcare reform measures could hinder or prevent the commercial success of AlloMap.

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 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 assure you 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 will report 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 will use the reported data to set new payment rates under the CLFS beginning 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 or repeal 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. Additionally, annual federal budget negotiations frequently include healthcare payment reform measures impacting clinical laboratory payments. 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. 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 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.

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our laboratory under California law. We are required to maintain a license to conduct testing in California. 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 and Pennsylvania. 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 in 2016 and recertified under the CLIA as a result of passing that inspection. We expect the next regular inspection under CLIA to occur in 2018. 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, 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.

Clinical laboratory tests that are developed and validated by a laboratory for its own use are called LDTs. The laws and regulations governing the marketing of diagnostic products for use as LDTs are extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws. For instance, while the FDA maintains that LDTs are subject to the FDA's authority as diagnostic medical devices under the Federal Food, Drug, and Cosmetic Act, or FFDCA, the FDA has in the past generally not exercised enforcement discretion with respect to most LDTs performed by CLIA-certified laboratories.

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 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.

On July 31, 2014, the FDA notified Congress (as required by the Food and Drug Administration Safety and Innovation Act of 2012) of its intent to publish a proposed and comprehensive risk-based framework for the regulation of LDTs. The notice to Congress provides the anticipated details and proposed timing of the implementation of the draft guidance and regulatory framework, including the requirement for premarket review and approval for higher-risk LDTs, such as our planned cell-free DNA solutions for heart, kidney and other organs. Such guidance, if and when finalized, will significantly impact the timing, availability and reimbursement of our future products, and will require us to modify our business model in order to maintain compliance with these new laws. For our cell-free DNA test and all similar testing solutions, we will be required to conduct additional clinical trials to clinically validate our test, and submit to the FDA a pre-market approval application, or PMA, or 510(k) clearance application and obtain approval or clearance for the test. We cannot predict the ultimate timing or form of any FDA final guidance or regulation of LDTs, or when we must obtain regulatory approval or clearance for our LDT solutions. There can be no assurance that any of our solutions or additional uses of solutions for which we will seek clearance or approval in the future will be cleared or approved on a timely basis, or at all, nor can there be any 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 solutions. Moreover, any new FDA requirements could conflict with CLIA requirements and thereby complicate our compliance efforts.

While we believe that we are currently in material compliance with applicable laws and regulations relating to our LDTs, we cannot assure you 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 our solutions under development as medical devices, it could require extensive premarket clinical testing prior to submitting a regulatory application for commercial sales. Conducting clinical trials generally entails a long, expensive and uncertain process that is subject to delays and failure at any stage. 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. Our reliance on third parties that we do not control would not relieve us of any applicable requirement to ensure compliance with various procedures required under good clinical practices. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our solutions under development. 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 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 approval as well as changes to the labeling. In addition, approval 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.

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.

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, 2016, we had 16 issued U.S. patents related to autoimmunity and transplant rejection. 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. 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 University 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.

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. As part of our April 2016 acquisition of Allenex and its subsidiaries, we obtained an additional five U.S. patents on donor matching technology and treatment for antibody mediated transplant rejection. 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. A recent decision in the Ariosa Diagnostics, Inc. v. Sequenom, Inc. (Fed. Cir. 2015) case decided 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. 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 guarantee 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, XM-ONE 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 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. From January 4, 2016 to December 31, 2016, our stock price ranged from $2.50 to $6.84 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 integrate the business of new acquisitions, such as Allenex and the assets we acquired from Conexio, efficiently;
- 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 in general, and the market for life science companies in particular, 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.

Prior to our initial public offering in July 2014, there had been no public market for our shares of common stock. 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 45% of our common stock as of December 31, 2016. This significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

Sales of substantial amounts of our common stock in the public markets, or sales of our common stock by our executive officers and directors under Rule 10b5-1 plans, could adversely affect the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, our executive officers and directors may adopt written plans, known as “Rule 10b5-1 Plans,” under which they will contract with a broker to sell shares of our common stock on a periodic basis to diversify their assets and investments. Sales made by our executive officers and directors pursuant to Rule 10b5-1, regardless of the amount of such sales, could adversely affect the market price of our common stock.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the U.S., which may adversely affect our operating results.

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

Further, failure to comply with these laws, regulations and standards might also make it 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 such 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.

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 equity financings which occurred in 2000, 2004, 2007, 2014 and through the current period. 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.

We have identified material weaknesses in our internal control over financial reporting, and 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 and 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 need to implement new and additional finance and accounting systems, procedures and controls for Allenex and as we grow our business and organization and to satisfy internal control and reporting requirements. We previously identified a material weakness in our internal control over financial reporting related to an entity acquired in 2014, which was remedied. 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 Majority Shareholders 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 have prepared a preliminary remediation plan to address the underlying causes of the material weaknesses described above. We cannot assure you 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.

As a public company, we require greater financial resources than were required when we were a private company before our 2014 initial public offering. 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 if we fail to remediate the four material weaknesses in 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 and Europe. The following is a summary of the locations, functions and approximate square footage of those facilities as of December 31, 2016:

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

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

On April 25, 2016, Oberland Capital SA Davos LLC, or Oberland, filed a breach of contract claim against us in the Supreme Court of the State of New York, County of New York, or the Oberland Complaint, alleging, among other things, that we breached certain provisions of the amended and restated commitment letter and the restated fee letter that we entered into with Oberland on February 8, 2016. Pursuant to the Oberland Complaint, Oberland is seeking damages against us in the amount of at least $1.4 million, plus costs and expenses, including the fees and expenses of Oberland's attorneys. On July 15, 2016, we filed an answer and made counterclaims against Oberland, or the Answer, generally denying the claims asserted by Oberland in the Oberland Complaint and asserting fraudulent inducement and breach of contract counterclaims against Oberland. Pursuant to the Answer, we are seeking dismissal of the Oberland Complaint in its entirety, rescission of all agreements with Oberland and damages of not less than $1.3 million, together with interest and punitive damages, if deemed appropriate under applicable law, and costs and disbursements of the action, including reasonable attorneys' fees. On August 4, 2016, Oberland filed a motion to dismiss our counterclaims and affirmative defenses asserted in the Answer. We believe that we have meritorious defenses to the claims asserted in the Oberland Complaint and that the counterclaims asserted by us in the Answer have merit. Oral arguments for this motion were held on December 8, 2016. Following that hearing and a subsequent mediation between the parties on February 8, 2017, we agreed with Oberland to find an alternative conclusion to the proceedings. Effective as of March 2, 2017 we and Oberland settled the matters covered by the Oberland Complaint and the Answer, or the Settlement. Pursuant to the Settlement, we paid Oberland $600,000 and each party agreed to forever release and not to sue the other party with respect to the claims asserted in the Oberland Complaint and the Answer.

In addition, on June 15, 2016, we received a letter from Nasdaq OMX Stockholm AB, or Nasdaq Stockholm, regarding our compliance with the requirements of the Nasdaq Stockholm Takeover Rules, or the Takeover Rules, and good practice in the securities market in Sweden in connection with our recently completed acquisition of Allenex. Nasdaq Stockholm concluded that we violated certain technical provisions of the Takeover Rules and acted contrary to good practice in the securities market in Sweden, and gave us the opportunity to submit our views before it decided whether to refer the matter to its Disciplinary Committee. On July 11, 2016, we submitted a response, which was considered by Nasdaq Stockholm in making a final determination whether to refer the matter to its Disciplinary

Committee for further assessment. On September 21, 2016, we received notice from Nasdaq Stockholm that, by letter dated September 20, 2016 from Nasdaq Stockholm to its Disciplinary Committee, Nasdaq Stockholm referred the matter to the Disciplinary Committee and sought a ruling from the Disciplinary Committee regarding disciplinary sanction. The Disciplinary Committee had the authority to impose a fine and/or sanctions. We were granted an opportunity to submit documents in support of our position to the Disciplinary Committee. This submission was filed by the November 24, 2016 deadline and a hearing before the Disciplinary Committee took

place on December 9, 2016. On December 21, 2016, the Disciplinary Committee informed us that it decided to impose a SEK 1.0 million (approximately $0.1 million) fine on us and this amount was paid in February 2017.

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 April 18, 2017, there were approximately 160 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, 2015	High	Low
First Quarter	$7.54	$5.54
Second Quarter	$6.92	$4.61
Third Quarter	$7.67	$4.11
Fourth Quarter	$6.68	$4.23
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

Stock Performance Graph

The following information is not deemed to be “soliciting material” or to be “filed” with the Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section , and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent we specifically incorporate it by reference into such a filing.

The graph and table below shows the cumulative total stockholder return on our common stock (change in stock price plus reinvested dividends) relative to the total returns of the NASDAQ Composite Index, and the NASDAQ Biotechnology Index. An investment of $100 is assumed to have been made in our common stock and in each index on July 22, 2014 (the date our common stock began trading following our initial public offering) and its relative performance is tracked through December 31, 2016. The comparison is based on historical results and is not intended to forecast or be indicative of future performance of our common stock.

Trade Date	CareDx, Inc.	Nasdaq Composite	Nasdaq Biotech
12/31/2016	$ 27.00	$ 120.81	$ 104.57
9/30/2016	$ 35.50	$ 119.21	$ 114.16
6/30/2016	$ 43.10	$ 108.68	$ 101.58
3/31/2016	$ 49.60	$ 109.29	$ 102.84
12/31/2015	$ 64.00	$ 112.37	$ 133.52
9/30/2015	$ 41.70	$ 103.68	$ 119.52
6/30/2015	$ 65.00	$ 111.91	$ 145.75
3/31/2015	$ 55.45	$ 109.98	$ 135.66
12/31/2014	$ 72.50	$ 106.28	$ 119.83
9/30/2014	$ 70.00	$ 100.84	$ 107.82
7/22/2014	$ 100.00	$ 100.00	$ 100.00

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. 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 2016.

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 2016.

ITEM 6. SELECTED FINANCIAL DATA

The following selected historical financial data should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data at December 31, 2016 and 2015 and the selected statements of operations data for each of the years ended December 31, 2016, 2015 and 2014 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,				
	2016	2015	2014	2013	2012
	(In thousands, except share and per share data)				
Revenue:					
Testing revenue	$29,680	$27,881	$25,842	$21,672	$19,730
Product revenue	10,715	—	—	—	—
Collaboration and license revenue	236	263	1,464	426	721
Total revenue	40,631	28,144	27,306	22,098	20,451
Operating expenses:					
Cost of testing	10,882	10,273	8,541	9,078	7,930
Cost of product	10,240	—	—	—	—
Research and development	12,385	9,333	3,846	3,176	4,752
Sales and marketing	11,166	8,349	6,472	5,892	5,417
General and administrative	20,725	12,247	8,436	4,809	4,694
Goodwill impairment	13,021	—	—	—	—
Change in estimated fair value of contingent consideration	(456)	(126)	(1,239)	—	—
Total operating expenses	77,963	40,076	26,056	22,955	22,793
(Loss) income from operations	(37,332)	(11,932)	1,250	(857)	(2,342)
Interest expense, net	(1,860)	(1,587)	(2,116)	(2,149)	(2,703)
Other expense, net	(1,920)	(188)	(78)	(13)	(14)
Change in estimated fair value of common stock warrant and derivative liabilities	(250)	—	225	(523)	—
Loss before income taxes	(41,362)	(13,707)	(719)	(3,542)	(5,059)
Income tax benefit	1,606	—	1,500	—	—
Net (loss) income	(39,756)	(13,707)	781	(3,542)	(5,059)
Net loss attributable to noncontrolling interest	(287)	—	—	—	—
Net (loss) income attributable to CareDx, Inc.	$(39,469)	$(13,707)	$781	$(3,542)	$(5,059)
Net (loss) income per share:					
Basic	$(2.39)	$(1.16)	$0.13	$(3.50)	$(5.01)

Diluted	$(2.39)	$(1.16)	$0.10	$(3.50)	$(5.01)
Shares used to compute net (loss) income per share:					
Basic	16,496,911	11,860,885	5,815,928	1,010,795	1,009,236
Diluted	16,496,911	11,860,885	9,283,001	1,010,795	1,009,236

Balance Sheet Data:

	As of December 31,	
	2016	2015
	(In thousands)	
Cash and cash equivalents	$17,258	$29,888
Working capital	(14,159)	24,210
Total assets	76,730	55,638
Total debt	23,944	15,753
Accumulated deficit	(212,553)	(173,084)
Total CareDx, Inc. stockholders' equity	19,482	29,494

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

The following discussion of our financial condition and results of operations should be read in conjunction with our 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. 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. We are also pursuing the development of additional products for transplant monitoring using a variety of technologies, including AlloSure, our proprietary next-generation sequencing-based test to detect donor derived cell-free DNA, or dd-cfDNA, after transplantation.

On November 29, 2016, we submitted our AlloSure test dossier to the Molecular Diagnostic Services Program, or MolDX, for a technical assessment in support of a coverage determination. Our submission was accepted by MolDx for technical assessment in early December 2016 and the assessment is currently in process and a coverage determination has not been made. The Molecular Diagnostic Services Program (MolDX), launched in 2011, is administered by Palmetto GBA for the Centers for Medicare & Medicaid Services. Palmetto GBA is responsible for conducting a complete technology assessment to determine coverage, coding, and pricing for molecular diagnostic tests and other molecular pathology services administered through MolDx. Moldx's policies are also followed by three other Medicare Administrative Contractors: Noridian, CGS, and WPS.

In April 2016, we acquired Allenex AB, or Allenex. 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. Olerup SSP, a set of Human Leukocyte Antigen, or HLA, typing, is used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. Olerup SSP is used to type HLA alleles based on sequence-specific primer, or SSP, technology, is one of the market leaders and has long been a well-established brand name in Europe and select other markets for pre-transplant solutions. We frequently update typing kits to include newly discovered alleles, resulting in what we believe is one of the most up-to-date and comprehensive allele libraries for the SSP technology. We also offer XM-ONE®, which we believe is the first standardized test that quickly identifies a patient's antigens against HLA Class I or Class II, as well as antibodies against a donor's endothelium. This crossmatch test has primarily been used prior to kidney transplants, and more

recent clinical trials are further demonstrating its value as a complement to traditional antibody testing prior to these types of transplants. In 2014, Allenex began active development of a new HLA typing product, QTYPE, and commercially launched the product at the end of September 2016. QTYPE uses real-time PCR, or q-PCR, methodology. This technology is based on SSP technology.

From 2011 to January 2017, Allenex, through Olerup SSB AB, was the exclusive global distributor of the HLA sequence-based typing products SBT Resolver and Assign SBT from Conexio Genomics, or Conexio, which is an

Australian-based company that specializes in the development of sequencing of HLA typing, among other technologies. Illumina, Inc. acquired Conexio, Inc. and, in January 2017, we acquired from Illumina the elements necessary to continue offering the SBT line of products to our customers and Conexio's legacy customers that were not included in the initial distribution agreement.

Since the launch of AlloMap in January 2005, we have performed more than 93,000 commercial AlloMap tests, including 14,148 tests during 2016, in our Brisbane, California laboratory. Since the commercial launch of AlloMap through December 31, 2016, we have received net proceeds of approximately $189.4 million from AlloMap testing revenues. During the year ended December 31, 2016, AlloMap was used in 100 of the approximately 125 heart transplant centers in the United States. As of December 31, 2016, substantially all of our testing and product revenues came from the United States and Europe, and substantially all of our assets and operations are located in the United States and Sweden. In 2013, we began a partnership with Diaxonhit SA, or Diaxonhit, the leading French provider of specialty in-vitro diagnostic solutions for transplantation, to expand our AlloMap offering in Europe for which we have secured a dedicated laboratory. On May 25, 2016, Diaxonhit announced that it had entered into a services agreement with University Hospital of Strasbourg to open a center dedicated to AlloMap testing. The lab meets all of the quality and safety requirements to ensure the accuracy and reproducibility of the results of AlloMap. Further, its Strasbourg, France location is centrally located in Europe, which is ideal for servicing heart transplant centers throughout Europe. As a result of our acquisition of Allenex, we have further increased our international presence.

AlloMap has received positive coverage decisions for reimbursement from Medicare and many of the largest private payers, including Aetna, Cigna, Humana, Inc., Kaiser Foundation Health Plan, Inc., TRICARE National Insurance and WellPoint. We believe our success in achieving reimbursement confirms the value proposition of AlloMap to our key constituents.

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 Transplantion 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.

In addition to our current offering of surveillance solutions, we are also engaged in efforts to develop additional testing solutions in the heart transplant market and new testing solutions in other organ transplant markets. For instance, AlloSure, our development stage transplant surveillance solution, applies proprietary next generation sequencing to detect and quantitate genetic differences between dd-cfDNA in the blood stream emanating from the donor heart. We believe this solution may help determine rejection-specific activity manifested as cell damage in the transplanted heart and other solid organs, irrespective of the type of organ transplanted. In late 2015, we announced the completion of analytical validation of AlloSure. Samples used in the analytical validation included donor recipient pairs with unrelated as well as closely related family members. A report describing the analytical validation of the dd-cfDNA test (AlloSure) including clinical validation information for heart transplant appeared in the November 2016 issue of The Journal of Molecular Diagnostics.

As part of our efforts to demonstrate the clinical utility of AlloSure, we initiated the Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients, or DART, trial in May 2015. DART is designed to establish clinical validation, or the clinical performance characteristics of dd-cfDNA in detecting clinical and sub-clinical rejection in kidney allograft recipients. DART is a multicenter observational study

of kidney transplant recipients where blood specimens are drawn periodically after transplant during follow up visits and also after treatment for acute rejection. DART is also designed to demonstrate the correlation of dd-cfDNA to renal function through comparison to both serum creatinine and estimated glomerular filtration rate. Patients will be followed in DART for a minimum of 18 months. We completed the first analysis of the data from DART in June 2016. By the time of completion 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 before enrollment was closed. The study demonstrated

increased levels of dd-cfDNA in acute rejection using the non-invasive AlloSure assay. Based on the analytical validity and first analysis clinical validation data, we, in collaboration with clinical investigators, submitted two manuscripts that have been accepted for scientific peer-review publication. The study reports will appear in the Journal of the American Society of Nephrology and the Journal Applied Laboratory Medicine in March 2017. With the relevant information from the first analysis, we have and are implementing a second clinical trial named Renal Transplant Utility of Level of dd-cfDNA (Allosure): Impact on Patient Management, or TULIP. TULIP will establish the clinical utility of our dd-cfDNA kidney solution and provide the framework to engage with payers in an effort to ensure future access to and reimbursement for this novel non-invasive test for transplant surveillance.

Financial Operations Overview

Testing Revenue

Our testing revenue is derived from AlloMap tests, which represented 73%, 99% and 95% of our total revenues for the years ended December 31, 2016, 2015 and 2014, 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 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. As of December 31, 2016, the list price of AlloMap was $3,600 per test. However, amounts actually 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 score 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 Olerup SSP products and other related product lines. Product revenue represented 26% of total revenue for the year ended December 31, 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

Revenue from our collaboration and license agreements was insignificant to total revenues 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. 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.

Royalties incurred 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. Royalties included in cost of testing are associated with a license of certain technology relating to polymerase chain reaction, or PCR, and quantitative real-time PCR, or q-PCR, in clinical laboratory services from Roche Molecular Systems, Inc., or Roche. In September 2014, we agreed with Roche to a downward adjustment of the royalty rate. As part of this agreement, no further royalties will be payable by us for periods after September 30, 2017.

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 represent costs incurred to develop new pre- and post-transplant diagnostic solutions as well as continued efforts related to improving our existing product lines. These expenses include payroll and related expenses, consulting expenses, laboratory supplies, 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. We expect our research and development expenses will increase in absolute dollars in future periods as we invest in research and discovery work to develop new surveillance solutions, as well as clinical outcomes studies for AlloMap and a clinical utility study for AlloSure.

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. We expect sales and marketing expenses to increase in the future as we continue to expand our presence in the transplant diagnostic marketplace.

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 billing and

collection, accounting, legal and other contract and administrative services and related infrastructure expenses, including allocated facility and overhead costs. We expect to continue to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and The NASDAQ Stock Market LLC, additional insurance expenses, investor relations activities and other administrative and professional services. For the year ended December 31, 2016, general and administrative expenses also included transaction related fees and expenses associated with the acquisition of Allenex and completion of the Private Placement and the Subsequent Financing. Following the completion of the acquisition of Allenex and excluding costs incurred in connection with the acquisition of Allenex, we expect our general and administrative expenses will increase as we incur additional costs to finance our operations and growth, to integrate Allenex's business with ours, comply with internal control requirements and other costs to operate globally.

Goodwill Impairment

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. We are required to evaluate whether the intangible assets and goodwill resulting from the acquisition of Allenex continue to have fair values that meet or exceed the amounts recorded on our balance sheet. In connection with our annual goodwill assessment on December 1, 2016, we performed step one of our annual goodwill impairment test and determined that the fair value of the Olerup reporting unit was $1.7 million, which was lower than its carrying value. A reduction in our forecasted revenue and operating results for the Olerup 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 Olerup 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 our analysis, the implied fair value of the goodwill was lower than the carrying value of the Olerup 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 IMX, which occurred in June 2014, includes a future payment that is contingent upon the achievement of a specified milestone. We recorded a contingent consideration liability at its fair value in June 2014, at the acquisition date. 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, 2016, other expense primarily consisted of a charge recorded to expense financing costs associated with a proposed six-month bridge loan with Oberland Capital SA Davos LLC, or Oberland, based on our determination that it was not probable that the bridge loan would be consummated partially offset by subsequent litigation settlement with Oberland related to the expense financing costs. For the year ended December 31, 2015, other expense primarily consisted of state franchise taxes.

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 will be remeasured at each subsequent balance sheet date

with changes recorded to 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.

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.

Such judgments include review of past payment history. AlloMap testing 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 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.

Revenue is recognized on an 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.

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 upon delivery of a score 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. In 2016, 2015 and 2014, approximately 64%, 68% and 64%, respectively, of our testing revenue was recognized on the accrual basis.

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. 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,		
	2016	2015	2014
AlloMap tests delivered	14,148	13,059	11,930
AlloMap tests for which revenue was recognized	9,677	9,155	9,786
AlloMap tests for which revenue was recognized, del			